The ADDIE Model
an Instructional Generic Design Model

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Strategy and Tactics of Task Analysis

INTRODUCTION
This article reviews the place of task analysis in the process of developing a standard operating procedure (SOP) and the subsequent training module. Task analysis is the process of defining the discrete steps, or tasks that, when executed, will ensure the effective and efficient performance of a job. We look initially at strategic issues and then review some tactical concerns. First, we will consider the strategic relationship between the analysis of training needs and task analysis; then we will examine how task analysis fits into the ADDIE model of instructional design. ADDIE is the acronym of a generic instructional design model, comprised of the following: Analyze, Design, Develop, Implement, and Evaluate. Turning next to tactical matters, we will review how an instructional designer plans and prepares for a task analysis, undertakes a task analysis, identifies best practices, completes the task analysis, and incorporates the data into a procedure. Throughout, we will pay special attention to the importance of standards in any SOP.

Analysis of Training Needs
When we analyze training needs, we typically look at four levels of analysis: the organization, its facility, the employee, and the task. The organization includes organizational structure, business case, and supervisory factors; it also includes the employee's compensation and upward mobility. The facility of the organization includes such specifics as working conditions, workplace hazards, and utilities. The organization and its facility are situational levels – they impact on training needs, but are not the object of training intervention. Should problems be identified with the facility or the organization, the typical remedy would not be training – it would either be a problem-specific (safety, environmental, etc.) corrective action or it would be an organizational development (OD) initiative. The organization and its facility are important for the analysis of training needs because they situate employees and the tasks they are to perform. The facility and organization can have a profound impact on training needs and training effectiveness.

In considering the required attributes of the employee within the organization, we consider the skill-set and the employee's disposition. The skill-set is encompassed by the employee's curriculum and training plan, which indicate the employee's completed training as well as competencies and qualifications. The dispositions include the employee's personality, insofar as it impacts on work-related attitudes, which contribute in turn to motivations and, ultimately, behaviors. Two different and important motivations are an employee's motivation to participate in the company's established training program, and his or her motivation to transfer the training to the job. The conjunction of skills and dispositions situated in a particular facility and organization creates the employee's workplace performance.

Finally, our analysis of training needs focuses upon the task. The task includes its component steps; the task itself is included in a larger process within a sequence of tasks. Of critical importance in an analysis of the task are the standards that define the acceptable levels of task performance, those levels that will allow the organization to attain its desired outcomes.

Task Analysis and Performance Gaps
Careful task analysis can add substantial value to an organization's training courseware. The purpose of courseware – learning management system (LMS) software, structured on-the-job training (SOJT) module, etc. – is to close
a performance gap for some group of employees. The term performance gap means that employee performance does not meet some standard.

Standards provide guidance for tasks and processes within manufacturing and quality control lab systems, as well as in clinical operations, Quality Assurance (QA), biometrics, and pharmacovigilance. As a result of task analysis, best practices are identified, and can be mandated as standards. These standards may be documented in procedures, protocols, manufacturing orders, packaging orders, etc. For example, if a manufacturing order in the pharmaceutical industry stipulates that tablet thickness should be X mm, the pressing cylinder height parameter of an appropriately qualified Fette Tablet Press is set to that standard. For brevity sake, all of these types of documents will be called standard operating procedures (SOPs).7

An SOP stipulates standards – and promotes consistent practice – for task performance. Once these standards are specified, it is possible to identify a performance gap, the difference between existing employee performance and the standard required by the SOP. Courseware can then be designed to address the performance gap.

Before the courseware has even entered the developmental process, the data derived from task analysis can be used to revise and improve the SOP that is the basis of the training. Thoroughgoing task analysis will, of course, add to the overall cost of developing the SOP and the subsequent courseware, but it is a cost that is well worth incurring, because the cost of quality training will be offset in fewer errors on the manufacturing floor.

**TASK ANALYSIS AND THE ADDIE MODEL**

The ADDIE model is a generic instructional design model. It provides guidance at a fairly high level for instructional designers, software engineers, etc., as they author and revise courseware. As we have noted above, the elements or phases of the ADDIE model are Analyze, Design, Develop, Implement, and Evaluate. These elements are sequential – each element depends upon the successful completion of the preceding phase.

Moreover, the ADDIE model is an iterative feedback model, which means that the results of the Evaluation phase are fed back, closing the loop, facilitating further refinement of the courseware. If the evaluation shows that the training module has shortcomings, for example, that the sequence of learning tasks is incomplete, those shortcomings are fed back to the author(s) of the courseware to be analyzed again. Further design and development efforts follow, until the courseware meets the organization's needs. Thus, the ADDIE model has an evident affinity with the DMAIC (Define, Measure, Analyze, Improve, Control)8 cycle of Six Sigma improvement efforts.

It is important to stress that the iterations within the ADDIE model continue until management decides that organizational needs have been met. More generally, any relaxation or deviation from the ADDIE model, such as a “satisficing” level of performance9 or the skipping of a phase, are management decisions. These decisions can take the form of criteria established before a project is initiated (e.g., a stopping rule) or while the project is underway (e.g., “That product has been refined enough.”)10

The initial phase of the ADDIE model, the Analysis phase, refers to the analysis of four aspects of the process that will be addressed by the courseware, be it a manufacturing facility, Quality Control (QC) lab, clinical operation, or drug safety process. These are the analysis of the facility or context, the analysis of the organization, the analysis of an employee's skill-set and disposition, and the analysis of the task. These four aspects – facility, organization, employee skills and disposition, and task – are to be analyzed to identify the sequence of tasks, the sum total of the process, which will lead to the outcomes that the organization desires.

A process is a systematically organized set of inputs, tasks or activities, outputs and standards – that pertain to, and control, the inputs, tasks, and outputs.11 There are several different types of processes.

The manufacturing or lab process may be a person-to-equipment (or instrument) process, a person-to-paper process, or a person-to-person process; it may be some combination of the three types. An example of a person-to-equipment process would be a technician calibrating an instrument; a person-to-paper process would be a technician recording the as-found and as-left data from a given calibration on the appropriate log; a person-to-person process would be a line supervisor who is responsible to immediately inform a technician when an instrument is available for calibration. For each of these types of process, the
standards are captured in a document.

An SOP documents the standards and tasks that make up a process. A well-formatted SOP facilitates correct task performance and consistent practice. It has a column identifying personnel or positions that are responsible for tasks, a correlative “activities” column indicating the tasks and their sequence, as well as the standards that define the satisfactory completion of the tasks. Once standards are specified, the performance gap between existing employee performance and that required by the SOP can be addressed. The courseware can then be designed to close the performance gap; this remediation activity begins in the Design phase of the ADDIE model.

The question at this point is, How do we winnow through a number of possible standards and tasks to settle upon the best practices for that process, and then document those best practices? How do we write good SOPs?

TACTICS OF TASK ANALYSIS

Clearly, we must analyze the tasks before we can document the tasks. Hence, task analysis comes first; a good SOP depends upon a good task analysis. Several questions about methods must be addressed before a facilitator can undertake a task analysis. How does the author structure the task analysis – will an informal approach or a more formal approach be employed? How will the author collect the data on tasks? There are several options – operator behavior can be directly observed, critical incidents can be reviewed (a case-study approach), questionnaires can be developed (and, if so, can be distributed to various employees); experts can be interviewed, etc. In this article, we will focus our attention on a less formal approach, involving the interview of experts. This approach is broadly applicable and relatively inexpensive.

Develop Project Plan

The first step is to develop the project plan for the task analysis. The project plan delineates the process to be analyzed, including its boundaries; the participants, including their levels of expertise, their responsibilities; and the intended outcomes of the task analysis; i.e., the expectations the participants will have, stated in terms of behavioral objectives or S.M.A.R.T. (Specific, Measurable, Achievable, Relevant, and Time-based) objectives.

Suppose, for example, the process to be documented was the manufacture of a petrolatum/wax-based topical ointment, with active ingredient X. The boundaries of the process would be Dispensing, on the input-side, and Distribution Center, on the output-side.

For this illustration, the participants would be SMEs who manufacture the ointment; their responsibilities in the task analysis include identifying relevant documents, generating a list of tasks, identifying the responsible parties, etc.

The finalized project plan has several uses. It will help to make the business case for the task analysis, direct the review of existing documentation, communicate with the participants – the SMEs – and help to ensure the continuing focus of the on-going task analysis.

Identify Subject Matter Experts

The second step is to identify the SMEs. The author of the SOP is not necessarily the expert, or even an expert, on the process to be documented. There may be several employees who are SMEs on this process. It is important to identify these SMEs, and to get the agreement of management, business owners, and other experts on the list of SMEs.

Among the criteria for identifying SMEs, the sum of their expertise should be comprehensive – it should cover the whole manufacturing or lab process that falls within the scope. It is important to select several SMEs, to ensure
that a range (and perhaps variability) of expert opinion is included. Moreover, there are several levels of expertise that should be represented – task analysis relates to proficiency at the task or sub-task level, while domain expertise relates to more comprehensive proficiency – the “big picture,” if you will. Also, a number of SMEs will make it more likely that the industrial safety, environmental, regulatory, quality assurance, and cultural aspects of the process are covered in the task analysis. And they should be covered! Once the SMEs have been identified, the list of invitees needs management approval.

Review Existing Documentation
The third step is the review of existing documentation. The project plan of the task analysis will raise several questions, including: Was there a prior version of the SOP? Are there similar SOPs with the same tasks and/or concepts? Are there pre-existing task analyses that can be utilized?

Sometimes the author of the SOP, or management, will suggest that the SOP can simply be a revision of the prior version, with no explicit task analysis. “Clean it up – add a few steps here, delete a few steps there.” This is the “literary” approach to writing an SOP, which runs the risk that the successively cloned versions of the SOP will take on a life of their own, taking a tangent that becomes ever more distant from the tasks and process they are intended to document. This literary approach is sometimes called “writing a procedure without leaving one’s desk.” It is not recommended – it is a major source of bad procedures.

Prior versions of a procedure should be reviewed as a preparatory step in a task analysis, not as an alternative to the task analysis. The key source of information for documenting the process is the SMEs who work within the process all the time, not a prior version of the SOP.

Schedule Task Analysis
The fourth step is to schedule the task analysis session. This includes developing the agenda, sending invitations to the SMEs, reserving the room, and assembling all materials for the session.

Prepare SMEs for Task Analysis
When getting the SMEs ready for the task analysis session, it is important to remember that they are the key source of information for documenting the process into an SOP. Treat them right! Make the SMEs comfortable with the agenda, the room, and the building. Locate the restrooms, water fountains, etc. Review the Emergency Response Plan and evacuation routes. Discuss the project plan with them, and then finalize it.

Identify Tasks in Terms of Outcomes
Next, prepare the SMEs to identify the tasks in terms of the outcomes. This involves distinguishing between steps, tasks, and processes. A step is a discrete action (e.g., throw a switch). A task is a set of steps that achieve a specific outcome (e.g., shut down the tablet press). A process is a set of tasks that achieve a more general outcome (e.g., produce a batch of topical ointment). Once these have been clarified, the SMEs can begin to identify tasks. As the group identifies and lists tasks, bear in mind the role of the facilitator of this task analysis session. Facilitators should focus on getting information from the SMEs rather than contributing themselves. The facilitator should provide direction as well; the session should focus on tasks, not processes. The SMEs should, at a minimum, provide action verbs and a direct object for each task statement. As SMEs identify tasks, begin to map out the process. Encourage the SMEs to review and correct the process map as the group proceeds; at this stage the process map is a work-in-progress.

Identify Task Responsibilities
Ask the SMEs to begin to identify task responsibilities. Which employee or position is responsible for each task? Be alert for ambiguous responsibilities – there can be no task without a unique, responsible party. If it appears that
a task has no responsible employee, or has a number of responsible employees, it is unlikely that the SMEs will be able to resolve the issue. Each ambiguity should be noted for later resolution by management. There may be a need to add “swim lanes” to the process map to distinguish the various responsibilities and collaborations.

Be alert for disproportional task responsibilities. If a position has only one responsibility in a lengthy procedure, this may signal that the task should be moved entirely to another SOP. For instance, the task responsibilities of end users, data managers, and system administrators in a typical database SOP are quite disproportionate. End users login, maintain the integrity of passwords, navigate the application, query, print pre-formatted reports, call the help desk with problems, and log off. In addition to these tasks, data managers enter, edit, and verify data, change fields, print customized reports, etc. In addition to all these tasks, system administrators maintain security, allocate rights, etc. Rather than including all these tasks in a single lengthy “Database SOP,” it is preferable to have several shorter procedures, one for each user group. The training implications are less formidable, and the possibility exists of consolidating SOPs, for instance an “End user SOP” for a number of applications.

In any case, identifying task responsibilities will prove useful for a preliminary training audience list of employees who must be trained on this SOP.

“Chunk” and Label Tasks
When the task analysis session is underway, begin to chunk and label the tasks to reflect the business process. Ask whether the tasks can be aggregated. For example, “Sign the calibration log,” “Date the calibration log,” and “Have supervision review the log” might be aggregated as “Complete the documentation of the log.” At this stage of the task analysis, it is important to chunk from the employees’ perspective; use audience-focused words. Labels provide a rationale for the chunks. Aim for about seven tasks per chunk. Be alert for the need to map subtasks, as well as decision points (and associated decision criteria), strategies, etc.

Also, establish the business order for the chunks. What is the flow within the process? If a clear logical order is not available, use a generic order. If a single order is not possible, establish a unique order for each of the main user groups. (This may be another signal that there are multiple SOPs involved.)

Identify “Chunk” Concepts
Finally, identify concepts for each chunk. Tasks describe how to do something; concepts provide the science for task performance. For example, “Completing the documentation of the log” might be conceptualized as “Making the calibration process ‘Audit Proof,’” ensuring that there is a complete audit trail for every calibration.

To this point, we have prepared the SMEs for the task analysis; we have identified the tasks related to the scope; we have identified the responsible party for each task; we have chunked and labeled the tasks to reflect the business process; we have established the business order within and across the chunks; and last, we have identified concepts for each chunk. Now we are ready to complete the task analysis.

Draft Process Map
The tenth step is to complete the draft of the process map. Start at a high level and work down, in an iterative fashion, to the desired level of detail. Be sure to include the beginning and the end of the process; check back to the scope statement. Do not include anything that is outside the scope. Keep a relatively uniform level of detail; do not have some aspects of the process mapped out in great detail, and other aspects merely sketched. Step back from the map, as you are drafting it, to review its overall appearance, its coherence.

Submit Process Map to Peer Review
When the draft is ready, submit it to a peer review by some or all the SMEs, other experts, or the business owner. On the positive side, the reviewers should look for best practices, value-adding steps, flexibility in light of changing demands,
Figure 1: 
Illustrative task analysis of the steps and sub-steps involved in copying a document on a photocopier.20

1. Prepare photocopier
   • 1.1. Switch on machine
   • 1.2. Wait for warm-up cycle to be completed

2. Select desired number of copies

3. Prepare first page of original for copying
   • 3.1. Raise lid
   • 3.2. Locate page in appropriate position on the glass
   • 3.3. Close lid

4. Activate copying cycle
   • 4.1. Press start switch
   • 4.2. Ensure that the original does not move

5. Check quality of photocopy
   • 5.1. If OK, go to Step 6
   • 5.2. If not OK, select appropriate corrective action
     • 5.2.1. Put in more copy paper
     • 5.2.2. Remove paper jam
     • 5.2.3. Readjust position of original
     • 5.2.4. Adjust toner setting

6. Remove copied original and replace with next page
   • 6.1. Raise lid
   • 6.2. Remove copied original
   • 6.3. Replace with next page to be copied
   • 6.4. Close lid

7. Repeat Steps 4-6 until all pages are copied

8. Remove last page of the original

9. Check that all pages have been copied satisfactorily

10. Switch off photocopier

11. Gather up all materials and depart
and scalability in light of changing output targets, etc. On the negative side, they should look for bottlenecks in the process, duplication of effort, unnecessary steps or tasks, non-value-adding steps, role ambiguities (several positions responsible for a task, or no one responsible for a task), etc. Document all the points raised by the peer review.

Then, we test the real-world applicability of the process map by challenging it step-by-step on the floor or at the lab bench. Select a seasoned employee within the scope – not an SME – and compare the process as mapped against the employee’s activities. Do they align? Ask questions – look for evidence of resistance, repetition, human factors problems such as task complexity. Document everything in the challenge.

**Assemble, Evaluate, and Revise Process Map**

The last step in the task analysis is to assemble all the data from this stage, evaluate it comprehensively, and revise the process map in light of it.

Now we have completed the task analysis. We have drafted the process map; we have highlighted best practices; we have challenged the process map in a real-world setting; and finally, we have revised the process map in light of all these inputs. It is time to seek management approval.

Once the task analysis has been finalized, and approved by management, the facilitator can translate the task analysis process map into the documentary form of the SOP, the actual procedure, protocol, manufacturing order, packaging order, etc. Many times, this translation will amount to the discursive writing-out of the process map captured in Visio®. Any time the documentary form deviates from the process map, the latter will provide the guidance.

After the SOP has been developed, revised, and approved, the author can turn to the design of courseware that will close any performance gap(s) that is evident in employee task performance.

**CONCLUSION**

We have considered how SOPs - and associated standards that allow us to identify performance gaps - are developed out of task analysis. At a strategic level, we have examined the relationship between the analysis of training needs and task analysis. Then, we considered the place of task analysis in the ADDIE model of instructional design. Turning to tactical issues, we have reviewed how the author of an SOP prepares for a task analysis, conducts a task analysis, and finalizes the task analysis and incorporates the data, including best practices, into the SOP. The SOP is then used as a point of comparison with employee task performance, to identify any performance gap. This points the way to the next phase of the ADDIE model, where courseware is designed to address that performance gap. GXP

**DISCLAIMER**

The content, views, and opinions expressed in this article are those of the author, and are not intended to express the views or approach of Schering-Plough.

**ENDNOTES**

1. We use the following terminology in this article:
   - Author: An instructional designer, the originator of a procedure, the facilitator of the task analysis session, a technical writer, etc.
   - Courseware: A training module, LMS software, job aid, organizational development program, etc.
   - Management: Referring to either supervision in a line of business or the supervision of a given author; which one will be clear in context.
   - SME: A subject matter expert in a task or process.
   - Task: A specific element of a job, set of duties, or activity that can be analyzed.
   - Training Needs Analysis: A process aimed at identifying the gap between the current level of employee performance and the desired level of performance.
   - Task Analysis: The process of identifying and describing the tasks that must be performed to achieve a goal.

7. The FDA refers to these documents as “procedures” in 21 CFR 211, and as “standard operating procedures” in 21 CFR 58.35.
8. See Kevin Linderman, Roger Schroeder, Srilata Zabner, and Adrian Choo, Six-Sigma: A goal-theoretic perspective, *Journal of Operations Management*, (2003), 21, 193-203. Indeed, Kalyym Islam has recently suggested that the Analysis phase of the ADDIE model be preceded by Define, and Measure, phases, to ensure that “true business requirements” are specified, and appropriate metrics are selected from the outset. See his “Designing an Effective Certification Program,” *LTI Newsline* (14 Dec 2005). The importance of identifying, and addressing, the business case for a proposed revision of an SOP, or for the subsequent training intervention, can hardly be overstated.

10. This consideration obtains within the phases of the ADDIE model as well. For example, the “P x C” rule for continuing (or concluding) a task analysis, where the probability “P” of performance failure times the cost “C” of performance failure, is estimated for a given level of granularity of the task analysis. If P x C is unacceptably large, the task analysis continues to a more fine-grained level; see Neville Stanton, Hierarchical task analysis: Developments, applications, and extensions, *Applied Ergonomics*, (2006), Vol. 37, No. 1, 55-79; also Liu Xijuan, Wang Yinglin, and Jaing Shouwei, A metrics based task analysis model for design review planning, *Design Studies*, (July 2003), Vol. 24, No. 4, 375-380. Specifying the value of the estimates of P and C, as well as the criterion of acceptability itself, is ultimately management's decision, which highlights the importance of ongoing communication between the facilitator of the task analysis, the facilitator's management, and the business owner of the SOP.


**ARTICLE ACRONYM LISTING**

- **ADDIE** Analyze, Design, Develop, Implement, Evaluate
- **DMAIC** Define, Measure, Analyze, Improve, Control
- **GMP** Good Manufacturing Practice
- **LMS** Learning Management System
- **OD** Organizational Development
- **QA** Quality Assurance
- **QC** Quality Control
- **SMART** Specific, Measurable, Achievable, Relevant, Time-based
- **SME** Subject Matter Expert
- **SOJT** Structured On-The-Job Training
- **SOP** Standard Operating Procedure

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The ‘Design’ Phase of the ADDIE Model

INTRODUCTION
The ADDIE model is a generic instructional design model. It provides guidance at a fairly high level for instructional designers, software engineers, etc., as they author and revise learning products. The phases of the ADDIE model are Analyze, Design, Develop, Implement, and Evaluate. These phases are sequential – each depends upon the successful completion of the preceding phase.

Moreover, the ADDIE model is an iterative feedback model, which means that the results of the Evaluation phase are returned to the origination point (fed back), closing the loop, facilitating further refinement of the learning product. If the evaluation shows that the module has shortcomings, for example, that the objectives of the module do not align with organizational objectives, those shortcomings are returned to be analyzed again. Further design and development efforts follow, until the module meets organizational needs.

In this article, we will examine the three components of the Design phase (see Sidebar, on facing page) in turn.

The Learning Product In The Larger Curriculum
Fitting the proposed learning product into the larger curriculum ensures the articulation of this product with all other learning products, and the alignment of this product with organizational goals. There are four aspects to this “fit” –
• The structure of modules
• The relationship between the learning product and the associated SOP
• The learning product’s reduction by consolidation of SOPs
• The relationship between learning product and the various regulatory requirements (e.g.: FDA, OSHA, EPA, DEA, etc.)

The Structure of Modules
The larger curriculum is comprised of a set of modules that focus the training effort on accomplishing organizational goals. The Design phase is where the fit between the proposed learning product and the larger curriculum is delineated. This means outlining the structure of the training

10 SPECIAL EDITION: The ADDIE Model, and Instructional Generic Design Model
module wherein the learning product will fit. Each module includes two types of learning product, an Overview Training element and one or more associated Skills Training elements. A module is configured as shown in Figure 2:

In the Design phase, the precise location of the learning product – as an Overview Training element or a Skills Training element – is determined. To briefly review the difference between these two types of elements: the Overview Training is more conceptually focused, while Skills Training is more task or performance oriented. Concepts tell what a thing is, why it is important; tasks describe how to do something. Concepts provide the “science” for task performance. For example, the tasks involved in sanitizing equipment might be conceptualized as “Reducing the levels of microorganisms and particulates to acceptable limits” thereby minimizing the risk of product contamination from the equipment.

The Overview Training element will typically be delivered by an instructor in a classroom; if a full-featured Learning Management System (LMS) is available, it may be delivered electronically. There will be an SOP for this Overview Training event. The Skills Training elements will usually be delivered, one-on-one, on the shop floor, by a subject matter expert (SME) who is also a trainer, as a Structured On-the-Job Training (SOJT) event. There will be an SOP for each of the SOJTIs in the module.

The Overview Training element includes an assessment of the learning product, a Measurement Research Assessment (MRA).

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**ADDIE Model**

**ANALYSIS:**
The Analysis phase of the ADDIE model identifies a performance gap, a discrepancy between a standard stipulated in a standard operating procedure (SOP) and some employee performance. A performance gap can be addressed by a learning product, i.e.: a set of training and assessment materials.

**DESIGN:**
The Design phase follows Analysis, where a planned approach to addressing the performance gap is outlined and approved. This planned approach has three components:

- Fitting the proposed learning product into the larger curriculum
- Outlining the proposed learning product
- Securing management approval of the outlined learning product

**DEVELOP:**
If management approves the design, a Development phase comes next, where the learning product - the training materials and the assessment materials - is developed to address the performance gap.

**IMPLEMENT:**
The Implementation phase follows, wherein the training materials and associated assessment materials are rolled out, on a provisional basis, to ascertain their real-world impact.

**EVALUATE:**
Finally, an Evaluation phase of the ADDIE model either:

(a) documents aspects of the learning product that require further development, whereupon that documentation is fed back to be analyzed again, or

(b) documents that the product meets the organization's needs, whereupon it is finalized and rolled out.
of training effectiveness – a Knowledge Transfer Assessment (KTA), for example. The training event is documented in a Training Record where the trainer and trainee concur that the trainee has, or has not, successfully concluded the event. In the case of classroom instruction, this training record is entered into the training tracking system and the entry is verified. In the case of a validated LMS, the training record will be an integral part of the learning product and will be electronically entered into the trainee's training history.

The precise fit of each of these modules into the larger curriculum is determined in the Design phase.

Once that Overview Training event is successfully concluded, the trainee goes on to the SOJT events. The several SOJT events are documented in Skill Demonstration Assessments (SDAs), where the trainee's ability to independently perform the task is documented. The results of the SDA are then entered into the training tracking system, and the entry is verified. After all the relevant SDAs are successfully completed, the trainee is qualified, meaning the trainee is ready to perform that module's tasks independently.

Let us consider several examples (see Figure 3).

**The Relationship between the Learning Product and the Associated SOP**

A second aspect of the fit between learning products and the larger curriculum is the relationship between the learning product and the associated procedure. That, too, will be delineated in the Design phase.

There are two ways that a learning product can be related to a procedure. The first is directly, where the product trains to the procedure; this is sometimes called “document based training.” The second is indirectly, where the learning product is mandated in the procedure, but the product does not train to the procedure; this is called “non-document based training.” An example of the latter is training in current Good Manufacturing Practices (GMPs), a Food and Drug

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Administration (FDA) requirement. The FDA requires that this training be both “current” and “conducted on a continuing basis.” These requirements are typically met by training on courseware that is repeatedly offered, say on a quarterly basis, and is also frequently revised to ensure current technological methods are included in training. The SOP that provides guidance for the GMP regulatory training is, by contrast, relatively fixed.

In the diagram seen in Figure 4, the procedure is on the left and the learning product is on the right. In the case of a procedure such as Management Notification, which identifies the routine as well as exceptional situations where employees must notify their management, the product trains directly to the procedure.

In the case of a procedure such as Train-The-Trainer (TTT), by contrast, there are several learning products; one trains to the management of the TTT program; another is the courseware for the TTT classroom sessions; and a third is the courseware for the subsequent TTT qualification session. These learning products have different training audiences; the first product – the program management product – has the organization’s training unit as its audience; the second and third products have the prospective qualified trainers as their audience.

Document based training and non-document based training must carefully be distinguished in the Design phase; if not, there is the possibility that all the learning products in non-document based training will be named after the same procedure. The author is aware of instances where a several-hour classroom session of mandated training had the same name and course number as a one-hour program management course, causing confusion in the training tracking system and among the several training audiences.

It is better to delineate clearly the more complex relationship between learning products and the associated procedure. The next diagram, shown in Figure 5, more clearly
SPECIAL EDITION: The ADDIE Model, and Instructional Generic Design Model

The ADDIE Model displays the non-document based training structure; it is now viewed as similar to a GMP regulatory procedure, where there is training to the procedure and also (a different thing) training on courseware that is mandated by the procedure.

Now the one-hour training on the management of the TTT program will have its own name in the training tracking system, and the several-hour long TTT classroom course will have a different name, as will the subsequent TTT qualification session. The two different training audiences can clearly recognize the relevant learning products.

The clear statement of the relation between the learning product(s) and the associated procedure should take place during the Design phase of the ADDIE model, and will be an important contribution to the ultimate success of the learning product.

The Learning Product’s Reduction by Consolidation of SOPs

Several learning products can be associated, directly or indirectly, with a single procedure. This suggests that a straightforward means of reducing training time within a training system might be to consolidate SOPs, thereby reducing the number of learning products. However, consolidation (or “streamlining”) of SOPs should be logical and be done to eliminate redundancies, not simply to reduce the number of SOPs. We will clarify this point.

Consider four examples that illustrate the issue:

1) The FDA requires gowning procedures. Department A has a gowning procedure. Department B has a different gowning procedure. Consolidation of SOPs would remove the redundancies here; Departments A and B would work together toward a single gowning procedure.
2) Department C has a protocol on the use of Equipment Specific Instructions (ESIs), say involving equipment maintenance manuals. Department D has a different protocol on the same kind of ESIs. Again, streamlining procedures would remove the redundancies; Departments C and D would work together toward a single protocol on the use of ESIs.
3) Department E has an SOP for operating an autoclave, and another SOP for operating a capping machine. There is no redundancy here; it would be counterproductive to consolidate the two procedures, since they deal with two distinctly different types of machines.
4) Department F has three SOPs and three packaging lines, one procedure for the operation of each line; each includes a brief section on equipment maintenance. There is redundancy here, but unlike that in examples one and two. The redundancy here is in the sections on maintenance. Consolidation of the procedures would remove the sections on maintenance and put them in a maintenance procedure of their own. [We will return to this issue in the next section.]

Consolidation of SOPs is essentially an issue of the correct writing of procedures. Very briefly, procedure writing has six steps, all but the last involving the collaboration of a procedure author (usually a technical writer) and one or more SMEs.

- First, the SME(s) and the author identify the process to be captured in this SOP.
- Second, they identify the audience for this SOP.
- Third, they develop the process map for this process. The process map breaks down the process into its elements and displays the logical interconnections between the elements.
- Fourth, the SME(s) and the author “chunk” the process. The chunks are developed from the process map, putting like elements together, and pulling unlike elements apart.
- Fifth, the text of the SOP will be written from the chunks. The author writes this up and the SME(s) reviews the text in light of the intended audience.
- Finally, the text will be revised by the author of the procedure into the standard format for SOPs.

Consequently, if procedures are correctly written, they will need little streamlining in the future, and will facilitate consolidation whenever new processes come online and procedures need to be created. Of course, if procedures have been poorly written, poorly chunked, or if there is a great deal of redundancy, then they must be revised along the lines sketched out above.

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The Relationship between Learning Product and the Various Regulatory Requirements

A fourth aspect of the fit between learning products and the larger curriculum is the relationship between the learning product and the various regulatory requirements. This aspect is also delineated in the Design phase. There are a number of regulatory regimes that impact on the training environment. These regimes include such agencies as the FDA, OSHA, EPA, DOT, DEA, and others, each with its own set of regulations.

On the one hand, the number of regimes means that there are simply more regulations to be taken into account. On the other hand, the various regimes can present the problem of regulatory overlap, where different agencies have differing regulations covering the same situation. We will consider how this impacts the design of the learning product.

If we conceptualize the manufacturing cycle where each process has a Setup Period, a Startup Period, followed by an Operate Period, and then a Shutdown Period, operating under GMP procedures, this cycle can be disrupted at any time by a malfunction or abnormal end event (Abend). The process is interrupted by a breakdown, jam, or some other malfunction. An initial question is, How do we deal with these Abends consistently, as a procedure? There seem to be two options: they can be captured in the same GMP procedures that cover the process, or they can be captured in procedures of their own.

In either case, when we create a procedure to deal with an Abend, we must include a trouble-shooting process, the original equipment manufacturer (OEM) technical manuals or other instructions that are specific to the equipment, a set of corrective and preventive actions, follow-up monitoring, and any safety or other relevant concerns.

The author has witnessed instances where the process of dealing with Abends is captured in the same GMP procedures that cover the routines of the manufacturing cycle. There are several problems with this approach. First, it overlooks the very abnormality of the Abend. After all, this is called an Abend because, in important ways, it is abnormal. Second, it overlooks the distinct division of labor between operators who enact the routine steps of the manufacturing cycle and the mechanics who address the abnormal events. This has substantial training implications; the procedures tend to be much longer, and both groups must train on the whole GMP procedure. Third, it confounds the “operational” level of detail in the routine situations with the more fine-grained level of detail in the abnormal situations, a level of detail that can only be addressed by reference to technical manuals. Fourth, it blurs regulatory requirements that differ between normal situations and exceptional situations, e.g.: OSHA safety regulations.

For these reasons, among others, it seems more appropriate to create a procedure dealing with Abends by having separate procedures; an illustration will clarify this.

If we represent the manufacturing cycle in a vertical process map, consisting of the Setup Period, followed by the Startup Period, then the Operate Period, and finally the Shutdown Period, abnormal events can be represented in a horizontal process map that intersects the manufacturing cycle at the point of the disruption. This horizontal map lays out the process of trouble-shooting, reviewing service or maintenance instructions that are specific to the equipment, implementing a set of corrective and preventive actions, conducting follow-up monitoring, as well as addressing safety or other relevant regulatory concerns.

At the point of an abnormal event, the GMP requirements of the manufacturing cycle are suspended, temporarily, by an OSHA-mandated Lockout/Tagout (LOTO). That is where the mechanics or engineers (in OSHA terms, the “LOTO authorized employees”) intervene with their Troubleshooting SOP and associated Equipment-Specific Instructions (ESI) to troubleshoot and maintain or repair the equipment. These troubleshooting procedures and ESI protocols make up the horizontal process map. Its training module will include a Troubleshooting SOP that would be delivered by an instructor in a classroom, or electronically; the ESI protocols would be SOJTs. These would appear on the curriculum of the mechanics (see Figure 6).

After the abnormal event is under control, the LOTO is removed and the LOTO affected employees (the operators) resume the manufacturing process, under the guidance of the GMP procedures.

Back in the GMP realm, and depending on the specifics of the abnormal event – for instance, the impact on the product – a Management Notification is prepared (a Notification of Event, NOE) that could lead to an investigation, corrective and preventive action, and follow-up monitoring.

By keeping these processes separated (vertically and hori-
The operators would have training on the GMP procedures on their curricula, and would qualify on these modules. The mechanics would have training on the troubleshooting SOPs on their curricula, and would qualify on those modules. Thus the operators would not need to train on the troubleshooting modules and the mechanics would not need to train on the operational modules. Of course, this would require that the SOPs would be written in a focused fashion.

We have seen how the proposed learning product is fit into the larger curriculum in the Design phase of the ADDIE model. The learning product thereby aligns with other learning products, and with organizational goals. We reviewed four aspects to this “fit” –

- The structure of training modules
- The relationship between learning product and SOP
- The reduction of training time by consolidating SOPs
- The relationship between learning products and various regulatory requirements

Now we will consider how the proposed learning product is outlined in the Design phase.

**Outlining The Proposed Learning Product**

Outlining the proposed learning product will usually consist of completing a Training Outline template (see Figure 7). We will first display an illustrative template, with twelve fields and instructions for completing each field. This will be followed on several of the fields.

Once the template is completed, it is ready for management signoff, which concludes the Design phase of the ADDIE model.

**Securing Management Approval Of The Outlined Learning Product**

The final component of the Design phase is management approval of the proposed learning product. This approval is important for at least three reasons. First, this ensures that resources allocated to the subsequent phases, Development, Implementation, and Evaluation, have approval at the appropriate organizational level. The investment of resources - particularly in the Development phase - will be substantial, and knowledge workers, be they instructional designers, software engineers, or whomever, are in no position to make the management decision about resource allocation. Second, Quality Unit approval ensures that the proposed learning product meets the organization’s quality criteria. Finally, there are a number of points where training implications of the proposed learning product - the training audience, the course length, etc. - can have a profound impact on business lines, and again, this impact must have managerial approval. The signatures on the Training Outline satisfy these needs.

**CONCLUSION**

The Design phase of the ADDIE model is the occasion for a planned approach to addressing a performance gap identified in the Analysis phase. This planned approach includes fitting the proposed learning product into the larger curriculum; it involves outlining the learning product in terms of a systematic template, the Training Outline; and, it includes the need for securing management approval of the outlined product.

When the proposed learning product has moved through the Design phase, it is ready for the Development phase where training materials and assessment materials are developed to address the performance gap.
## Figure 7

**Training Outline Template**

<table>
<thead>
<tr>
<th><strong>FIELDS</strong></th>
<th><strong>INSTRUCTIONS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COURSE TITLE:</strong></td>
<td>Enter the title of the document or course.</td>
</tr>
<tr>
<td><strong>COURSE NUMBER and VERSION:</strong></td>
<td>Enter the number and version of the procedure, protocol, or document.</td>
</tr>
</tbody>
</table>
| **TRAINING AUDIENCE:** | Those required job positions included in the scope of the learning product. Identify the areas, departments, and positions. For example, a training audience may consist of:  
  • All managers in a department  
  • All managers and supervisors in an area  
  • All employees in a department  
  • All employees who operate the bottler on Packaging Line 84. |
| **CURRICULUM FIT:** | Identify the training module; other associated courses |
| **PREREQUISITE COURSES/ REQUIRED SKILLS:** | List any prerequisite courses; any required skills |
| **TRAINERS:** | All qualified trainers who have been identified as SMEs on the course, including the Originator and Business Owner, if they are qualified trainers. |
| **BEHAVIORAL OBJECTIVES:** | Specify the observable competencies that trainees will demonstrate upon completing the training. For example, “At the end of this training session, the trainee will be able to demonstrate the following skills or perform the following tasks…” |
| **TRAINING DELIVERY METHOD:** | Check as appropriate:  
  • Classroom  
  • Structured On-the-Job Training  
  • Computer Based Training, etc. |
| **COURSE LENGTH:** | Enter the approximate time required to deliver the training session. This information is for planning purposes only. |
| **SPECIAL INSTRUCTIONS:** | Instructions to facilitate the preparation and execution of the event (e.g.: safety issues, logistical requirements, pre-work, handouts, etc.) |
| **MEASURES of EFFECTIVENESS:** | The KTA (and Answer Sheet) or SDA should be attached. The content of the KTA or SDA is derived from the Behavioral Objectives. |
| **APPROVAL:** | Includes signatures from:  
  • Originator  
  • Department Management and/or Business Owner  
  • Quality Unit |
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TRAINING AUDIENCE:

The personnel included in the learning product’s training audience must be negotiated. Many times a learning product will impact not only the business unit of the business owner of the SOP, but will impact other units as well. Personnel in those impacted units will be listed on the Scope Statement of the SOP, and also in the list of Task Responsibilities within the SOP itself. Unfortunately, these two lists of personnel do not always coincide.

Precisely defining the training audience becomes critical because those are the personnel who must be trained on the learning product associated with the new or revised SOP. After a new or revised SOP has been approved, there is a “training window” before the procedure goes into effect within which the impacted personnel can be trained on the SOP. This window is typically a week or two in length. It is critical that the training audience be defined before that window opens – before the SOP is approved – so that all the training will be completed before the effective date. Thus, the risk of untrained personnel “touching” the regulated product will be minimized.

When the learning product is in the Design phase, the author of the product can provisionally prepare a Training Audience List based on a review of the SOP Scope Statement as well as the Task Responsibilities. When the Training Outline is circulated for approval, the Training Audience List can be circulated as well. Management of each impacted unit reviews the list and recommends limiting it or expanding it, based on their direct responsibility for the task assignments of the impacted personnel. The author of the learning product can then take those recommendations into account as the product is finalized. Moreover, management in the impacted areas are alerted for the approval and implementation dates of the SOP, and can accordingly schedule personnel for necessary training.

As an additional comment, it is important to recognize the different kinds of personnel that may be included in the training audience for a given SOP: (1) employees (in the strict sense), (2) independent contractors, (3) contract company (third-party) workers, and (4) temporary agency workers. These four types of employees are cross-cut by several levels or ranks: (a) subordinates, (b) supervisors (i.e., managers, directors, etc.), and (c) executives. The finalized Training Audience List must identify impacted (and non-impacted) personnel from each of these groups.

BEHAVIORAL OBJECTIVES:

There is a strong case to be made for behavioral objectives, sometimes called S.M.A.R.T. (Specific, Measurable, Achievable, Relevant, and Time-based) objectives, in training. On the one hand, behavioral objectives permit the alignment of the intended training outcomes with organizational objectives. Anyone who advocates cognitive (i.e., non-behavioral) objectives for training must be prepared to explain how these objectives are to be aligned with those of the organization. On the other hand,
**BEHAVIORAL OBJECTIVES continued:**

Behavioral objectives permit the trainee to have clear expectations of the trainer’s (and the organization’s) intended training outcomes. These clear expectations play a critical role in effective adult learning. Many academics reject the role of behavioral objectives in the university classroom; this highlights the difference between training in industry, on the one hand, and higher education on the other. In higher education, accredited institutions award diplomas to students on the basis of a series of learning experiences over an extended period of time. The organizational objectives include (a) awarding the diplomas and (b) maintaining the accreditation. This has very little to do with training in industry, where the organizational objectives include (a) improving employees’ task performance on-the-job, and (b) addressing the requirements of various regulatory regimes.

**TRAINING EFFECTIVENESS:**

Assessment of training effectiveness must be distinguished from evaluation of training programs. There is a difference in kind – trainees are human individuals; training programs are organizational entities. Of course trainees participate in training programs, but the difference in kind means that the measures are different. For instance, trainee reactions (Donald Kirkpatrick’s Level One) are perhaps useful in evaluating training programs – favorable trainee reactions may factor in decisions about program continuity. Trainee reactions are much less useful in assessing training effectiveness, which involves assessing performance improvement that will impact on-the-job – a supervisor’s reactions are much more relevant.

In the present context, training effectiveness is assessed by one of two types of measures – a KTA or an SDA. The KTA in particular need not be validated in terms of the task(s) at hand. If the KTA is validated, then performance improvement on-the-job can be predicted from trainee performance on the KTA. If the KTA has not been validated, the measure can still be included in the learning product, as an interactive element of the courseware, and as a promissory note of future validation, if you will. The training event will be concluded in this case by the trainee (and trainer) concurrence that the trainee was trained on this courseware, and thereby on the SOP.

An SDA, by contrast, directly and validly documents the trainee’s ability to independently perform the task(s). Furthermore, once the relevant SDAs for a process are completed, the trainee is qualified, able to independently perform the tasks in that process.

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Gordon Welty, Ph.D.
REFERENCES

1. See D. Zielinski’s discussion of “blended learning models” in “A Closer Look,” Training (Nov 2005), Vol. 42, No. 11, pp. 21, also Harvey Singh “Building Effective Blended Learning Programs,” Educational Technology (Nov 2003), Vol. 43, No. 6, pp. 51-54. As B. Hall and J. LeCavalier put it in their “E-Learning across the Enterprise: The Benchmarking Study of Best Practices,” Sunnyvale, CA: BrandonHall.com (2000), p. 6: a across a range of industries, the emerging best practices model “is a highly compatible mélange à trois” uniting online learning for information transfer and procedural skill acquisition (often this constitutes pre-work for the next tier of the model), classroom or other site-based learning for higher order competencies, and structured on-the-job learning integrated with knowledge management and competency evaluation.


7. See 29 CFR §1910.147, “Control of Hazardous Energy.” This standard mandates that each workplace, with few exceptions, must develop a program to “disable machinery or equipment and prevent the release of hazardous energy while maintenance and servicing are being performed.” Hazardous energy includes electrical, mechanical, hydraulic, pneumatic, and other energy sources. The mandated LOTO program will have three components: (a) a set of written procedures for the control of hazardous energy, (b) an employee training program to ensure that the procedures are implemented, and (c) an annual inspection to ensure that the procedures continue to be followed. See also Federal Register (Nov 06, 1989), Vol. 54, No. 213, p. 46610; and Danny P. Liggett, “Training and Qualifying your Employees,” Petroleum and Chemical Industry Conference, 2005. Industry Applications Society 52nd Annual Conference (Sept. 2005), pp. 327-332.

8. The corrective and preventive actions (CAPA) may, in the event, be the same for the troubleshooting process and the manufacturing process.


11. As Craig Cochran has stated, “People have trouble contributing to fuzzy, undefined objectives,” “Creating and Meeting Objectives,” Quality Digest (September 2004), Vol. 24, No. 9, p. 56.


SUGGESTED READING


•  Kirkpatrick, Donald, Evaluating Training Programs, San Francisco: Berrett-Koehler (1994).”


### ARTICLE ACRONYM LISTING

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADDIE</td>
<td>Analyze, Design, Develop, Implement, Evaluate</td>
</tr>
<tr>
<td>CIP</td>
<td>Clean-In-Place</td>
</tr>
<tr>
<td>DEA</td>
<td>Drug Enforcement Agency</td>
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<tr>
<td>DOT</td>
<td>Department of Transportation</td>
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<tr>
<td>EPA</td>
<td>Environmental Protection Agency</td>
</tr>
<tr>
<td>ESI</td>
<td>Equipment Specific Instruction</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
</tr>
<tr>
<td>KTA</td>
<td>Knowledge Transfer Assessment</td>
</tr>
<tr>
<td>LMS</td>
<td>Learning Management System</td>
</tr>
<tr>
<td>LOTO</td>
<td>Lockout/Tagout</td>
</tr>
<tr>
<td>NOE</td>
<td>Notification of Event</td>
</tr>
<tr>
<td>OEM</td>
<td>Original Equipment Manufacturer</td>
</tr>
<tr>
<td>OSHA</td>
<td>Occupational Safety and Health Administration</td>
</tr>
<tr>
<td>SDA</td>
<td>Skill Demonstration Assessment SIP Sterilize-In-Place</td>
</tr>
<tr>
<td>SMART</td>
<td>Specific, Measurable, Achievable, Relevant, Time-based</td>
</tr>
<tr>
<td>SME</td>
<td>Subject Matter Expert</td>
</tr>
<tr>
<td>SOJT</td>
<td>Structured On-the-Job Training</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
<tr>
<td>TTT</td>
<td>Train-The-Trainer</td>
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Originally published in the July 2007 issue of *Journal of GXP Compliance*
Developing Assessments of Trainee Proficiency

In the world of training, the development of assessments is as essential to training administration as keeping score is to any professional sporting event. The author identifies the four key components of the process for developing assessments and how to incorporate them into the training module.

INTRODUCTION

Employees in regulated industries must be trained before they “touch” the product. According to the Food and Drug Administration (FDA), the “person” must have the “education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions.” This requirement has substantial implications for both managers and regulators. It also has substantial implications for the assessment of trainee proficiency.

Education and experience are dealt with differently than training. Education is typically documented in terms of grade level completed by - or diplomas awarded to - students in accredited institutions on the basis of a series of learning experiences over an extended period of time. Experience typically refers to work experience, and is documented by the employee's length of time in a specific job position; many times that is an extended period of time. None of these measures is entirely adequate; in both work experience and education, the qualitative richness of the process is obscured by the measure of duration. But they provide guidance to corporate policy nonetheless.

The pharmaceutical or other regulated company seeks to ensure that employees have requisite educational attainment by effectively implementing recruitment policies or policies in support of continuing education. The company can either recruit employees who meet educational levels or can subsidize the employees' further education until they meet the desired level. Likewise, the company strives to ensure that employees have the requisite work experience. The company can either recruit employees who have specific work experience or can retain employees until they acquire the desired level of on-the-job experience.

Training, by contrast, is typically documented in terms of specific training events in which the employee has participated. Management develops an Individual Training Plan (ITP) for each job position, listing the various training modules that incumbents must complete.

The ITP and the associated training can be contrasted to the employees' educational attainment and work experience in several ways. First, the ITP tends to foreground short-term objectives rather than long term. Second, it tends to focus on enhancing employees' task performance on-the-job, rather than their more general knowledge and experience. Third, because of the longer time frames associated with educational attainment and work experience, these factors are taken as givens by management. Training, however, is widely seen as a corrective action for many problems. To the extent employees manifest performance gaps, those gaps will typically be remediated by training. Jack Gordon has pointed out that:

“Managers send people to [training] courses precisely because they want to see observable behavior changes that will produce observable business results.”

So management's concern is with behavior change, which necessitates assessment of the effect of training on the trainee's task performance. Should the training not correct the performance gap, the management will then turn to the more extreme measures of progressive discipline or discharge.

This concern is shared by regulators, who want to ascertain how well the organization has its processes in control. If there are problems in pharmaceutical manufacturing, let us say, the regulator wants to know how the organization
responded to the problem. How was management notified? Was an investigation conducted, and if so, how well? How was the root cause identified? How was the corrective action formulated, and how was it executed? Many times the “cause” of the problem is identified as the residual category “human error,” hardly a root cause at all. And then “re-training” is proposed as the “corrective action,” as though the initial training could unexceptionably have been ineffective. Regarding auditors, as James Vesper has put it,

“GMP auditors and regulatory inspectors are becoming more savvy about training and performance. They are asking to see evidence that the training was effective.”

Following the lead of management and regulators, we will focus in this article on the development of training assessments. There are four components to the process of developing assessments: (1) identifying the behavioral objectives of the training module, based on the relevant operational procedure and the Training Outline, (2) determining the kind of assessment to be used, (3) preparing the assessment materials, and (4) incorporating these assessment materials into the training module.

We will now examine the four components of the process of developing training assessments.

**BEHAVIORAL OBJECTIVES IN THE ADDIE MODEL**

The ADDIE model is a generic instructional design model. It provides guidance at a fairly high level for instructional designers, software engineers, etc., as they author and revise learning products. The phases of the ADDIE model are Analyze, Design, Develop, Implement, and Evaluate. These phases are sequential - each depends upon the successful completion of the preceding phase.

Behavioral objectives have been specified in the Design phase of the ADDIE model. These objectives have several important functions. First, they permit intended training outcomes to be aligned with organizational objectives. Second, they permit trainees to have clear expectations of intended training outcomes. Third, they provide a sound basis for the design and development of training materials.

Behavioral objectives have a number of dimensions. Each must specify:
- The training audience
- The trainee performance
- Conditions for the performance
- The measure of the performance
- Criteria for successful performance

Let us consider each of these dimensions in turn.

**Training Audience**

The training audience is the set of job positions whose incumbents must receive training before they “touch” the product, or, in the case of supervisors, before they supervise employees who will be touching the product. All job positions that have responsibilities in a given Standard Operating Procedure (SOP) are part of the training audience for that procedure. For example, by regulation, sanitization SOPs apply to contractors and temporary employees as well as to full-time employees. As Roelof Kuipers has pointed out, it is important to define who needs what kind of training in a given organization.

“With a large pool of electrical, mechanical and maintenance engineers, electricians, machine operators, contractors, and many more, not everyone needs the same skill set.”

The Boones have summarized this nicely: “Your behavioral objective should identify the specific audience you plan to target.”

**Trainee Performance**

Trainee performance is the set of behaviors that the trainee will demonstrate upon completing the training. In sanitization processes, regulations stipulate that employees must follow written SOPs. As an example of a behavioral objective that highlights observable performances, “At the end of this training session, the trainee will be able to demonstrate the correct mopping technique for sanitizing controlled areas.” This demonstration - this performance - will be observable to the trainer who will certify the performance took place; in principle, the performance would be observable to the trainee’s manager or an auditor as well.
Conditions of Performance
The conditions of the performance is a list of conditions under which the trainee is expected to perform the behavior. For example, a behavioral objective might state “At the end of this training session, the trainee will be able to demonstrate the correct mopping technique for sanitizing controlled areas, using the double-bucket process.” The bolded text in the objective would be (part of) the conditions of the performance.

Measure of Performance
The measure of the performance provides the categories or scale that represents the performance in qualitative or quantitative terms. A measure of performance on a paper-and-pencil quiz could be the number of correct answers (perhaps compared to the total number of questions). The measure of sanitization of an area could be provided by environmental monitoring data. In James Popham’s terms, it is a major shortcoming when

“No behavioral objectives were not accompanied by assessment instruments specifically linked to those objectives.”

He continues that learning objectives

“Will have little effect on day-to-day instruction if not accompanied by relevant assessment devices.”

FDA regulations stipulate that

“A protocol is required to contain …A description of the observations and measurements to be made to fulfill the objectives of the study.”

Performance Criteria
Finally, criteria for performance specify the limits of successful performance. For instance, many times, the performance on a paper-and-pencil quiz is considered successful when 80% of the responses are correct. Again, the sanitization of an area has been successful when environmental monitoring data for each room after sanitizing is within acceptable limits. The inclusion of criteria is important because it highlights that the behavioral objectives are built into the assessment measures. As Jack Gordon (ibid) has put it,

“When you know what targets you’re shooting at, keeping score becomes much easier.”

Section Summary
In this section we have considered the five dimensions of behavioral objectives - training audience, trainee performance, conditions for the performance, the measure of the performance, and criteria for successful performance - and the role they play in providing focus to the training module. Given the behavioral objectives and their associated measures and criteria, the particular kind of assessment can be stipulated.

WHICH KIND OF ASSESSMENT
At a very general level, training involves two components - a Training Event, followed by a Performance that demonstrates whether the training had (or did not have) the desired impact on the job, in the workplace.

The Training Event might be a structured on-the-job training (SoJT) event; it might be a classroom event; it might be an e-learning event. The Performance might be the SoJT trainee’s independent execution of the relevant tasks; it might be the trainee’s accurate logbook entry following a classroom session; it might be the trainee’s completion of a quiz at the end of an on-line session with 80% of the responses correct. Of course, the performance might be unsuccessful - the trainee might fail to execute the relevant tasks, might make an inaccurate logbook entry, might score less than 80% on the quiz.

The Training Event is a set of independent variables (the predictors); the associated Performance is a set of dependent variables (the criteria). Both components - the Training Event and the Performance - are multi-dimensional.

The Training Event includes trainer(s), trainee(s) with skill-set(s) and disposition(s), training organization (supervisory factors, business case), training facilities (allocated space, allotted time, utilities), and training materials (instruments and equipment, raw and in-process materials). Training materials also include the training script - for a typical SoJT event, for instance, the script would spell out
in some detail the steps in the Prepare, Tell, Show, Do, and Follow-up cycle to be followed in this event.  

The Performance component (continuing with the SoJT illustration) includes the trainee’s independent and satisfactory performance of the relevant tasks in a real work setting, as judged by a supervisor or as indicated on some business-process metric, and usually has both individual level and group level (work team) elements. There is a feedback loop between the performance and the training event. As we observed before, it is possible that the task performance by the trainee was unsuccessful. In that case, the adequacy of the trainer’s ability or preparation, the suitability of the training materials, the capability or motivation of the trainee, as well as the timing or situation of the training event (or a combination of these) can be called to account.

The core concepts of Performance are as follows:
- a real work setting wherein
- a task is completed

This concept of performance is not always logistically feasible. Which tasks in a specific process must be completed? How can a real work setting - with all the demands of production and output - be accessed for training purposes? These are difficult questions to answer, difficult enough that it is frequently necessary to use proxies for purposes of training assessment.

Whether core concepts or their proxies are utilized in assessment of training, they must be documented in procedures, protocols, SOPs. An SOP stipulates the standards for the core concepts of Performance or for the proxies.

Turning first to the core concept “real work setting,” if that setting is unavailable for task samples, a surrogate measure must suffice. Brinkerhoff gives the example of training on cardiopulmonary resuscitation (CPR) techniques:

“Barring a workplace heart attack, we would find no on-the-job application of the skill learned.”

The surrogate in such a case is a Skill Demonstration Assessment (SDA), where the trainee independently performs the task(s) on relevant equipment outside of the real work setting - off-hours, on placebo batches, during production shutdowns, etc.

Turning next to the core concept “task completion,” there are situations where the process cannot be broken into discrete tasks, or is for some reason inaccessible. Consider, for example, equipment that has a biennial preventive maintenance schedule. That equipment may not be available for the training of mechanics for more than a year. In such a case, another kind of proxy must suffice. That is a Knowledge Transfer Assessment (KTA). A KTA is a paper-and-pencil test that predicts performance on-the-job. If task completion or non-completion can be correlated with a test score, so that high scores correlate with task completion and low scores correlate with non-completion, then the KTA is validated, and performance on-the-job can be predicted from trainee performance on the KTA.

If the KTA has not been validated, it can still prove useful as an interactive element within the courseware itself. It can take the form of “study questions,” providing guidance to trainers as they interact with trainees in facilitating the course. Perhaps needless to say, in this form the questions are not part of any assessment.

We have not included Donald Kirkpatrick’s Level 1, the “trainee reaction” measure, in our list of assessments for several reasons. First, there is no evidence that a trainee’s appreciation of - or affective response to - a training event correlates with the trainee’s task performance. Thus the trainee reaction is not a surrogate for performance. Second, if an assessment of the utility of the training content or materials is needed, a review of the module during the pilot implementation, by the training and development peers, will likely provide a more focused and accurate assessment than the reactions of the trainees. Third, the use of trainee reactions raises the possibility of documented negative judgments. For instance, suppose the trainee reaction form uses a question such as “What can be done to improve this training module (or training event).” What shall be the corrective action of the trainer to negative judgments? A regulator may come across these documents during an audit, and can rightly ask about the remediation that followed from them. Better these judgments were not documented in the first place, if there were no intention to take corrective action.

**SECTION SUMMARY**

In this section we reviewed several kinds of assessments that
can be considered for incorporating in a particular training module. These range from assessments that approximate the core concept of a Performance, through a series of increasingly distant proxies, to an assessment based on the trainee’s knowledge of the job, as reflected in a validated KTA.

PREPARING THE ASSESSMENT MATERIALS

Once the kind of assessment has been selected, the assessment materials can be prepared. The first step in preparing assessment materials is to complete a task analysis. Once the task analysis has been completed, the specific tasks and sub-tasks will be listed, groups of tasks will be aggregated or “chunked,” the flow of the process will be indicated, and concepts providing the “science” for task performance will have been associated with each chunk.26

This completed task analysis will include an extensive set of tasks. The second step is to winnow through the particular tasks whereby the trainee’s performance will be assessed. One way would be to take a representative or random sample of the set of tasks. Another would be to take a purposive sample of those tasks that are judged critical to the whole process.

Once the list of tasks is a manageable length, this becomes the work sample for assessment. The third step is to prepare a protocol for the assessment, indicating that the trainee is expected to perform the listed tasks under specified conditions, and meeting certain criteria for success. As Vivian Bringslimark has expressed it,27

“Using an approved [operational] SOP, a qualified observer or trainer should observe the employee performing the [operational] procedure, compare the performance to the [operational] SOP, and record the results on a qualification or competency assessment sheet. The results should be communicated to the employee, his or her supervisor, and to the trainer responsible for the original training, indicating whether the prescribed level of competency has been attained.”

As we have noted above, there are circumstances where task sampling is not practicable, and a surrogate is necessary for assessment. That surrogate is the SDA. A training procedure stipulates how, when, and where the trainee can independently perform the task on relevant equipment outside of the real work setting. As Bringslimark (ibid) has put it, the process of how the assessment sheets are approved, distributed, and evaluated also should be defined in that [training] SOP as part of the overall training system. We will briefly describe that process.

The originator uses the number and version of the relevant operational SOP as the course number and version for the SDA form. The form includes a number of yes/no statements. These describe the identified critical or representative tasks to be assessed on the SDA. These are the items assessing the trainee’s performance. (See Figure 1)

The trainee performs, and the trainer or some other subject matter expert (SME) monitors the performance and checks each item in turn: “yes” if the performance was successful, “no” if not. When the performance is complete (whether successful or not), the trainee and the trainer sign and date the SDA. Area management may sign as well. The completed form is submitted to the data entry personnel of the validated training tracking system, or, in case of manual data processing, to the staff of the document repository.

If SDAs are not available, situational judgment testing can be a proxy. In a typical situational judgment test, trainees are presented with a variety of situations they might encounter in the workplace. Most situational judgment tests take a paper-and-pencil form, although they could take an on-line form. These situations (or scenarios) are usually established on the basis of a job or task analysis. The trainee selects the best way to handle each situation. The trainee’s choice is compared to a response called “correct.” The “correct” response is established either empirically or by the collective judgment of a panel of SMEs.28

Should situational judgment testing not be a feasible alternative, a job knowledge test can be a surrogate. A KTA is a paper-and-pencil test that predicts performance on-the-job. The items in the KTA can be constructed either (a) out of material contained in training courses, user manuals, technical handbooks, etc. or (b) from material provided by a panel of SMEs; in either case the material reflects the content of the job. The items that should be selected are the best discriminators between employees who are judged more proficient and less proficient performing the task. Thus high scores correlate with proficiency and low scores correlate with less proficiency; the KTA is validated, and
performance on-the-job can be predicted from trainee performance on the KTA.

Section Summary
In this section we have sketched out the preparation of several forms for assessing training, ranging across the continuum from work sampling, through SDAs, situational judgment tests, and finally to KTAs. Once the assessment forms have been prepared, they can be incorporated into the training module.

INCORPORATING ASSESSMENTS INTO THE TRAINING MODULE
Assessments can be incorporated into a training module in several ways: as a pre-training assessment, as a post-training assessment, and interspersed throughout the training material.29

Pre-training assessments (pre-tests) are administered before the training begins. These assessments can take the form of task samples, SDAs, or KTAs. If they have been administered before the trainees congregate at the training site, the trainer can compile the scores, which may allow the trainer to adapt the training materials to the specific levels of trainee preparedness.

Post-training assessments (post-tests) are administered after the training has been completed. Again, they can take many forms. They can be administered before the trainees leave the training site, or they can be administered at a later date, or both. If the post-tests are administered while the trainees are still on-site, and then at one or more later times, they can serve as measures of the sustainability of the training as well as the effects of the training. Tennant, et al, (ibid) suggest three kinds of post-training assessments: an “immediate test,” to be carried out when the training has been completed, an “intermediate test” when the trainee has returned to the job, and an “ultimate test” to be employed “after an appropriate time has elapsed in order to measure the improvement of the skills, and behavioral changes.”

Post-test scores can also be compared to pre-test scores. Given equivalent forms, differences in scores can be taken as some evidence of training effects.

Finally, depending on how the work process has been chunked and conceptualized, assessments can be incorporated throughout the training material, in addition to any other assessments that are used as pre- or post-tests. Assessments throughout the material serve to reinforce training at a more fine-grained level, to break up training material into lengths closer to adult attention span, etc.

Not only is the timing of assessments critical, but the security of the assessment process is critical as well.

Test Security
Assessment of training can place trainees under considerable personal and organizational pressure to succeed.30 In addition, valid assessment forms can be quite costly to develop. Therefore, attention must be paid to ensuring test security - that is ensuring that the training event and associated performance comply in terms of the five dimensions of the behavioral objectives listed above. The performance must be identifiably that of the individual trainee, under the stipulated conditions, and demonstrably successful (or not). These compliance issues have been highlighted by the
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CONCLUSION

In this paper, we considered four components to the process of developing assessments. First, we reviewed five dimensions of behavioral objectives - training audience, trainee performance, conditions for the performance, the measure of the performance, and criteria for successful performance - and the role they play in providing focus to the training module. Next, we examined the kinds of assessments that can be incorporated in a particular training module, ranging from assessments that approximate the core concept of a performance, through a series of increasingly distant surrogates, to an assessment based on the trainee's knowledge of the job, a KTA. Third, we outlined the preparation of several kinds of forms for assessing training, ranging across the continuum from work sampling, through SDAs, situational judgment tests, and finally to KTAs. Fourth, we commented on several issues that arise as we incorporate assessments into the training module, including the timing of assessments as well as how to ensure the integrity of the assessment process.

Returning then to the ADDIE model, the Analysis phase identifies a performance gap, a discrepancy between a standard stipulated in a procedure (SOP) and some employee performance. A performance gap can be addressed by a training module, that is, a set of training and assessment materials. This is followed by the Design phase, where a planned approach - documented in a Training Outline - is prepared to address the performance gap. Also, behavioral objectives are specified in the Design phase.

If management approves the design, a Development phase comes next, where the training module is created and approved. This phase is where training materials - trainee activities, instructional content, delivery methods, and instructional technologies - and assessment materials are created to close the performance gap. We focused our attention in this article on the development of training assessments.

After the training materials and assessment materials have been developed, the training module can be rolled out in the Implementation phase, and finally studied in the Evaluation phase.

ENDNOTES AND REFERENCES

1. Thus for pharmaceuticals - see 21 CFR 211.25; for non-clinical lab personnel, 21 CFR 38.29; for biopharm personnel, 21 CFR 600.10; for medical device personnel, 21 CFR 820.25; for human tissue recovery personnel, 21 CFR 1271.170.
9. See 21CFR 211.23 (b), “Personnel Qualifications.”
10. See 21 CFR 211.56 (d), “Sanitation.”
12. Boone and Boone, ibid.
14. Merrill, M. David, “Hypothesized Performance on Complex Tasks as a
41. This is a broader social issue; see Carolyn Kleiner and M. Lord, “The Cheating Game,” *US News & World Report*, (22 Nov 1999).
43. This is a broader social issue; see Carolyn Kleiner and M. Lord, “The Cheating Game,” *US News & World Report*, (22 Nov 1999).
45. This is a broader social issue; see Carolyn Kleiner and M. Lord, “The Cheating Game,” *US News & World Report*, (22 Nov 1999).
47. This is a broader social issue; see Carolyn Kleiner and M. Lord, “The Cheating Game,” *US News & World Report*, (22 Nov 1999).
49. This is a broader social issue; see Carolyn Kleiner and M. Lord, “The Cheating Game,” *US News & World Report*, (22 Nov 1999).
The ADDIE model is a generic design model. Our focus here will be the role of ADDIE for instructional design projects in Food and Drug Administration (FDA) regulated industry. The model provides guidance at a fairly high level for instructional designers, software engineers, and others as they author and revise training modules or courseware - the learning product. There are several application values of the ADDIE model. First, the model clarifies and standardizes the process of addressing performance gaps in an organization, allowing best practices in instructional design to be identified and implemented. Second, this model is widely utilized in the industry, which facilitates benchmarking of instructional design between organizations. The phases of the ADDIE model are Analyze, Design, Develop, Implement, and Evaluate. These phases are sequential - each depends upon the successful completion of the preceding phase.

The ADDIE model is scalable to all size pharmaceutical, biopharm, and medical device companies. The model can be scaled to various size organizations, and fitted to the particular needs of a specific organization on a case-by-case basis, or by an overall decision. As an example of a particular case, the decision may be made in the Analysis phase to forego the needs analysis of the employees' skills and dispositions - these attributes may be well-known and documented, requiring no further analysis. Thus management makes the decision to limit the analysis phase to a task analysis.

As another example, management may make the overall decision to forego Pilot Implementation - and the associated Formative Evaluation - and roll out every learning product directly. In this instance, the Implementation phase is followed by Summative Evaluation. In both examples, it is a management decision to save costs by limiting the ADDIE model.

The Analysis phase of the ADDIE model identifies a performance gap, a discrepancy between a standard stipulated in a Standard Operating Procedure (SOP) and some employee performance. A performance gap can be addressed by a learning product, that is, a set of training and assessment materials.

This is followed by the Design phase, where a carefully planned approach to addressing the performance gap is outlined and approved. This planned approach has three components: (1) fitting the proposed learning product into the larger curriculum, (2) outlining the proposed learning product, and (3) securing management approval of the outlined learning product.

If management approves the design, the Development phase comes next, where the learning product - the training materials and the assessment materials - is developed to address the performance gap.

The Implementation phase follows, where the training materials and associated assessment materials are rolled out, on a provisional basis, to ascertain their real-world impact. This is the first of two kinds of implementation - Pilot Implementation or pilot testing - followed by a Formative Evaluation phase; the second kind of implementation is Final Implementation, followed by a Summative Evaluation of the relative cost and benefit of the finalized program to the organization.

Pilot testing of a learning product can add considerable value for an organization. While the learning product - e.g. training module, organizational development program, LMS courseware - is still in the developmental process, not yet approved for final rollout, a pilot can provide significant data about the real-world impact of the product, going well beyond the data that can be inferred from the material that appears on the story-board. The data derived from the pilot can be used to revise and improve the learning product before it is rolled out to the department, site, or entire workforce. This will of course add to the overall cost of module
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1. development, but it is a cost that is well worth incurring.

We review the role of a pilot implementation in the process of developing a learning product, looking initially at strategic issues and then reviewing some tactical issues. First, we consider the relationship between a pilot and the ADDIE design and development model. Next, we compare pilot implementation to other pilot projects in the pharmaceutical industry. Then, we consider a number of conditions that will facilitate or inhibit the implementation of a learning product. Turning to tactical issues, we review how an instructional designer prepares for a pilot implementation of a learning product, conducts a pilot implementation, and finally, evaluates a pilot implementation.

PILOT IMPLEMENTATION AND ADDIE

There appears to be some confusion about the meaning of the term “Implement.” We hear folks saying that the “Implementation” phase means that the training module is developed, finalized, and ready to be rolled out. However, this viewpoint gives rise to two questions. First, what then are we to make of the “Evaluation” phase that comes after the Implement phase? Is this to be only a summative evaluation? Does this mean that there is no place in the ADDIE model for formative evaluation? That would be an unduly restrictive view of this generic model.

Second, the ADDIE model is an iterative feedback model, which means that the results of the Evaluation phase are fed back, closing the loop, facilitating further refinement of the learning product. If the evaluation shows that the module has shortcomings, such as lacking clarity, those shortcomings are fed back to the author(s) to be analyzed again. Further design and development efforts follow until the module meets the organization’s needs and standards, but that feature of the model, iterative feedback, strongly suggests that the “Implementation” phase cannot simply be the finalized rollout of the learning product.

Indeed, the “Implementation” phase of the ADDIE model includes pilot implementation as well as final implementation. As Gillis and Beauchemin have put it, “The term ‘pilot’ warns everyone to expect some adjustments. […] Revisions and modifications make even the best training programs more effective, and evaluating the pilot reveals potential program improvements.” The notion that the phase is a “pilot” of the learning product, rather than a finalized rollout, highlights the iterative feature of the model.

Thus the ADDIE model should be conceptualized as having two paths out of the Development phase. One path leads to pilot implementation, followed by formative evaluation, from which a feedback loop allows further analysis, design, and development. At some point, determined by management, the learning product is judged to be ready for the other path. It then moves to final implementation, followed by summative evaluation. (See Figure 1).

In this article we will focus on the place of pilot implementations in the development process.

PILOT PROJECTS IN THE PHARMACEUTICAL INDUSTRY

In the pharmaceutical industry we have a well-known example of a pilot activity that illuminates the relationship between the (Pilot) Implementation phase and the rest of the ADDIE model. That is the transition between laboratory research and development, and commercial manufacturing.

When a pharmaceutical company has discovered a promising product in the R&D laboratory, it goes into a development phase. The company subjects the product to clinical trials to determine its safety and efficacy. If it is deemed safe and efficacious, it is a candidate for commercial manufacture and marketing. The question is: how does the company move from the scale of laboratory production, perhaps...
several ounces of product in total, to the commercial scale of thousands or millions of units of product? This is where the pilot project fits in.8

The company pilots the manufacture of the product, as a transition from the laboratory scale to the commercial scale. The pilot has a number of outcomes, four of which are particularly important:

• It demonstrates the feasibility of the scale-up in general.
• It demonstrates the validity and reliability of the particular process selected for the pilot.
• It generates parametric product and process data for commercial manufacturing.
• It provides data for budgeting, planning and scheduling of subsequent manufacturing.

Each of these outcomes may prove positive or negative for the future of the product. As examples of negative outcomes: the scale-up may not prove feasible, the particular process may be unreliable, there may be off-spec findings during scale-up, and the process may not be economically feasible.

The relationship between the (Pilot) Implementation phase and the rest of the ADDIE model is similar. When a pharmaceutical company has discovered a promising solution to a training gap, it goes into a development phase. The company assigns an instructional design team to take the promising solution and develop it into a draft training module. If the training module seems to be efficacious, in terms of face validity and peer-review, for example, it becomes a candidate for department-wide, site-wide, or even corporate-wide rollout. The question is: how will the company move from the instructional designer’s desktop and storyboard to the whole workforce? This is where the pilot implementation fits in.

The company pilots the training module, as a transition to the entire workforce. The pilot has several outcomes. It shows whether or not the promising solution can be scaled up in general. The pilot shows the validity and reliability of the specific interpersonal and institutional process selected for the pilot (or perhaps it shows unreliability). It generates process and outcome data that may be important for the finalized learning product. And it provides data on cost and scheduling considerations that should be taken into account in the wider rollout.

There are two basic possibilities for the pilot implementation of a learning product, depending upon two kinds of participants in the pilot. These participants involve end-users on the one hand, and training and development peers on the other. End-user testing intends to assess how representatives of the target audience interface with the learning product that has been developed for them. The peer inspection subjects the learning product to a review for consistency with design standards and program logic; it also can identify problems such as repetition, overtaxing of memory, etc.

These two possibilities may disclose different kinds of problems with the learning product. End-user testing can find problems that are overlooked by peer inspection; likewise, peer inspection methods can find problems that are overlooked by user testing. In many cases, the best results can often be achieved by combining the two approaches.10

CONDITIONS FACILITATING IMPLEMENTATION
There are specific conditions that facilitate the pilot implementation, and eventual rollout, of a learning product. The absence of these conditions can inhibit the implementation and rollout. We should ensure that these conditions are present for our pilot implementation.

Donald Ely has discussed eight conditions.11 There must be the following:

• A dissatisfaction with the status quo - things could be better
• Sufficient knowledge and skills on the part of those who would implement the learning product
• Adequate resources
• Time - as Ely puts it: “Good time; Company time; Paid time.”
• Rewards or incentives for participants
• The expectation and encouragement of participation in decision-making about the implementation
• Commitment by those who are involved
• Evident leadership

Ely points out that this list of conditions has been validated, and can be used to develop a checklist for the implementation project. But, he cautions, they must not be viewed as formulas or rules; they should be subject to local conditions.
Moreover, there can be a profound political aspect - either pro or con - to an implementation effort. As Carol Weiss has expressed it, “This is because policies and programs are proposed, defined, debated, enacted, and funded through political processes, and in implementation they remain subject to pressures both supportive and hostile.”¹²

**OBSTACLES TO IMPLEMENTATION**

There is also a series of obstacles to implementation. Abt Associates has identified a number of these;¹³ of particular interest to us are the following three obstacles:

- Disappearing training intervention
- Variable implementation
- Shifting training audience

**Disappearing training intervention**

The training intervention is the trainer’s execution of a script.¹⁴ This script is executed (or performed) by the trainer(s) in specified training facilities, within allocated space and allotted time, and employing requisite training materials. It is performed for a specific group of trainees. The training intervention disappears when the trainer fails - for any number of reasons - to perform the script within that space and time, for those trainees. The trainer might not be proficient in performing the script, resulting in a clumsy performance; the trainer might not have physical access to the script, resulting in an impromptu performance; the trainees might be inattentive or asleep, etc. In any case, should the training intervention disappear, there is no predictor of interest for the subsequent trainee performance.¹⁵

**Variable implementation**

The trainer performance of the script must be relatively standardized across trainers, facilities, times, and trainees. The word “standardized” is critical here: standardization implies standards, or criteria for the performance. The training intervention becomes (unacceptably) variable when the performance deviates from those standards. On the one hand, the criteria will be set by management; on the other hand, the trainer’s preparation must include an assessment of the relevant scripted tasks, as judged by a supervisor or as indicated on some business-process metric. In the case of team-led training events, it will include both individual level and group level (training team) elements. In the absence of such standards and criteria, as Gamse, et al., have pointed out, “if no impact were to be found, it would be impossible to know if it was because of a failure of implementation, a failure of [the training design], or both.”¹⁶

**Shifting training audience**

There are obstacles to implementation on the trainee side as well. Employees are transferred or reassigned and are no longer part of the training audience. Curriculums and individual training plans (ITPs) change and the training is no longer relevant to the employee’s work assignments. This attrition and change has an obvious effect on implementation of training modules and the assessment of sustainability of training. Gamse, et al., have commented that it is not so much “that such changes create a bias between groups;” they go on that what is especially “problematic is that the changes create noise or unknown variation against which it is difficult to detect [program] impact.”¹⁷

These three obstacles are listed in order of increasing seriousness. The disappearance of the training intervention can be addressed and perhaps controlled by a suitable train-the-trainer program, a remediation that is within the scope of the Training Department. Likewise the variability of implementation can be remedied by well-known quality control measures, which are within the scope of the Quality Assurance Department. The problem of shifting training audiences is less tractable, since it is directly caused by the business needs of the organization.

With those strategic considerations in mind, let us turn to some tactical issues. Based on our own experience with pilot projects, we will review how to prepare for, conduct, and evaluate a pilot implementation.

**PREPARING FOR A PILOT IMPLEMENTATION**

Preparing for a pilot implementation has seven steps. The first step is to review all relevant material that has been developed so far, including any pertinent SOPs, the training materials, the trainee assessment materials, and the evaluation materials. It is important to distinguish between trainee assessments that measure the trainee skill acquisition,¹⁸ and
the evaluation measures of the training module's adequacy in terms of some set of institutional standards. Just as the organizational or institutional purpose of a training module should not be confused with its behavioral objectives, so evaluation should not be confused with assessment. The two are, of course, related - trainee success will contribute to program adequacy - but the two are, nonetheless, distinct.

Next, we should prepare a plan for the pilot, sometimes called an Execution Plan. We can turn to the Training Outline for a brief overview of the module. This is the brief, one- or two-page outline that lists the name and course number of the module, identifies the training audience, indicates how the module fits in the larger curriculum, lists the behavioral objectives, indicates the delivery modality, the anticipated duration of the training session, identifies the assessment materials, etc. In addition to the information derived from the Training Outline, the plan should sketch the various roles and responsibilities for the preparation, execution, and evaluation of the pilot implementation.

This plan will indicate the extent to which end-user testing, and peer inspection, will be involved. Once the plan is ready, it is important to get management approval of the plan for the pilot.

Our third step is to prepare a checklist for the pilot implementation. As with any well-planned training event, it is hard to imagine too much detail in the checklist. Better the checklist should be overly detailed than to realize at the last minute, with the participants coming in the door, that we have neglected some critical factor. Once we have developed a comprehensive checklist, this can provide a template for subsequent pilots.

Next, we must schedule room(s) in the case of classroom training, or work station(s) and equipment in the case of Structured On-the-Job Training (SOJT) sessions. When scheduling, try to get the same room, work station, or equipment that would be used in any other training event.

Fifth, we must prepare all required materials for the pilot session, including training materials, safety materials, and process materials. These materials can be listed on the comprehensive checklist, and can be ignored (N/A’d) if not needed.

Training materials include:
- Flip charts and markers
- Handouts for trainees

Safety materials include:
- Job Safety Analysis (JSA)
- Material Safety Data Sheet (MSDS)
- Personal Protective Equipment (PPE)

Process materials include:
- Equipment
- Controls (make sure the switches work, etc.)
- Instruments
- Utilities (make sure the water runs when you open the tap, etc.)

The sixth preparatory step is to review the set of end-users, the target audience for the learning product. Who is in the scope of this training? Ensure coverage of all significant groups within the scope. This means including differing technical skill levels; different cultural, language, and ethnic groups; different sites and facilities; differing tenures - some new hires, some old timers, etc. It is important to estimate the percentage of invitees that will actually be attendees; that estimate will ensure you have enough participants attending the pilot to provide reliable and credible data on outcomes and process. The estimate of invitees who will actually attend will depend upon your experience, or the experience of your training and development peers. Then you can assemble the list of invitees, and again be sure to get management approval. Each attendee’s manager will need to approve participation.

The final preparatory step is to send invitations to the pilot session. Invitations should be sent to each participant (trainee), as well as to your training and development peers. Inviting your peers is a courteous collegial gesture, and these attendees can provide peer evaluations of the session that the participants may not be prepared to do. The invitation should include a brief overview of the module indicating that this is a pilot; be sure to mention that training credit in the employee training history will depend on extent of
CONDUCTING A PILOT IMPLEMENTATION

Conducting a pilot implementation has eight steps. When the day and time of the pilot session arrive, use your checklist to make sure that everything is in place and ready to go. Welcome the end-user trainees and your training and development peers. Indicate again that this is a pilot implementation; repeat that credit to the participants’ ITPs will depend upon the extent of revisions that are needed. Even if credit cannot be given because major revisions are called for, the trainees’ participation in the development of this module will be noted and appreciated. Discuss the logistics of this facility, where the water fountains, coffee machines, and restrooms are located, etc. Address relevant Emergency Response Plans, fire escape routes, etc.

The second step in conducting the pilot is to distribute the training materials, and indicate criteria for success - 80%, 100% or whatever. The preliminary knowledge check, if applicable, should then be administered.

The third step is to explain the content of the pilot module. This is an opportunity to present the “science” of the process; it is more than a sequence of tasks. Present the behavioral objectives for the module. It is worth repeating that adults learn best when they have crystal clear expectations about their projects; hence we always use behavioral objectives. Invite questions or concerns from the participants (trainees), and specify the feedback process. Stress that you welcome feedback; that the main purpose of a pilot implementation is to elicit feedback for program improvement. Specify how the participants should make their feedback - whether they should interact immediately with the trainer(s) when they have an issue, or they should note the issue for later discussion.

In either case, every issue should be recorded for later attention. Also, mention that they will be called upon to evaluate the pilot session before they leave - we will return to this point in the next section.

The fourth step is to move through the module, section by section, task by task. For each section and task, discuss the purpose of the task; the importance of the task; when and where to perform the activity; and the expected results of correct performance and the potential results of incorrect performance. Highlight critical safety points for each task (as needed); also highlight key Good Manufacturing Practice (GMP) points for each task (as needed). Then invite questions or concerns. It perhaps goes without saying that training and development peers should hold their questions and concerns for a post-session debriefing. The author has seen training sessions where the peers raise questions while the trainees are present, and it can be quite disruptive. On the one hand, the trainees can be confused by the different “spins” on the training material. On the other hand, the exchange between training and development peers can suggest that there is dissention within the training unit.

The fifth step is to demonstrate each task (as needed). This will be particularly important in SOJT sessions. Also in SOJT sessions, allow the trainee to practice; record the trainee’s progress through the sequence of tasks. It is important to track trainee progress on an explicitly non-GMP progress form. Since trainee progress will only be on part of the module - representing part of a SOP - that progress cannot be recorded on a controlled (GMP) form. The non-GMP progress form can be disposed of after the module is completed, after the session is duly recorded on a controlled training tracking form.

While the trainees are progressing through the sequence of tasks, provide assistance as needed - while the trainee prepares for independent performance (for SOJT), and while the trainee prepares for an assessment (for a classroom module).

In the case of SOJT, after the session is completed, allow independent performance by the trainee. Observe the trainee perform each task safely, correctly, and without any coaching from the trainer.

When the independent performance is completed, or when the classroom session is completed, assess each trainee’s performance. Utilize the appropriate GMP assessment form, and assess independent performance (for SOJT); assess knowledge transfer (for a classroom module).

The final step in conducting the pilot session is to record the completion of the module. Use the training tracking form, which as we have noted is a GMP form.
Once the pilot session is completed, it is time to evaluate the adequacy of the training module, propose revisions as needed, and prepare a report to management.

EVALUATING A PILOT IMPLEMENTATION

Evaluating a pilot implementation has six steps. The first step is to invite the end-user trainees to evaluate the pilot module. Explain the evaluation process, and how the evaluations will be used in feedback for program improvement. Use explicitly non-GMP evaluation forms. Since at this point we are evaluating a work in progress, the training module that is under development, not yet approved - there should be no record of that progress on a controlled (GMP) form. Sometimes “sticky notes” - clearly not controlled documents, can be used to record the trainees’ evaluations. The non-GMP evaluation forms can be disposed of after the module is completed and approved. Collect the evaluations from the trainees as they depart the room.

The second step is to collect evaluations of the session and the module from your training and development peers. This can be done by a face-to-face debriefing or, again, by the use of an explicitly non-GMP evaluation form.

The third step is to review all the evaluations of the module and the pilot session.

Then, prepare an evaluation report summarizing the evaluations; consider making revisions to the learning product. Propose needed revisions to the module, and get management approval of these revisions. As Gillis and Beauchemin have put it, “Revisions may include incorporating new material to help the program meet its objectives or changing the objectives themselves based on trainees’ or managers’ input. Changes must support specific, measurable objectives.” In light of the seriousness of the needed revisions, determine the appropriate training credit for participants.

The fifth step is to dispose of all non-GMP evaluation forms.

The last step is to submit the training tracking form for appropriate credit to each participant’s ITP.

CONCLUSION

The well-executed pilot implementation of a learning product can add considerable value for an organization, providing significant data about the real-world impact of the product. This data can go well beyond what can be inferred from the material that appears on the story-board. The data from the pilot implementation can be used to revise and improve the learning product - as part of a formative evaluation - before it is finalized and rolled out.

ENDNOTES

1. There are some slight variations in the terms applied to the phases of the ADDIE model. For instance, with reference to medical devices, the FDA has used the term “establish” to encompass three of the phases; “define,” “document,” and “implement.” However, similarly, critics of the ADDIE model occasionally refer to the implementation phase as the “Instruct” phase of the model. See Jack Gordon and Ron Zemke, “The Attack on ISD: Have we got Instructional Design all wrong?” Training, Vol. 37, No. 4 (April 2000), p. 42.


15. Gamse et al. (op cit) give the example of an educational intervention which intended to compare two methods of training school personnel: some were trained by university staff, while others were trained by utilizing a videotape series developed by the same university. The evaluators soon discovered that few schools had ordered the videotapes, and those that did, weren’t using them appropriately. Hence that arm of the intervention had “disappeared.”


20. As Annie Koh has put it, “you need to segment the people in the company by functions and give them what they need to get the job done;” see “Rolling Out Major IT Projects,” Business Times Singapore (02 Aug 2007)


22. Gillis and Beauchemin, “The Ideal Rep” (op. cit.), p. 60; also David Gallup, K. Beauchemin and M. Gillis, “Competency-based Training Program Design,” (op. cit.), p. 244 on “Refining.”

ARTICLE ACRONYM LISTING

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tr>
<td>ADDIE</td>
<td>Analyze, Design, Develop, Implement, Evaluate</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<td>ITP</td>
<td>Individual Training Plan</td>
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<td>JSA</td>
<td>Job Safety Analysis</td>
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<td>LMS</td>
<td>Learning Management Software</td>
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<td>MSDS</td>
<td>Material Safety Data Sheet</td>
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<td>PPE</td>
<td>Personal Protective Equipment</td>
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<td>R&amp;D</td>
<td>Research and Development</td>
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<tr>
<td>SOJT</td>
<td>Structured On-The-Job-Training</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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Originally published in the January 2008 issue of Journal of GXP Compliance
Strategy and Tactics of Training Recordkeeping

Recordkeeping is necessary for any training system that is subject to audit. This necessity may come to be recognized as early as the point in program development when training assessments are created. It certainly comes to be recognized when the program is being implemented (or even piloted) and actual training records are generated. This documentation could include training records (or attendance sheets), training assessments, and curricula or individual training plans (ITPs). These documents could be in electronic form or hard copy.

This article examines training recordkeeping in the pharmaceutical, biopharmaceutical, medical device, blood product, and other regulated industries. First to be considered, in this paper, are some strategic aspects of recordkeeping before turning to tactical issues.

In the mid 1990s, the University of Pittsburgh conducted a major study of functional requirements for recordkeeping, called the Electronic Records Project. Reporting on this project, and specifically describing records, Wendy Duff stated: “[Records] are created in the first instance to control or direct an organization and to help orient staff to a common goal or purpose.” That is, records serve the purpose of controlling and directing the organization. She continues, “They have residual value because they document the outcomes of the directing and controlling activities and because they provide evidence of an organization’s rights as well as its obligations to its staff and society. For records to fulfill these roles, they must be readable, understandable, and trustworthy.”

There are two main audiences for recordkeeping: operational staff and various quality auditors. The operational perspective is typically proactive, while the auditor’s perspective is typically retroactive. There are also other audiences including the training unit itself.

Operations staff includes employees (the trainees) and their supervisors. Both employees and supervisors are interested in the trainees’ currency in their ITPs, for purposes of work assignments. At the beginning of each shift, the supervisor wants to know if the employees on this shift are trained to the current versions of each and every standard operating procedure (SOP) that is listed in the ITP, that will be executed during that shift. The supervisor reviews the employees’ training histories (i.e., the summary of the training records). Then the supervisor makes work assignments accordingly. Thus, the training records are used proactively to control and direct the organization.

Auditors include internal and external auditors (e.g., regulatory investigators, etc.) who are interested in whether the signer of the particular operational document (i.e., a batch record) was trained to the appropriate SOP before signing. The auditor reviews the signer’s training history in light of a set of documents being inspected. In these cases, the training records provide evidence of the organization’s past fulfillment of its regulatory obligations.

RECORDKEEPING REQUIREMENTS

As the Electronic Records Project at the University of Pittsburgh has indicated, recordkeeping requirements can be considered at several levels—that of the organization, that of the recordkeeping system, and that of the record itself (see Figure 1).

The organization level (I), the highest level of requirements, must be compliant with all relevant legislation, regulations, and best practices concerning training records.

The training recordkeeping system (II)—whether electronic, paper based, or hybrid—must be implemented, responsible, consistent, and appropriately backed up according to the following definitions:

- Implemented means that training events can be duly recorded in the system
- A responsible system’s controlled documents (i.e., SOPs
for training recordkeeping) are written and followed, plus the procedure clearly identifies the responsible party for each task. As an example of the failure to meet this functional requirement, and its GXP implications, consider the US Food and Drug Administration’s Warning Letter to Arrow International dated 10 October 2007: “According to procedure #CHR-001. ‘Training Administration, Documentation, and Recordkeeping Procedure,’ your firm has 30 days to complete the training. One training requirement was over six (6) months late.”

- Consistent systems have been validated, so identical processes generate identical outcomes. Vendors sometimes suggest that their software has been validated or audited. However, FDA has specifically stated that the organization using the software must validate it for that situation.

- Appropriately backed-up systems protect documents from loss or corruption by being subject to a regularly scheduled backup. As an example of the failure to meet this functional requirement, see FDA’s Warning Letter to the Cordis Corporation in Warren, NJ dated 01 April 2004: “…validation did not include testing and verification of backup and restoration of the electronic data files.”

The documentation of the training itself can be viewed as a captured record, a maintained record, and a usable record.

The required characteristics of a captured training record are authorized, comprehensive, identifiable, and complete according to the following definitions:

- Authorized training records have been created by an authorized person, for example a qualified trainer
- Comprehensive means that a training record has been created for every training event. For an instance of not meeting this functional requirement, see FDA’s Warning Letter to Rhytec, Inc. (24 April 2007): “Documentation of training is not consistently maintained.”
- Identifiable means only one training record has been created for a given training event, and it is linked to that particular training event.
- Complete training records include all information about the training event, for instance, which employee was trained, on which SOP, by whom (the trainer), and at what time and date. As an instance of the failure to meet this functional requirement, consider FDA’s Warning Letter to Omnicare, Inc. dated 11 January 2007: “all of the employee records lacked the ‘Supervisor Signature’ to show that the training was given.”

Maintained records must be inviolate, auditable, and appropriately retained according to the following definitions:

- Inviolate is defined as any alteration or modification of the record is traceable, and further, that repudiation of the record is not possible. As an illustration of not meeting this functional requirement, consider FDA’s Warning Letter to Concord Laboratories dated 11 July 2006: “Appropriate controls are not exercised over computers or related systems to assure that changes in analytical methods or other control records are instituted only by authorized personnel.”

- Auditable means that every use of the record leaves an audit trail. As an example of the failure to meet this requirement, see FDA’s Warning Letter to Concord Laboratories dated 11 July 2006: “…review of audit trails is not required.”

- Appropriately retained training records must be subject to a retention schedule and then disposed according to procedure.

Usable training records must be exportable, retrievable, and accessible to authorized parties according to the following definitions:

- Exportable records must be portable from one system to another without loss of information
- Retrievable training records are in a form that can be searched and retrieved within a reasonable period of
time and expenditure of resources
• Documents accessible to authorized parties must be accessible to those who are authorized to access them and unavailable to those who are not authorized.

After identifying two main audiences for the documentation of training—operational staff and auditors—the training recordkeeping must possess characteristics of good documentation management. If at each level—organization, training recordkeeping system, and documentation of training—characteristics are present that are appropriate for that level and proceduralized, that level will be "audit proof," which is to say it can survive an internal or external GXP audit, and will moreover have business value to operational staff.

PART 11 COMPLIANCE

When document management is discussed with reference to training and assessment, the topic of Part 11 compliance frequently comes up (Part 11 refers to “Electronic Records; Electronic Signatures," which is Part 11 of 21 CFR). In keeping with the emergence of electronic technologies, FDA issued regulations in 1997 for e-records and e-signatures that sought to permit wide use of electronic technology, compatible with the protection of public health. Soon after they became effective, FDA announced a reconsideration of these regulations. In 2003, FDA withdrew the guidelines that had accompanied the regulations. While the reconsideration of the regulations was under way, FDA indicated they would narrow interpret the scope of Part 11 and promised to exercise enforcement discretion. During this period, records and recordkeeping need still comply with the underlying regulations.

A typical example of FDA regulations and associated recordkeeping is quality complaints about drug products. 21 CFR 211.204 requires written procedures for the handling of all product quality complaints. This requirement ("predicate rule") further stipulates that “a written record of each complaint shall be maintained in a file designated for drug product complaints.” That is a second predicate rule; since it deals with recordkeeping, it implicates Part 11, if the organization has chosen to manage that record electronically. Moreover, the initial regulation also stipulates that a record shall be maintained, should an investigation of the product complaint be conducted; or the record shall include the reason and the name of the person responsible for a decision not to conduct an investigation. That is a third predicate rule; since it also deals with maintaining records of investigations, it also implicates Part 11.

Equipment cleaning and maintenance under GLP, GMP, and medical device regulations have broader scope (see Table I). The cleaning and maintenance requirement (first predicate rule) also stipulates that the cleaning and maintenance must be recorded (second predicate rule).

The form of these typical regulations involves two aspects: a requirement (one predicate rule) that a task or activity be proceduralized and the SOP be followed, and a requirement (a second predicate rule) that an associated record be kept of the activity or task. The second predicate rule, dealing with recordkeeping, implicates Part 11 if the organization had decided to manage the record electronically. Insofar as Part 11 is implicated, procedures and controls must ensure the authenticity and integrity of electronic records. Moreover, procedures and controls must hold individuals accountable and responsible for actions initiated under their signatures.

TRAINING RECORDS

By contrast, the documentation of training, including training records and training assessments, is not covered by such predicate rules. FDA regulations for areas such as pharmaceutical and biopharmaceutical operations, clinical trials, medical device operations, or human tissue processors require that personnel be trained. These are examples of the first predicate rule noted in Table I.

The only requirement for documentation of training is found in FDA’s GLPs, where it is stipulated that “Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a nonclinical laboratory study.” That implicates a “current summary” of the individual's training records, which might take the form of the individual's training history, not the training records, or training assessments themselves.

Regarding clinical trials, FDA stipulates that “A protocol is required to contain the following […] The name and address and a statement of the qualifications (curriculum vitae or other statement of qualifications) of each investigator,
and the name of each sub-investigator (e.g., research fellow, resident) working under the supervision of the investigator on a given clinical study. Notice that this predicate rule about “curriculum vitae or other statement of qualifications” of the clinical trials investigator was not extended to the subordinates, the research fellows, residents, etc.

Finally, the GMPs require “records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.” It is instructive that the rulemaking that applied this predicate rule to the qualifications of consultants did not apply it to the majority of pharmaceutical operations employees and supervisors covered in 21 CFR 211.25.

FDA regulations are silent about training records for other areas such as pharmaceutical and biopharmaceutical operations, medical device operations, blood products processors, or human tissue processors. Indeed, 21 CFR Part 11 does not include such a requirement for itself. It requires only a “determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks,” which is another example of the first predicate rule noted in Table I.

In light of this, the documentation of training does not fall within the scope of Part 11. What are the implications of this limited scope? We assume throughout that this documentation is controlled, as well as duly signed by the party responsible for the action described. The documentation of training can be considered as instances of what FDA has called a hybrid situation. In such a situation, paper record and signature components can co-exist with electronic record and signature components, “so long as […] the content and meaning of those records are preserved.”

Consider the following scenario: A GXP training event—either technical training or regulatory training—has just occurred. All the trainees have been assessed as “successful” in the training. There is a training record—a controlled document—and its use is proceduralized, including entry into a validated Learning Management System (LMS). Trainees then sign and date the paper-training record, and the trainer

<table>
<thead>
<tr>
<th>Regulation</th>
<th>First Predicate Rule</th>
<th>Second Predicate Rule</th>
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<tr>
<td>21 CFR 58.63</td>
<td>(a) Equipment shall be adequately inspected, cleaned, and maintained.</td>
<td>(c) Written records shall be maintained of all inspection, maintenance, testing, calibrating and/or standardizing operations.</td>
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<td>21 CFR 211.67</td>
<td>(a) Equipment and utensils shall be cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, integrity, strength, purity, and quality (SISPQ) of the drug product beyond the official or other established requirements.</td>
<td>b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product.</td>
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<tr>
<td>21 CFR 211.182</td>
<td>Equipment and utensils shall be cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, integrity, strength, purity, and quality of the drug product beyond the official or other established requirements.</td>
<td>A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed.</td>
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<td>21 CFR 820.70</td>
<td>(g) Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.</td>
<td>(1) Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.</td>
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countersigns and dates the record. At this point, the event is fully documented; the trainees are fully trained to perform the GXP tasks. They can “touch” the product or supervise those touching the product. Then, according to procedure, duly authorized data entry clerks enter the data from the training record into the LMS within 72 hours, and sign off on the entries. A duly authorized data steward verifies the data entries and signs off. At this point, by procedure, the electronic record becomes the controlled document, and the paper copy can be archived or disposed.

Sounds straightforward; however, there have been situations where it is assumed that all training records fall within the scope of Part 11. Instead of the scenario outlined in the previous paragraph, the documentation of the training event is treated like a regulatory submission, say, where each of the parties involved must provide an electronic signature to the electronic record. So the “draft” training record is routed to each trainee for their review and electronic signature, then is routed back to the trainer for review and electronic signature, and finally routed to QA for “release.” The number of “transactions” increases dramatically. When finally released, the training record ceases to be a draft, and becomes “effective.” Before the training record became “effective,” employees who had just been trained were in-

<table>
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<th>TABLE II: Necessary Fields in Training Records.</th>
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In a study of a random sample of training records (n = 11) processed this way, involving employees—not consultants, not non-clinical lab staff, not clinical trials investigators—the average time between the conclusion of the training event and the “release date” was 10 days.

If training records had been recognized as outside the scope of Part 11 and the first scenario had been followed, the time between conclusion of the training event and the full documentation of the training would have been about 10 minutes—the time it takes the trainer to check all the trainees’ signatures and dates and countersign the training record.

FDA regulations require that personnel touching the product be trained. The regulations, with few exceptions, do not address training records, including training assessments. It is important to review carefully the cases where the regulations do apply and ensure compliance. It is equally important to ensure that the organization is not wasting time and resources in overbuilding (i.e., hyper-scoping the training recordkeeping process).

Training records, for instance, have a number of necessary fields. These fields are listed in Table II, insofar as the documentation corresponds to the first scenario.

The training procedure must not only list each of these fields, plus any optional “nice-to-have” fields, but must indicate the roles and responsible party for each field. If the training SOP describes a fully electronic scenario where trainees record their participation in the training event online, and trainers also record their facilitation of the event online, the SOP must additionally describe the fall-back process in the event there are connectivity problems, training in remote locations, etc. Thus the roles and responsibilities of the data clerk and data steward are still critical.

If hard copies are archived following data entry into the validated LMS, they should be placed in the document repository with, at a minimum, the following indexing information: record type, file names, date ranges, and positions (titles of personnel) who are authorized to access the archived records. Or, by procedure, the hard copies should be appropriately disposed.

**THE TRAINING UNIT AS AUDIENCE**

The training unit itself is another audience for the documentation of training. First of all, the training unit can use training records to document the level of effort of the unit. This documentation can be used in annual budget sessions to justify requests for more training staff or other resources.

Second, the training unit can use training records and training assessments to test the accuracy of statements about training.
Documentation of training impact can be represented as a continuum ranging from an endpoint reflecting training inputs to an endpoint reflecting training outputs (see Figure 2). At the first endpoint on the continuum, training impact is documented by staffing levels of the training unit. The supposition is, “The larger the training staff, the greater the training impact.” This is clearly only a measure of inputs, a very rough proxy for training impact.

At the other end of the continuum, training impact is documented by return on investment (ROI) for training. This can be calculated in a number of ways. For instance, the marginal benefit/cost ratio is the change in trainee proficiency divided by the change in the training unit’s expenditure on this training module.\(^25\) ROI is clearly a direct and salient measure of training outputs. Effective training leads to improved performance, hence performance measures should be used to document training impact. These measures might include numbers of documents with defects, amount of rework, and other business metrics.

The number of seats occupied in training sessions falls on that continuum, somewhere between staffing levels and ROI, nearer to the rudimentary endpoint of staffing levels.\(^26\) Other points on this continuum of the documentation of training impact include training assessments such as knowledge transfer assessments (KTAs) and skill demonstration assessments (SDAs).\(^27\)

How can training documentation be used to test the accuracy of theoretical statements about training? Consider the following statements and accompanying graphic by Harold Stolovitch: “Because training is costly and removes workers from productive tasks, we expect significantly improved performance after training. Reality, however, is usually very different, as illustrated by the post-training solid line” (see Figure 3).\(^28\) These statements and the graphic are quite intriguing to trainers.

Two methodological questions about Stolovitch’s figure arise: What kind of evidence would be required to determine whether there is a dip in performance during the training event (the second panel in the triptych)? What kind of evidence would be required to determine if there is a dip in performance following training (the third panel in the triptych)?

This article stresses the methodological point that the answer to each question depends on continuous tracking of performance—throughout the training event for the first question, and during the immediate post-training period for the second. Such tracking, taking the form of performance assessments (most likely in the form of SDAs), will require a substantial recordkeeping effort.

In the typical case, however, assessments are conducted at only two points in time—one a pre-training assessment just before the training event, and a second, post-training assessment, say an “intermediate test” conducted after the trainees have returned to the job. Given only two data points, the average performance level would appear to be a straight line, perhaps upward-sloping to the right, perhaps flat; in any case we would not be able to address the questions about Stolovitch’s figure.\(^29\)

These uses of the documentation of training do not have the enterprise-wide significance of the other two audiences—the operational use and the auditor’s use. The operational staff represents the line of business. This audience and its proactive use of training records for work assignments directly relate to the bottom line. The auditors represent the regulatory requirements within which the organization will be profitable (or not).

The training unit is usually viewed as an overhead department, engaging in capacity building and thereby (only indirectly) contributing to the bottom line. Donald Kirkpatrick and others have held that “trainers must justify their existence.”\(^30\) An effective training department should address business performance issues, and “justify their existence”
by pointing to the improved performance of the workforce. Otherwise the training department will be viewed as overhead and not active contributors. In this sense, trainers are indeed an audience for training recordkeeping. However, we see that this is a distinctly secondary audience, behind the two major audiences.

Good training recordkeeping may well contribute to a corporate climate that supports widespread and disciplined use of organizational metrics. Such metrics allow benchmarking and trending to enhance organizational control.

CONCLUSION

There are two main audiences for training records, operational staff and auditors. In addition, there are other audiences such as the training unit itself. To serve these audiences, training recordkeeping must possess characteristics of good document management. At each level of the organization, document management must be appropriate so that training recordkeeping will be “audit proof,” and will, moreover, have business value to operational staff.

Regulatory compliance, as it relates to training recordkeeping, requires that personnel touching the product be trained. FDA regulations, with few exceptions, do not address training records. It is important to review carefully the several cases where the regulations do apply and ensure compliance. It is equally important to ensure that the organization is not wasting time and resources overbuilding the training recordkeeping process.

The fields that are necessary for training records, as well as necessary roles and responsibilities, need to describe the fall-back process in case there are access or other system problems in a fully electronic approach to training recordkeeping. Validated electronic training tracking systems should be employed to manage training records and training assessments in an effective manner.

Training records can provide data to justify budget requests. They can provide data to test the accuracy of statements about training. The training unit’s use of these records will not have enterprise-wide significance; yet, such use can contribute to the overall impact of organizational metrics. GXP

ENDNOTES


4. Duff, op. cit., pp. 33-35. These are functional requirements of recordkeeping, not necessarily GXP regulatory requirements. As we shall see, the functional requirements do have GXP implications. For the current situation on organizational compliance, see Roger Matus, “It’s No Longer Business As Usual When It Comes to Handling Electronic Documents,” Journal of Health Care Compliance, Vol. 9, Issue 2 (March 2007), pp. 11-14, p. 73, and Darwin Stephenson, “Accelerating Compliance,” E-DOC Magazine, Vol. 21, Issue 4 (July 2007), pp. 27-29.


6. Available at www.fda.gov/foi/warning_letters/66535c.htm. See also “Arrow warned about quality systems,” Reading Eagle (16 October 2007).


10. Available at www.fda.gov/foi/warning_letters/g6208d.htm.

11. Available at www.fda.gov/foi/warning_letters/archive/g9573d.htm.

12. Available at www.fda.gov/foi/warning_letters/archive/g9571d.htm.


14. Authorization involves authenticated users, usually this is two-factor authentication involving two of the three factors: (a) What you know (e.g., a password), (b) What you have (e.g., a security swipe card), and (c) What you are (e.g., a biometric characteristic). See Joan Engebretson, “Federal Agencies Must Begin to Support New Standard for Logical Access Protection,” Federal Computer Week (16 Aug 2007), pp. 1, 7; also “Two-Factor Authentication,” Communications of the ACM, Vol. 48, No. 4 (April 2005), p. 136.

15. On predicate rules, see Tammala Woodrum, “21 CFR Part 11: The role of predicate regulations and associated internal policies,” Drug Information Journal, Vol. 37, No. 2 (2003), pp. 159-164. See also 21 CFR 211.198 (a) on the requirement of written SOPs, 211.198 (b) on the requirement of written records for each complaint, and 211.198 (b) (1) on the requirement of written records for each investigation or the decision not to investigate.

16. For GLPs, see 21 CFR 38.63, “Maintenance and calibration of equipment,” and for GMPs, see 21 CFR 211.67, “Equipment cleaning and maintenance,” also 21 CFR 211.182, “Equipment cleaning and use log,” and for medical devices, see 21 CFR 820.70, “Production and process controls.”

17. For pharmaceutical employees, see 21 CFR 211.25; for biopharm personnel, 21 CFR 58.29; for non-clinical lab personnel, 21 CFR 58.29; for medical device personnel, 21 CFR 820.25; for human tissue recovery personnel, 21
Gordon Welty, Ph.D.


19. See 21 CFR 312.23(a)(b)(ii)(b). A curriculum vitae is more a record of educational attainment than a training history. Since the protocol is part of the IND regulatory submission, it will implicate Part 11 on that ground.

22. See 21 CFR 211.34, “Consultants.”

23. Office of Compliance, CDER, “Guidance for Industry: Computerized Systems Used in Clinical Investigations,” Washington, DC. FDA (May 2007), p. 7. “Those who use computerized systems must determine that individuals (e.g., employees, contractors) who develop, maintain, or use computerized systems have the education, training, and experience necessary to perform their assigned tasks…We recommend that computer education, training, and experience be documented.” Neither a guidance nor a recommendation constitutes a predicate rule.


28. On KTAs and SDAs, see Welty, “Developing Assessments of Trainee Proficiency,” op. cit., pp. 67-70. It is not the case, contrary to Wise-Blackman, op. cit., p. S-10, that “documenting the transfer of knowledge about the SOP is best accomplished through a Web-based system that incorporates short quizzes as a prerequisite to receiving approval for training,” because there is a substantial legal exposure to the use of unvalidated KTAs (short quizzes), and there are serious costs to validating KTAs; see Welty, op. cit. p. 68, esp. note 23. The trainee’s completion of prerequisites would best be ascertained through a SDA, as would the documentation of trainee proficiency.


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INTRODUCTION
The ADDIE model provides high-level guidance for the development and revision of programs of all sorts, including GXP training programs. The phases of the ADDIE model are analyze, design, develop, implement, and evaluate. These phases are sequential; each depends upon the successful completion of the preceding phase.

The analysis phase of the ADDIE model identifies a performance gap that can be addressed by a training program (i.e., a set of training and assessment materials, a qualified trainer, and a training audience). A performance gap is a discrepancy between a standard stipulated in a standard operating procedure (SOP) and some employee performance.

This is followed by the design phase, where a carefully planned approach, documented in a training outline, is prepared to address the performance gap. Also, behavioral objectives are specified in the design phase.

If management approves the design, the development phase comes next, where the training program—the training materials and the assessment materials—is developed to address the performance gap. There are four components of the development phase: identifying the objectives of the training module, based on the relevant operational SOP and the training outline; preparing the training materials, with special attention to structured on the job training (SOJT) materials and e-learning materials; preparing the assessment materials; and assembling these materials into the training program.

The implementation phase of the ADDIE model follows, where the training materials and assessment materials are rolled out, either provisionally in a pilot implementation (e.g., a proof of concept study) or in a final implementation. The notion that this phase may be a “pilot” of the training module, rather than just a finalized rollout, highlights the iterative feature of the model.

The evaluation phase follows implementation. In the case of a pilot implementation, the results of the program evaluation can be fed back, closing the loop, facilitating further refinement of the training program. This is called a “formative evaluation.” As Robert Gagné and Leslie Briggs have stated, “Formative evaluations provide data on the basis of which to revise and improve the materials, the lesson plans, the performance tests, and indeed the operation of the entire instructional system.” If the evaluation shows that the training module has shortcomings, those shortcomings are fed back to be analyzed again. Further design and development efforts follow, until the module meets organizational needs. Thereupon there is a final implementation, and an evaluation that documents the extent to which the training program meets the organization’s needs. This is called a “summative evaluation.” “Summative evaluation is usually undertaken when development of an instructional entity is in some sense completed, rather than on-going. Its purpose is to permit conclusions to be drawn about how well the instruction has worked,” state Gagne and Briggs.

The ADDIE model can be conceptualized as having two paths out of the development phase. One path leads to pilot implementation, followed by formative evaluation, from which a feedback loop allows further analysis, design, and development. At some point, determined by management, the training program is judged to be ready for the other path. As Gagne and Briggs have pointed out, “There is no standard number of formative evaluations that small components or segments or the entire system undergo. The number depends on the budgets and time available, the degree of excellence set as the system design objective, and the total circumstances surrounding the project.” The program then moves to final implementation, followed by summative evaluation (see Figure 1).

There are several ways to conceptualize the ADDIE model at this point. One is to include pilot implementation and formative evaluation within the development phase. When
the pilot and the formative evaluation are completed, the program moves into the (final) implementation phase, followed by the (summative) evaluation phase. Another conceptualization is to include two types of implementation, pilot and final, within the implementation phase, and two types of evaluation, formative and summative, within the evaluation phase. These different conceptualizations bear on the logic of the ADDIE model, but not on the process of program development.

As a final introductory point, it is clear that management has one very significant role in a formative evaluation; that is specifying the overall goal, and level of effort, for the evaluation. What might be management’s response to evaluative findings gathered during the formative evaluation of a program? The response of the program designers and developers to evaluative findings is clear; they will consider making program improvements based on the evaluative findings. What about the response of management?

FEEDBACK VERSUS RESEARCH DESIGN
The question often arises in the formative evaluation of a training program or other program: what is the effect of the dissemination of evaluative findings during the life of the program? It is often assumed that the “experimental design” dictates that intervention (e.g., training materials, training “script,” etc.) must remain invariant during the program cycle. Friedman, Furberg, and DeMets\(^8\) state that a clinical trial study protocol “should be developed before the beginning of subject enrollment and should remain essentially unchanged except perhaps for minor updates. Careful thought and justification should go into any changes. Major revisions which alter the direction of the trial should be rare.” If preliminary findings were fed back, this would allow a modification of the training materials and other aspects of the program, thus invalidating design and the evaluative research findings.

This position has until recently been held regarding clinical trials in the pharmaceutical industry. As Derek Lowe\(^9\) has expressed it, in a clinical trial, you “establish your ‘null hypothesis’ (typically that your drug is no better than a placebo or the current standard of care) and you start collecting data, in the hopes that you’ll fail to prove it. Everything stays carefully blinded. The investigators have no idea what they’re administering and the patients have no idea what they’re taking until a predetermined endpoint—to do otherwise would destroy the statistics.” Notice the significance of “blinding” in clinical trials, particularly “double blinding,” where both subjects and investigators are unaware of the assigned intervention—whereby findings for program improvement cannot straightforwardly be fed back\(^10\). In contrast to the logic of blinding, the actual conduct of blinding in randomized clinical trials (RCTs) has been assessed in several recent studies, including Boutron et al.\(^11\) and Fergusson et al.\(^12\).

This position has been held by researchers outside the field of clinical trials as well: Michael Brooks\(^13\) states that continuous feedback of evaluative findings “... has the unfortunate effect of tossing a monkey-wrench into the research design constructed at the program’s outset.” Daniel Stufflebeam, a leading figure in the evaluation community, describes\(^14\) the development of his own position, “I had to reject basically everything I had thought necessary for evaluating educational projects, including behavioral objectives, experimental designs, and standardized tests. Instead, I advised educators to key evaluations to provide information for decision making.”

The argument against the “experimental method” is a methodological, not a practical argument\(^15\). The critics of
experimental design are speaking of characteristics inherent to evaluation theory that account for a sharply limited utility. The critics are not suggesting that formative evaluation would be more successful if the experimental designs were more precisely constructed, if randomization of subjects were more diligently pursued, or if experimental methods were more carefully practiced. According to the critics, experimental method in program evaluation, especially RCT, is defective.

The importance of this matter can hardly be overstressed. As indicated above, feedback of evaluative findings is of vital importance for improving the process in training and development. If there is an incompatibility between feedback and the “experimental method,” one obviously must be abandoned. But to abandon the former, evaluators forego their mandate to provide timely and relevant information for program adaptation. To abandon the latter, they seriously limit the research techniques they have available for evaluating the program; instead of Donald Campbell and Julian Stanley’s famous “Experimental and Quasi-experimental Designs,” the formative evaluator is restricted to just the quasi-experimental designs and even more inferior approaches, such as “pre-experimental designs.” As Green states, “RCTs are the gold standard of treatment trial methodology, and to deprive complex (often psychosocial) interventions of their imprimatur is potentially to undervalue these areas in an evidence-based climate.” Moreover, this limitation sacrifices what rigor the evaluators’ discipline has. We find, however, that the critics of “experimental design” have misplaced their criticism.

The next section will give an existence proof that formative evaluation can be conducted within the framework of experimental design, and evaluative findings can at the same time be provided for improvement of the training program. This means that the full range of evaluative approaches is available to the formative evaluator, including experimental designs (i.e., RCT) as well as quasi-experimental designs.

THE GOOD NEWS, PART 1
It is not the case that training intervention must remain invariant. Program enhancement, in light of feedback from a formative evaluation, can take place concurrently with an evaluation in the framework of the RCT experimental design. Of course, desirable modification practice does not (or should not) mean a hodgepodge array of “random” interventions resulting from poor program definition; this should have been preempted in the design phase of the ADDIE model. Nor should “random” interventions result from the capacity of those who implement training programs to understand adequate definitions; that should have been addressed in the implementation phase. It makes no difference, for the experimental method, whether an evaluative judgment of program ineffectiveness is available for program adaptation or not. It makes no difference, for the experimental method, whether changes in training intervention are implemented or not. Evaluators can fill their mandate for dissemination of timely data and concomitant programmatic change.

The evaluator can realize, based on an on-going program evaluation, that “training intervention G will not produce the desired results.” The intervention can be revised in the “middle of the stream,” so to speak, and evaluators can still complete their formative evaluation. The dissemination of evaluative findings through an appropriate study monitoring committee, and a managerial reaction to such findings, enhancing the likelihood of program success, will not invalidate the evaluation effort, even though an initial judgment predicted program failure. Only a misunderstanding of the nature of evaluative research could foster the view that the training intervention is fixed.

Assume that an evaluation of a training program is underway. The program, in essence, takes a set of inputs and given conditions, Z, and by means of some process G, transforms the inputs into an output described by the dependent variable x. We assume x to be a behavior. The dependent variable may be a business measure, such as number of re-worked batches, or an index, such as OSHA recordables. The evaluator is randomly assigning employees to control or treatment groups, manipulating variables, recording and communicating results, etc.

Thus behavior x is a function G of a complex state of affairs z, given by

\[ x = G(z). \]  

[Equation 1]

This says G and an index z of the set of independent variables Z are sufficient for the prediction of the dependent
variable $x$, in the absence of dissemination of $G$ or $z$. This can be represented by a two dimensional diagram (see Figure 2).

We note that for a given interval $[z(o), z(i)]$, $x$ will have a range of $[x(o), x(i)]$. Thus $z$ might be an index of prior training history, on-the-job experience, etc. and $x$, a measure of productivity such as unit output, impounded batches, or quantity reworked. The set $Z$ would include such items as appear in the employee's training history, etc. We assume throughout that the interval of $x$ is continuous and closed.

**THE COEXISTENCE OF RCT AND DISSEMINATION OF RESULTS**

Consider the following scenario. $G$ is the training and qualifying process, exemplified in a particular training program and including training materials, training “script,” etc. Through an appropriate channel such as the study monitoring committee, the program manager has discovered a credible RCT evaluation report indicating that some aspect of $G$ was tending to increase the quantity of rework. Say this aspect was the hour in the shift (i.e., whether the training event occurs early in the shift or late). Say further that the manager would be held accountable for the increase of rework. Then the manager might react to the report and implement a change from $G$ to $G^*$. An example of such a change would be mandating all training programs be offered early in a shift. Then the output, rather than being $x$ would be $x^*$.

Let a reaction function $R$ be introduced, indicating the dependence of the actual outcome $x^*$ on the program manager’s knowledge of the disseminated judgment (or prediction) of $x$. This is given by

$$x^* = R(x) \quad \text{[Equation 2]}$$

Given the relevant range $[x(o), x(i)]$, we can represent the reaction function by a two-dimensional diagram (see Figure 3).

With the variance of $x$ through the range $x(o)$ to $x(i)$ will be associated a variance of $x^*$ between $x(o)^*$ and $x(i)^*$. If $R(x)$ is continuous over $[x(o), x(i)]$, and if $R(x)$ is bounded (i.e., $0 < R(x) < F$) then by the generalized Brouwer Fixed-point Theorem there exists at least one $x$ and one $x^*$ such that, $x = x^*$. Also, for $x = x^*$, the system described by equations 1 and 2 is in equilibrium (i.e., the manager will cease to react to $x$). Thus, for $x = x^*$, that value of $x$ is the correct public prediction, as well as the correct formative evaluative judgment.

In this section, we have shown that formative evaluation...
can be conducted within the framework of experimental design, and evaluative findings can at the same time be provided to the manager of the training program that is being evaluated, via the study monitoring committee or another appropriate channel. This means that the full range of evaluative approaches is available to the formative evaluator, including not only quasi-experimental designs but experimental designs (i.e., RCT) as well.

**THE GOOD NEWS, PART 2**

The preceding material incorporated an existence proof, showing that under specified conditions, training program modification could take place in response to evaluative findings developed within an experimental design. The following questions can still be raised: What are the implications of this for evaluation practice? Does anyone care? The answer to these questions is yes.

Let us look at a methodologically analogous situation, that of clinical trials of investigational new drugs. There is a long history of interest in adaptive designs in clinical trials, dating from Abraham Wald’s pioneering researches in the 1940s. The US Food and Drug Administration has expressed interest in adaptive clinical trials and the associated research designs. The dilemma of clinical trials has been described well by Derek Lowe:

> “In too many cases, the chief result of a trial is to show that the trial itself was set up wrong, in ways that only became clear after the data were unblinded. Did the numbers show that your dosage was suboptimal partway into a two-year trial? Too bad—you probably weren’t allowed to know that. Were several arms of your study obviously pointless from the start? Even if you knew, what could you do about it without harming the validity of the whole effort?” (22)

The problem is to conduct clinical trials so that both the rigor of the experimental design (RCT) will be maintained throughout, and program revision can occur, based on the timeliest data. And, methodologically speaking, that is precisely the problem cited by Lowe, with reference to the evaluation of training programs.

As Scott Gottlieb, FDA Deputy Commissioner for Medical and Scientific Affairs, has expressed it, FDA is interested in “adaptive sampling designs, including response-adaptive designs for statistical experiments, where the accruing data from experiments—the observations—are used to adjust the experiment as it is being run.” He goes on to say “the advantages of these approaches, rigorously designed, are becoming more evident, including among the ranks of our experts at FDA. It’s essential that we at the FDA do all we can to facilitate their appropriate use in modern drug development.” Gottlieb discusses several adaptive approaches to the design of experiments including the following:

- In an adaptive clinical trial, patient outcomes can be used as they become available to adjust the allocation of future patients or some other aspect of the study design
- A second type of adaptive trial design involves ongoing assessment of the sample size, to avoid under- or over-allotment of patients.
- [Another includes] seamless designs that allow learning to be more iterative and less method-limited. That allow continuous discovery that isn’t defined by phases but rather by what we learn as we go.

Gottlieb acknowledges that “adaptive approaches are not a panacea to all of our challenges, and enabling them is not a sure thing. Adaptive procedures are more complicated to design and to analyze, and in some settings are more difficult to implement.” Moreover, he is well aware of “trepidation about the use of adaptive features and reluctance to consider a variety of enrichment and adaptive designs. In many cases, researchers are still unaware of the option to use adaptive designs because standard statistical courses and packages do not include them.” (op. cit.)

There are political and ethical issues here as well. “Purists will argue that changing a trial midway through a study somehow benefits pharmaceutical companies by potentially allowing them to manipulate results. Some worry that bias is more likely when results are known during the trial, compared with keeping trials blind,” notes Steve Zisson. Concrete proposals are under consideration to mitigate such worries.

Since FDA is interested in adaptive designs for the study of investigational new drugs, it is unlikely they would object to the use of adaptive designs in the formative evaluation of training programs. What works for clinical trials can just as
well work for the evaluation of training initiatives.

Several uses of such adaptive designs include the following:
• The formative evaluator can communicate interim training outcomes through a channel such as the study monitoring committee to the program manager, allowing timely revision of the training intervention, including revision based on comparison of programmatic alternatives
• The evaluator can use interim training outcomes to allow more effective assignment of trainees to particular training sessions, for example by sequential sampling.

“The manner of conducting formative evaluations varies widely,” state Gagné and Briggs.28 We are suggesting that one approach to formative evaluation of training programs is utilizing an adaptive RCT design. “Quantitative data are definitely necessary for formative evaluation,” state Gagne and Briggs.29

The steps in conducting a formative evaluation can be summarized as follows:
• The first step is to develop a formative evaluation plan for the training module, including an evaluation design, and any evaluative instruments
• The second step is to collect evaluative data as you begin to pilot the training module, including data from both the pilot trainees and from your training and development peers
• The third step is to review all the evaluative data you have gathered, in light of the statistical portion of the formative evaluation plan
• Then, prepare an evaluation report summarizing the evaluations; propose revisions to the training module
• Get the study monitoring committee as well as management approval of these revisions
• The sixth step is to utilize the feedback for program improvement
• Then, continue the pilot (with further adaptations as required), until management is satisfied that the training module meets the organization’s needs.

The essence of this process is the negotiation between the evaluator and program manager. This negotiation works towards a settlement that takes into account both methodological rigor on the one hand, and program goals and values on the other.

MANAGEMENT’S PREROGATIVE
Management has an overarching role in a formative evaluation. That role is to specify the overall goal, and level of effort, for the evaluation. What does management want from this evaluation? There is a range of possibilities here. Does management want the most credible evaluative report possible? Or does management want the most blatant problems in the pilot project to be corrected? The evaluator must negotiate with management to determine the actual goal.

Once management’s goal is set, the evaluator can recommend approaches to aspects of the formative evaluative design, such as the following:
• Parallel group or cross-over design
• Recruitment of trainees
• Random assignment
• Blinding
• Sample sizes
• Statistical analyses.

With recommendations of costs and benefits of each approach, management can decide between the approaches. A memorandum of understanding between management and evaluator can then be prepared, including a statement of the level of effort that will be required to attain the goal that management has set.

At that point the evaluator can begin to plan the logistics of the formative evaluation. The primary audience for this evaluation will be the instructional designer who will make program revisions as warranted.

CONCLUSION
This article has reviewed the possibilities for formative evaluation of training programs as well as any other kind of program, within the framework of the ADDIE model. It can be concluded that the formative evaluation of training programs can utilize the full range of experimental and quasi-experimental designs, as well as any other approaches. In this paper, the possibilities of employing adaptive designs have been considered. Thereby, the data gathered in that evaluative effort can at the same time be made available to management, during the course of the training process, to allow decisions to be made about program improvement. FDA has recently expressed interest in the use of adaptive designs in clinical trials.
This does not mean that the evaluator must use any particular design or approach. While the full range of methods and techniques is available, the decision about which of those techniques and methods will depend upon two factors. One is management’s goal for the evaluation; the other is the needs of the main audience of the formative evaluation, namely the needs of the instructional designer who will revise the training program. The formative evaluation and re-piloting of the training module can continue until management has decided that the needs of the organization have been met. Once the formative evaluation has been completed and all necessary changes to the module have been made, it is time to move to final implementation of the training program. **GXP**

ENDNOTES


5. Robert Gagné and Leslie Briggs, *Principles of Instructional Design* (2nd ed.) NY: Holt, Rinehart and Winston (1979), p. 37; see also p. 290. “Evidence of an instructional programs worth is sought for use in making decisions about how to revise the program while it is being developed. In other words, the evidence collected and interpreted during the phase of development is used to form the instructional program itself.”


14. Daniel S. Stufflebeam, “The CIPP Model for Evaluation: An Update,” Presented at the 2003 Annual Conference of the Oregon Program Evaluators Network (OPEN), Portland, OR, October 3, 2003. See also his early “The Use and Abuse of Evaluation in Title III,” *Theory into Practice*, Vol. VI, 3, 1967, p. 128: “the application of experimental design to evaluation problems conflicts with the principle that evaluation should facilitate the continual improvement of a program. Experimental design prevents rather than promotes changes in the treatment because treatments cannot be altered in process if the data about differences between treatments are to be unequivocal.” Subsequently, in “Meta-Evaluation,” *Occasional Paper Series*, No. 3. Kalamazoo, MI: Evaluation Center, Western Michigan University, 1975, p. 54; he maintained that “experimental design often would not provide timely feedback for decision making.” See also his “Evaluation Checklists,” *American Journal of Evaluation*, Vol. 22, Issue 1, Winter 2001, p. 72: “almost everything I had learned about experimental design, measurement, and statistics was largely irrelevant to evaluating new, heavily funded, but ill-defined projects […] Gradually, I began to evolve an approach to evaluation that seemed to work […] The approach was directed to designing evaluations that would address stakeholders’ evaluative questions and provide them a flow of timely, relevant information.”


24. See also Paul Gallo, op. cit., pp. 281-282.
25. See also Paul Gallo, op. cit., pp. 280-281.
27. See Paul Gallo, op. cit., pp. 278-279.

ARTICLE ACRONYM LISTING

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ADDIE</td>
<td>Analyze, Design, Develop, Implement, Evaluate</td>
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<td>FDA</td>
<td>US Food and Drug Administration</td>
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<td>RCT(s)</td>
<td>Randomized ClinicalTrial(s)</td>
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<td>SOJT</td>
<td>Structured On the Job Training</td>
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<tr>
<td>SOP(s)</td>
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INTRODUCTION

The ADDIE model provides high-level guidance for the development and revision of programs of all sorts, including GXP training programs. The phases of the ADDIE model are analyze, design, develop, implement, and evaluate. These phases are sequential; each depends upon the successful completion of the preceding phase.

The final implementation of a training module comes among the last phases of the ADDIE model. A performance gap or a training gap initiated the process, and a carefully planned approach to address the performance gap has been prepared during the design phase. If management approves the design, the training program, including training materials and assessment materials, has been created in the development phase. These training materials and assessment materials are rolled out in a pilot implementation; a proof of concept study highlighting the iterative feature of the ADDIE model. In the case of a pilot implementation, the results of the program evaluation are fed back, closing the loop, facilitating further refinement of the training program. In the evaluation phase this is called a “formative evaluation”. Further design and development efforts follow, until the module meets organizational needs. Then comes the final implementation of the training module. When the module has finally been implemented, it can be the object of a “summative evaluation” that will estimate the relative cost and benefit of the finalized program in terms of organizational goals.

In this age of technological change, much attention has focused on the timing of training. On the one hand, training is optimally delivered close enough to task performance to ensure that the skill enhancement is still relevant but not yet forgotten. These requirements have led to just-in-time training (JITT), which has benefited from e-learning and other developments. On the other hand, in the pharmaceutical, biopharmaceutical, medical device, blood product, and other US Food and Drug Administration regulated industries, the need for optimal delivery of the training is constrained by the requirement that employees be trained before they are assigned to “touch” the product.

At first glance, that requirement might seem to be trivial—just ensure that the training has been delivered “before,” and be done with it. But the very dynamic of change that has driven manufacturing technologies as well as e-learning can create a climate of turbulence in process and procedure that makes ensuring “before” quite risky, and raises the prospect of serious compliance consequences if it turns out to be “after.” The requirement that employees must be trained before they touch the product becomes especially acute in the case of final implementation of a training module, when it is no longer a matter of selecting the trainees as it is in the case of a pilot. Each and every employee impacted by a new or revised procedure must be trained. This article examines that problem and considers several approaches to addressing it.

First, we will review the scope and impact of the FDA regulations for pharmaceutical manufacturing in general, and about training in particular. The case for other regulated industries mentioned previously is the same. Next, we will critically examine several approaches to ensuring that employees are trained before they touch the drug product, and find that each has shortcomings. Third, we will propose an alternative approach that facilitates the communication necessary to ensure the requisite training has taken place in a timely fashion.

SCOPE AND IMPACT OF THE FDA REGULATIONS

The FDA regulations for pharmaceutical manufacturing, set out in 21 CFR 211, are comprehensive in both scope and impact. Regarding scope, these regulations provide guidance for each person engaged in the manufacture, process-
ing, packing, and holding of a drug product. The phrase "each person" includes both employees and supervisors.

The phrase “manufacture, processing, packing, and holding” is also comprehensive. It includes packing and labeling operations, testing, and quality control of drug products. In sum we can say the scope of the regulations includes any person who is touching the drug product or supervising the persons who are directly touching the drug product.

How do these FDA regulations impact on these persons? The regulations require that the pharmaceutical manufacturer develop written standard operating procedures (SOPs) that provide guidance for a broad range of activities, including the following:

- Equipment and facility cleaning
- Equipment calibration and maintenance
- Handling of drug components and containers
- Production and process controls
- Batch records
- In-process sampling and controls
- Quality lab controls
- Reprocessing of batches
- Packaging and labeling operations
- Warehousing
- Distribution
- Returned drugs, among other activities.

Moreover, these must be written procedures.

So a set of SOPs is required that will provide comprehensive guidance for dealing with the inputs, processes, and outputs of drug manufacturing, as well as quality control over this manufacturing. Not only are written SOPs required; the regulations insist the quality unit approves them—they are controlled documents—and the procedures be followed.

Moving from the general to the particular, the FDA regulations stipulate that all employees and supervisors be trained. 21 CFR 211.25(a) states that each person engaged in the manufacture of a drug product shall be trained in the following:

- In the particular operations that the employee performs
- In current good manufacturing practices (CGMPs)
- Including the CGMP regulations in chapter 211
- The dozen or so written procedures required by these regulations.

The scope of this training will “relate to the employee’s functions;” the objective of this training will be “to enable that person to perform the assigned functions.”

Moreover, 21 CFR 211.25(b) goes on to say that the supervisors of these persons shall be trained so as “to provide assurance that the drug product has the safety, identity, strength, purity, and quality (SISPQ) that it purports or is represented to possess.” In particular, these supervisors will make the task assignments to the employees who will actually touch the product.

Three points follow from these stipulations. First, employees must have technical (or skill) training in their particular assignments. Second, the employees must have training in CGMPs that constrain the exercise of skills. Third, supervisors are responsible for the SISPQ of the drug product and must be trained to fulfill that responsibility. All this training must take place in a timely fashion.

Training Or The Lack Thereof

How well have companies within the scope of 21 CFR 211 responded to these requirements? In a review of a sample of the FDA’s GMP warning letters sent during the five-year period between January 2003 and December 2007, there were 25 warning letters that mentioned deviations regarding aspects of 21 CFR 211 during that time period. They listed a number of observations that the FDA investigator had made during site visits to companies within the scope, including such issues as cleaning, contamination, sampling, etc. Seven of these warning letters (over 25%) also cited inadequacy of training or inadequacy of the documentation of training, including inadequacy of skills training, training in GMPs, and supervisory training.

This pattern is not a historical anomaly; FDA has been concerned about the adequacy of training in the pharmaceutical industry for some time. For example, regarding a somewhat earlier time period, FDA senior compliance officer Philip Campbell asked, “Are the employees trained?” He further inquired, “Are the supervisors trained?” Finally, he asked “Are there records of that training, and is it ongoing?”

The fact that more than a quarter of these FDA findings point to problems in training should come as no surprise. On the one hand, whenever there is a remediation (corrective action and preventive action [CAPA]) for any deviation...
The ADDIE Model, and Instructional Generic Design Model

investigation or audit observation, that remediation will usually involve a revision of procedure or other controlled document, which in turn almost invariably involves training to the revised SOP. As Carl Draper, Director of the FDAs Office of Enforcement, has stated, “The implementation of revised SOPs should include employee training.” So training will be the indirect outcome of a remediation and will be the focus of some attention in the follow-up of the CAPA. Thus we expect that any warning letter directly addressing issues of cleaning, contamination, lab work, sampling, testing, utilities, whatever may also include a call for training, or for better training.

On the other hand, it seems that FDA has come to expect ineffective training, or inadequate documentation of training. These expectations, along with the relative ease of assessing the occurrence and documentation of training via the ubiquitous tracking systems and learning management systems (LMSs), make the investigator’s focus on these areas understandable.

Training Versus Retraining

sequacy of training does not amount to a call for “retraining,” by which the employees that were originally trained are retrained to the same training materials, by the same trainer, in the same fashion. There is a substantial difference between training as an indirect outcome of a CAPA and retraining as a direct outcome of an investigation as a CAPA itself. Investigators quickly recognize the fallacy of retraining as a solitary or even major remediation. For an example of such a fallacy, consider the FDAs Adverse Determination Letter regarding the Baltimore manufacturing facility of the American Red Cross, dated 27 July 2006. A Red Cross employee was not trained before touching the whole blood product. When this problem was discovered two months after the event, the Red Cross conducted an investigation and concluded that this was a training problem. “The corrective action was to fully retrain all employees” (12). FDA responded that “as a result of the incomplete investigation, [the Red Cross] failed to determine all root causes of the problem.” The Red Cross was then fined more than $700,000.

A manufacturing unit is strongly inclined to release an impounded batch by declaring that the catchall category “human error” was the root cause of the deviation or failure, and suggest retraining of the employee(s) as the corrective action. This is goal displacement; it places the unit’s goal, releasing the batch, above the organization’s goal, which is identifying the root cause and implementing a remediation that will ensure the deviation will not recur. This goal displacement results in a false alarm, where retraining is the direct outcome of an investigation. The fallaciousness of retraining is amply demonstrated—retraining, retraining, retraining of the same employee(s), ad infinitum. As Philip Lindemann points out, “Not identifying the cause of failure may lead to additional failures.” The investigator will recognize this, as will upper management, if there are metrics tracking CAPAs. The investigator and upper management will thereupon question the adequacy of the organization’s investigations.

Moreover, if “human error” were proposed as the root cause of the deviation requiring retraining, then the actual root cause would be the following:

• Unreceptive trainee(s)
• Inadequate training materials
• An unprepared or incompetent trainer
• Ineffective interaction of trainee(s) and trainer
• Some combination thereof.

For none of these cases would remediation be as simple as retraining, because the trainee would need to be motivated, the training materials would need to be revised, the trainer would need to be qualified, or the interaction would need to be enhanced before the remediation could go forward.

When John Levchuk calls for reinforcement training as a remediation for “future skills deficiencies,” he indicates that refined or redefined training materials may be indicated, because “usually, only those skills most likely to be forgotten or suffer compliance erosion over time would be targeted for inclusion in a periodic reinforcement program.” Moreover, when he goes on to call for remedial training as a remediation for “acquired skills deficiency,” he states that it would be “more appropriate and efficient if it were targeted to an incumbent’s specific skills deficiencies.” Thus Levchuk is not calling for retraining in either case.

In this part we have reviewed the scope and impact of FDA regulations of pharmaceutical manufacturing in general, and of training in particular, and found them to be comprehensive. Any person who touches the drug product, or who supervises someone who directly touches the drug
product, falls within the scope of the regulations. These regulations impact on these persons via written SOPs that provide comprehensive guidance for dealing with the inputs, processes, outputs, and the quality control of drug manufacturing. These employees must be trained on these procedures insofar as they relate to the employees’ functions, so as to enable those persons to perform the assigned functions. As the process and procedures change, the impacted employees must be trained in a timely fashion, hence, the critical issues attending the rollout of a finalized training module.

The issue can be summarized as follows. An SOP is identified as subject to revision. The SOP is revised and routed for approval. At the point of approval, a “training window” is opened (typically two weeks in length) before the SOP is implemented. Within this training window, all impacted employees (i.e., those who will be assigned to touch the product while executing the tasks controlled by the SOP) must be trained. This is schematized in Figure 1, where the four critical points are indicated on the timeline, delineating the three periods: Revision, approval, and training window.

There are two major logistical complications that follow. First, all training and assessment materials must be prepared before the SOP is approved; if not, they won’t be available for the training that must be conducted within the training window. Second, the participants in the training must be identified and scheduled for training, again before the SOP is approved. This includes both the trainer(s) and the impacted employees who will be the trainees. In particular, the employees must be those who will be assigned to touch the product under the guidance of the SOP. These two complications suggest that the timing of the requisite training is critical, especially with reference to the points in time where the revision of the SOP is initiated and the employees will touch the product.

THREE TYPICAL RESPONSES
This section reviews three typical organizational responses to the necessity that all required training on the finalized module has occurred before the employee is assigned to touch the drug product. Organizations tend to move through these three responses in turn; when one is found to be inadequate, the next is tried. The first proposal is typically the notion that there is a “training burden” and suggestions are advanced to alleviate this burden. The second proposal is to create a procedure for the supervisor’s checking of the employee’s training status. Last, various “technological solutions” to the issue are proposed. None of these proposals are adequate to the problem. They address the logistical complications in part, but fail to take into account the leadtime and communication process that is necessary.

Reduce The Training Burden
Many organizations within the scope of 21 CFR 211 respond to the requirements listed therein by focusing attention on reducing the “training burden.” The organization’s management believes that employees are spending too much time in training—time removed from more productive activities. Furthermore, the more time spent in training, or the more training events that are attended, the greater the likelihood that a mistake will occur, and the untrained employee will end up touching the product. The proposed solution is to reduce the number of SOPs required for any given position’s curriculum and reduce the training burden. This is no solution at all. The number of procedures

Figure 1
Three periods of SOP revision including training window.

<table>
<thead>
<tr>
<th>Revision period</th>
<th>Approval period</th>
<th>Training window</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify the SOP</td>
<td>Revise the SOP</td>
<td>Approve the SOP</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Implement the SOP</td>
</tr>
</tbody>
</table>
required for a position depends upon the technological sophistication (complexity) and proximity to the product (criticality) of the tasks associated with that position. If the person is a janitor, there may be a few SOPs required. If the person is a supervisor or SME of an aseptic filling line, the number of SOPs may be very large. It is not a training burden. It is a “technology burden,” and it is necessary to face the implications of the fact that FDA regulates science-based industries. These are technical operations issues, not training issues.

Managers are the only ones who can reduce the technology burden. Line management must review each and every SOP that goes into a position’s curriculum. Essentially, the line manager must make a business case for each SOP versus each job. Certain SOPs (e.g., one controlling the employee’s maintenance of his or her locker) may well be eliminated. This is where the following four elements would clear up these misunderstandings and mistaken senses of responsibility:

- Proceduralization of the training process
- Initiating an annual training plan
- Instituting an explicit risk analysis for every procedure
- The development of a training council (of line management).

The only training issue is how to bring the employee up to task proficiency once an SOP is included in a given curriculum, and ensure that the level of proficiency (and documentation thereof) is “audit proof” (i.e., will stand a regulatory inspection). This means that line management, from the VP of Tech Ops on down, must factor in the time and money (resources) to allow the training to take place. Via the training council, the line managers who have identified the training needs will also approve the training resources, for example, less training for janitors and more training for supervisors of aseptic filling operations. No amount of talk about a “training burden” will help ensure that the employee is trained before being assigned to touch the product.

**Creating A Procedure For The Checking Of The Training Status**

In many cases, an organization will realize that it must take further steps to ensure that employees are trained on the relevant SOPs before they are assigned to touch the drug product. Sometimes this is a result of a deviation investigation or an audit observation. Other times it may be the result of cost considerations, seeking to reduce rework and reprocessing, or because of compliance concerns. In any case, a typical organizational response is to develop a new SOP that calls upon supervision to check the employee’s training status. Such a controlled document can be called a task assignment procedure.

Such a procedure might require that the supervisor ensure all necessary training and qualification requirements have been completed and documented prior to assigning an employee to touch the product. This check is typically performed by looking at the employee’s training record in the validated tracking system or LMS during task scheduling. If employees have been trained on all the procedures listed in their curricula, the supervisor makes the task assignments.

What if the supervisor makes a mistake in checking the training records? What if the supervisor is not diligent, overlooks a particular employee, or misses a page of the training record? Referring again to the Red Cross example, where the employee was not trained before touching the product, the Red Cross concluded that, “the Education Coordinator failed to compare the employee’s previous training transcript with the training requirements.”

Thereupon an organization might develop an even further SOP that requires periodic checks by the quality unit of a random sample of employees found in GMP areas at a given time, to ascertain if they are in fact qualified for their assigned job functions. Such a controlled document can be referred to as an “assignment monitoring procedure.” Should discrepancies be found, the assignment monitoring procedure would require the generation of a notice of event (NOE) to inform management that a deviation has occurred. That NOE would need to address both the impact on the batch, to the extent the untrained employee had touched the drug product, and the supervisory error itself.

There are several major problems with this organizational approach. It presupposes that employees’ training curricula, listed in the tracking system, correctly and currently include the procedures that are relevant to the tasks to which the employees may be assigned. On the one hand, the curriculum may not correctly reflect the procedures. How does a supervisor ensure that every single procedure that relates to this task, or this process—regardless of who the originator of the SOP may be—has been included in this curriculum? On the other hand, the curriculum may not currently reflect
the procedures. How does the supervisor ensure that the versioning up of each procedure has been the occasion for an update of the employee’s curriculum?

These are hardly trivial questions. Change control and change management are substantial problems in a regulated industry subject to pervasive and persistent technological development. As if that weren’t enough, procedures are versioned up to change a single word. Procedures are versioned up and then found to be misaligned with higher corporate policies and standards; then they are versioned up still further to restore the status quo ante and alignment. Procedures are versioned up, omitting key paragraphs; they are subsequently versioned up to reinsert the omitted paragraphs. Multiple procedures coexist for similar functions (e.g., gowning); these procedures are versioned up, one by one, by their disparate business owners independent of each other.

The remedy for the constant revision of procedures is a combination of making better business cases for proposed changes, and having critical review of the documents in process. But that remedy will not resolve the supervisor’s dilemma of task assignment.

If the curriculum is either incorrect or not current, the supervisor cannot ensure the employee is adequately trained, no matter how diligently the training record is checked, no matter how carefully the task assignment procedure is executed. And the assignment monitoring procedure will most likely identify non-compliant task assignments after the fact. The only way to ensure compliance in this case is by over-training (i.e., by providing training to employees for whom the SOP may not be relevant). Of course, that is not cost-effective training.

Moreover, over-training may result in employee resistance to training. Many times this occurs among high-performing individuals, say in a research and development institute, and presents special problems for organizational morale and productivity.

It is crucial to recognize the misspecification of task responsibilities in the proposed task assignment procedure. This procedure places the key responsibility on the supervisor for ensuring that employee training and qualification requirements are completed and documented prior to task assignment, while not giving that supervisor necessary information about the accuracy and currency of the curricula, the status of procedure initiation, the status of procedure revision.

Instead, the task assignment procedure should stipulate that the originator (or business owner) of any new or revised SOP should communicate with each and every impacted functional area to determine who the impacted employees are (i.e., the training audience for the forthcoming SOP). In terms of the timeline given in Figure 1, the originator of the new or revised procedure must indicate to the management of each impacted functional area, the precise location on the document management timeline of that SOP. In particular, the originator must indicate the SOP that has been identified as subject to revision, and is in the process of being revised.

Implement A Technological Solution

Many organizations recognize that the proceduralization of task assignment is inadequate and believe that a technological solution, usually in the form of a learning management system, will address the problem. For instance, Ed Cohen has recently identified three LMS “innovations” that might jointly suffice to “effectively manage organizational compliance requirements.” The first innovation is where “LMSs can automatically cascade all [procedural] changes through the system; incorporate information and training assignments tied to the change into development plans for every employee impacted; and monitor employee records to determine whether system-assigned [training] tasks have been completed”.

This innovation is clearly the technological counterpart to the task assignment procedure; the technological solution similarly begs the question by assuming that the employees’ training curricula correctly and currently include the SOPs that are relevant to the tasks that may be assigned.

The second innovation discussed by Cohen is where an LMS protects the integrity of compliance related data. “LMSs also are capable of safeguarding compliance-related data through audit-trail functionality that allows any action impacting compliance data to be tracked and recorded.” This innovation simply prevents an unauthorized intervention into the functioning of the LMS, so doesn’t bear on the issue of the supervisor’s task assignment.

The third innovation is the integration of the LMS with other business systems to ensure compliance. “For ex-
ample, a pharmaceutical industry employee who has not completed the necessary training required to operate a specific drug dispensing machine cannot use his credentials to access and operate that machine until required training is completed." This innovation provides controls over the execution of tasks by untrained employees. It does not facilitate task assignment. It is a matter of timing; the supervisor must ensure that training has occurred for revised procedures prior to making the task assignments, not prior to the employee's executing the tasks. It is very late in the game when an employee is prevented from using credentials to enter a GMP area or to operate a specific machine. The employee may have been assigned a task for which the requisite training has been completed, yet would be denied access to the area or machine because other training has not been completed. Such an innovation might limit the number of employees available, resulting in the shutdown of the entire production line. The supervisor still does not have the necessary lead time and information to make task assignments.

It is critical that none of the LMS innovations that Cohen discusses address the supervisor's real-world problem of task assignment. Like the preceding proposal for a task assignment procedure, this "technological solution" makes the supervisor responsible for employee training and qualification requirements, while not giving that supervisor timely information about the status of procedure initiation and the status of procedure revision.

Instead, we must ensure that the originator of a new or revised SOP has communicated with each impacted functional area to determine the training audience for that forthcoming SOP. And this brings us to the final part of this paper, where we propose an alternative approach to ensuring that requisite training on the finalized module has occurred before the employee is assigned to touch the drug product.

THE ROLE OF THE TRAINING OUTLINE
This section addresses four topics. First we will compare and contrast the purpose of an SOP with the purpose of training to a procedure. Next we will delineate the role of a training outline as a brief summary of the training implications of a new or revised SOP. Third, we will present a process map of the development and utilization of a training outline, and the associated training audience list. Fourth, we will discuss the use of the training audience list as the alternate approach to ensuring the requisite training occurs. To anticipate, the training outline will be recommended as best practice to ensure that all requisite training on the finalized module has occurred before employees are assigned to touch the drug product.

The Purpose Of An SOP
A procedure lists the necessary steps (tasks) that, taken together, are sufficient to produce the desired process result. It can address several kinds of process: a person-to-machine process, a person-to-paper process, a person-to-person process, or some combination of the three types. An SOP, typically in documentary form, indicates the sequence of tasks, the personnel or positions that are responsible for the tasks, and the standards that define the satisfactory completion of the tasks.

The Purpose Of Training To A Procedure
Training is a person-to-person process that prepares each employee (the trainee) to successfully execute the steps (tasks) in a procedure, in the appropriate setting, stipulated order, mandated workgroup, and specified timeframe. Training is the combination of trainee(s), training materials, virtual or actual trainer, and the interaction of these elements. Thus procedures and training are different. The procedure is a controlled document subject to the quality unit's approval. Training is an interactive process. Of course a procedure can be the object of training, and training can be made into a procedure. But the two are distinct; reading a procedure (a person-to-paper process) is not the same as being trained on that procedure; being trained on a procedure is not the same as being a subject matter expert on that process.

How do we align the procedure and its associated training? How do we provide the supervisor with necessary information about changes to relevant procedures so as to ensure that employee training and qualification are completed and documented?

The Role Of The Training Outline
The training outline is a controlled document that provides
a brief summary of the training implications of a new or revised procedure. The following are the typical 12 fields in a training outline:

- Course title
- Course number and version
- Training audience
- Curriculum fit
- Prerequisite courses and required skills
- Trainers
- Behavioral objectives
- Training delivery method
- Course length
- Special instructions
- Measures of effectiveness
- Approval.

The training outline allows any employee to quickly ascertain critical dimensions of training associated with a particular SOP, including the behavioral objectives of the training, the training module’s fit in the larger curriculum, the delivery method, assessment materials, and of course the training audience. Figure 2 displays a process map of the development and utilization of a training outline, and the associated training audience list.

**Developing And Utilizing The Training Audience List**

When a performance gap or training gap is identified, management must decide on the appropriate corrective action and preventive action to respond to the gap. The following are two possibilities:

- It involves a life cycle document or documents
- It involves non-lifecycle or GMP regulatory training

In either case, the associated training will require the development or revision of a training outline. The instructional designer (or originator of the procedure) will ask, “Does a training outline exist?” If one already exists, the training outline will be reviewed and revised as necessary. If not, one will be prepared.

The instructional designer will review the following five points:

- Does the SOP or other document contain background history or perspective of the process that would aid in the training?
- Does the SOP or other document cover all related processes?
- Does the SOP or other document thoroughly identify CGMP aspects?
- Is all relevant training information covered in the training outline?
- Will all facilitators present the training and information consistently?

In the case of non-lifecycle documents and GMP regulatory training, the instructional designer can ask management about the range of the training audience; usually it will straightforwardly be all employees, all managers, etc.

In the case of a lifecycle document, the instructional designer will review the SOP scope statement as well as the task responsibilities, and generate a provisional training audience list. This is the problematic case. These are the employees who must be trained to the new or revised SOP, based on the finalized training module, before they are assigned to touch the drug product.

The instructional designer will then attach the training outline and the associated (provisional) training audience list to the procedure's change request. When the procedure and its training outline are circulated for review and approval, the training audience list will be circulated as well. Management of each unit impacted by the procedure will review the list and recommend limiting it or expanding it, based on their direct responsibility for the task assignments of the listed employees.

The instructional designer will then take those recommendations into account as the procedure, training outline, and training audience list are reviewed and approved. Moreover, management in the impacted units are alerted for the approval and implementation dates of the SOP, and can accordingly schedule impacted personnel for necessary training on the finalized module.

After the new or revised procedure has been approved, the training window opens, within which the impacted employees can be trained to the SOP before the procedure goes into effect. It is critical that the training audience be defined before that window opens, hence before the SOP is approved, so that all training on the finalized module will be completed before the implementation date. At this point, the other proposals noted above, especially the use of a task assignment procedure and various technological solutions such as a validated training tracking...
Figure 2
Process map of the development and utilization of the training outline.

- Training gap recognized
  - SOP-based training?
    - Yes: Prepare training outline
    - No: Does a training outline exist?
      - Yes: Generate target audience list
      - No: Review training outline and revise as necessary
  - Is this a new life-cycle document?
    - Yes: New Existing
    - No: Route training outline and target audience list with SOP for review
      - Yes: Submit training outline to originator, dept, and QA for approval
      - No: Review and revise as necessary
        - Yes: Originator, dept, and QA approval
        - No: Tech docs forwards to GMP training unit
          - Yes: File training outline in GMP training unit
          - No: Review and revise as necessary

Gordon Welty, Ph.D.
CONCLUSION

This paper first reviewed the scope and impact of FDA regulations of pharmaceutical manufacturing in general, and of training in particular, and found them to be comprehensive. Any person who touches the drug product, or who supervises that person, falls within the scope of the regulations. These regulations impact on these persons via written SOPs that provide comprehensive guidance for drug manufacturing. These persons must be trained on these procedures insofar as they relate to the employee’s functions prior to their being assigned to touch the drug product; hence the importance of ensuring that the final implementation of the training module includes all these employees.

Next we considered several organizational responses to the need to ensure employees are trained before being assigned to touch the drug product. One took the form of trying to reduce the training burden. A second took the form of a procedure requiring that the supervisor ensure all necessary training and qualification requirements in the employee curricula are completed and documented prior to assigning an employee to a task. The third took the form of proposing a technological solution. There are several problems with these approaches, especially the failure to provide the supervisor with timely and necessary information about the accuracy and currency of the employee curricula, and the revision status of the SOPs.

Finally, an alternative response was presented whereby the training outline, a controlled document in which a training audience list, is employed by the originator of a new or revised procedure to communicate with each impacted functional area to determine which employees require training. Those employees’ curricula are revised to correspond to the new or revised procedure, and supervision is alerted to the opening of the training window before the changes are effective, ensuring the employees are trained on the finalized module before being assigned to touch the drug product.

ACKNOWLEDGMENT

The author would like to thank his colleague A.W. for helpful comments.

ENDNOTES


3. As an example of the failure to meet the requirement of written procedures, consider the FDA’s Warning Letter to Greer Laboratories, Inc. dated 24 June 2005: “Your firm failed to establish written procedures applicable to the function of the quality control unit,” available at www.fda.gov/foi/warning_letters/archive/g6159d.pdf.

4. As an example of the failure to follow these written procedures, see the FDA’s Warning Letter to Intermax Pharmaceuticals, Inc., dated 13 May 2003: “Although your firm has a written procedure for training; it was found that these procedures are not followed,” available at www.fda.gov/foi/warning_letters/archive/g6159d.pdf.

5. For biopharm personnel, 21 CFR 600.10; for non-clinical lab personnel, 21 CFR 58.29; for medical device personnel, 21 CFR 820.25; for human tissue recovery personnel, 21 CFR 1271.170. For further itemization of the content of training, see FDA, Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing, Rockville, MD: CDER (2004), page 13; “Fundamental training topics should include aseptic technique, cleanroom behavior, microbiology, hygiene, gowning, patient safety hazards posed by a nonsterile drug product, and the specific written procedures covering aseptic manufacturing area operations.” See also FDA, Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations, Rockville, MD: CDER (2006), page 13; “Typical quality systems training should address the policies, processes, procedures, and written instructions related to operational activities, the product/service, the quality system, and the desired work culture (e.g., team building, communication, change, behavior).”


from 2001 to 2003, inadequacy of training was the seventh most cited observation, with 173 observations out of a total of 1933.


15. As Levchuk, op. cit. has commented, however, “usually, available information is inadequate to establish a specific reason beyond failure to have a training program, failure to follow the written training program, or failure to ensure that personnel received training.”

16. Levchuk, op. cit.

17. See also Vesper, “Performance: The Goal of Training,” op. cit., p. 46.

18. The very real, but very different, problem of poorly written and overlapping SOPs has been discussed under the heading “Consolidation of SOPs” in G. Welty, “The Design Phase of the ADDIE Model,” op. cit., pp. 44-45.


21. Assuming for just a moment that each employee’s curriculum is correct and current, this proposed approach presupposes that recourse to a notice of event is an adequate organizational response for supervisory error. Regulators typically find this unacceptable, because recourse to a NOE also requires a list of immediate and specific corrective actions that will be taken. As an example of the failure to meet this requirement for NOEs, consider the FDA’s Warning Letter to Pharmaceutical Formulations, Inc. dated 05 May 2004. “Process failures resulting in the rejection of substantial quantities of drug products were not investigated and there is no documentation to show any corrective actions;” available at www.fda.gov/foi/warning_letters/archive/g4683d.pdf.


23. This is obvious for skill training; as Michael Swartz and Ira Kruil, “Training and Compliance,” LCPC North America [Liquid Chromatography—Gas Chromatography], Vol. 22, No. 9 (2004), pp. 906-912, esp. p. 906, have expressed it for training in CGMP regulations: “It is of little value to train or educate an employee on all of the regulations if there is no impact on the job that person fulfills every day.”


29. See also the discussion in Gordon Welty, “The Design Phase of the ADDIE Model,” Journal of GXP Compliance, op. cit, esp. pp. 49-51.


Suggestions for Better Training Reports

Upgrade your training reports. Consider ways to make your electronic data report writer work for you.

INTRODUCTION
Training and the documentation of training are important tasks in Food and Drug Administration (FDA)-regulated firms. Firms with relatively few employees can and do function satisfactorily with paper-based training records. However, as the number of employees increase and the number of Standard Operating Procedures (SOPs) grows, many firms rely on some form of electronic database management software to capture and report the training of personnel. The on-going task of capturing data and then generating meaningful and timely reports can be daunting and time-consuming. This article directs attention to the output of such database management programs—the training report—and offers several suggestions for improving the value of such reports.

TRAINING AND DOCUMENTATION: FDA REQUIREMENTS
The requirement to provide appropriate and adequate training to personnel who manufacture, package, test and hold drug products is a clearly defined current Good Manufacturing Practice (cGMP) requirement.¹ There is an implicit expectation and regulatory requirement that written evidence be available (or retrievable) for the training provided to personnel. This evidence, which is the output of such software, is often collectively referred to as “training records.” This article invites users and customers of database management programs to consider what reports may be needed and how they should be titled before the selected software is validated.

Database administrators will likely agree that the mechanics of maintaining training data is relatively straightforward once the fields within a database record have been defined. The specifics of a training event are entered into a training record. Employee identification, typically name and employee number, is vital information. Identification is coupled with coding for the training, i.e., the date, the SOP number and revision, and the department or functional area. The more challenging task is assembling these hundreds or thousands of “single events” into a meaningful and accurate report. The training report may be printed to provide “written documentation” that listed employees are qualified to perform the tasks identified. These reports, which typically contain a list of personnel, can be easily understood when properly titled and their references to relevant training curricula are also cited and/or provided. What may be adequate “titling” for internal personnel may be confusing to an outside auditor or an FDA investigator. Each training report should be self-explanatory.

FROM THE BOX TO THE REPORT
Training and the accurate capture of training records is an on-going and time-consuming component of the training effort of any firm. The process should be appropriately controlled, that is, there should be dedicated personnel and restricted access to the records and report generation. Records should be reviewed as a separate step-to ensure that data have been captured accurately. Many firms use training forms that are “input friendly” to speed the keying of data into the firm’s database management program. The original source documents should be archived for an appropriate period-based on a firm’s defined retention schedule-to answer questions that might be raised about the accuracy of the computer records.

Many firms opt for configurable off-the-shelf (COTS)
software that is specifically designed for training records. Most of these software programs offer validation assistance in the form of test scripts that are incorporated into a generic protocol. The software is configured by qualified personnel to meet a particular firm's requirements, which are based on functional organization and the training curricula of various personnel — to name a few. Validation is then typically focused on the faithful reproduction of the records into reports created or configured to meet a particular firm's needs.

In the all-too-typical rush to get software validated so it can be used, user requirements may not be thoroughly explored and incorporated into the design of reports. Even when company personnel have accurately identified their needs, an outsider—such as an auditor—may have slightly different needs. This outside perspective can improve the “stand alone” quality of the various reports.

**SUGGESTIONS FOR IMPROVING TRAINING REPORTS**

Here are suggestions that the author believes to be important components of computer-generated training record reports.

1. Before designing or configuring the reports, consider the capabilities of the database management program. Should a report be sorted alphabetically by last name? Should a report be sorted by employee number? Should the report display both employee name and employee number? [Imagine the challenge of working with a training report listing 200 individual names that are not sorted alphabetically.]

2. Although the curriculum for any employee will typically include both general plant training and task-specific training, will it be easier to generate two reports? Or, will all training be incorporated into a single report?

3. A classic task for an auditor is to verify that each person who has signed a batch record for a particular part of the manufacturing or packaging—or quality testing—has been trained in the relevant SOPs. A departmental training report can be a particularly useful report for this function versus having to verify that each of thirty employees have been trained on the latest version of each of the relevant SOPs.

4. Each report should have a title that is descriptive of the contents of the report. The title should appear on the first page of the report—preferably in a font and size that is easily decipherable—and be included on each subsequent page along with the page number. The page numbering should be in classic CGMP style of “Page n of nn pages.” Some firms also include a report number as a further refinement of the naming process. For instance, “Packaging Department” is descriptive (See Figure 1), but “Blister Packaging-Line #2” is even more descriptive (See Figure 2). The goal in titling reports is to clearly define the personnel who are qualified to perform a task and/or use specific equipment. (Although “Packaging Department” is selected for the

**Figure 1**
Report Title and Descriptive Information Should Be Improved

**Figure 2**
Report Title and Descriptive Information Is Better
The reader now knows the list contains information on personnel who are qualified to perform any task related to Blister Packaging Line #2 and the curriculum on which personnel have been trained. The “training valid” date shows the period during which the listed personnel were trained on all applicable SOPs.

5. When a functional area training report is created, it should refer to a readily available list of Standard Operating Procedures (SOPs) and revision numbering of the SOPs. If training records are grouped according to a training module as opposed to a functional group, the report should clearly state this. See Figure 4.

6. Further, and related to #4 above, a subtitle should indicate the period for which the training is valid. For example, “Blister Packaging #2, Fully Qualified Personnel (those who can perform any task in the department) for November 2006 (if that is the valid period). The header or footer (or equivalent) should indicate when the par-
7. A common industry practice is to have operators both sign and initial the batch record as they begin work on the batch. This can be very useful in identifying a particular operator especially when initials are commonly used to verify various tasks throughout the batch record. It is useful to “standardize” the name shown on the batch record and on training records. Here are three examples of confusing, non-standardized name use: (1) An operator is entered in the training records as Robert K. Smith; the operator signs the batch record register as “Robbie” Smith. (2) Two operators, Thomas Baker and Terrance Blackwell each initial their entries as “TB.” (3) An operator is entered into the training records as Maria Lopez, but signs the batch record as Maria L. Rodriguez.

8. Training records change over time as personnel are added and deleted and as training lapses and training is added. Imagine the difficulty of reviewing the status of training when the latest generated record is more than 90-days old and new revisions of SOPs have been introduced during this period. The process of updating a record should be relatively easy and done on a timely basis.

CONCLUSION

The design of reports that document the training of personnel is a task performed by database management administrators and/or other qualified individuals. The relatively simple “tweaking” of the title of reports along with appropriate pagination and reference to training curricula can improve the clarity-and thus the value-of such reports to the user. GXP

REFERENCE

1. Code of Federal Regulations, Part 21. “…§ 211.25 Personnel qualifications. (a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee’s functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them…”

ARTICLE ACRONYM LISTING

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<thead>
<tr>
<th>ACRONYM</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>COTS</td>
<td>Configurable Off-The-Shelf (software)</td>
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<tr>
<td>CGMP</td>
<td>Current Good Manufacturing Practice</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration (U.S.)</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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