Developing Supplier Quality Auditor Training Programs

Seth A. Mailhot, lead of FDA Regulatory Practice Group
Yardstick for Effective Supplier Audits

• The goal of a supplier audit is to ensure the quality of the supplied service or component and the ability of the supplier to meet supply requirements.

• The ideal is to identify deficiencies with the supplier’s processes and procedures before they impact the supply of the service or component.

• The supplier audit program must balance two, sometimes competing, interests:
  › Business
  › Regulatory
What are the Alternatives to a Supplier Audit?

• Supplier Questionnaires
• Component Testing
• Certificates of Analysis / Conformity
• ISO Certification and FDA Inspectional History
• Hoping for the Best
Considerations for Having an Internal vs. External Auditing Team

• The small company predicament:
  › The smaller the company, the more likely that the internal RA/QA staff are overburdened
  › Despite this, there is not enough work to warrant hiring additional staff
  › Consultants on the surface may appear to be expensive, but their assistance is targeted and limited to the job at hand

• As companies expand:
  › RA/QA staff audit responsibilities must be shared with other functions
  › As such, RA/QA staff may be less focused on their supplier audit responsibilities.
Staffing: The Audit Team Coordinator

• Assign or hire an Audit Team Coordinator with the following capabilities:
  › Able to keep the trains running on time
  › Has significant auditing experience
  › Capable of teaching and training others
  › Can serve as a leader/supervisor of the Audit Team

• Oftentimes Audit Team Coordinators will grow into the job, or have the job thrust upon them based on their other responsibilities
Staffing: Selecting or Hiring Auditors

• Attributes of a good auditor:
  › “Likeable enough” – polite, friendly, but not a pushover
  › Inquisitive – the drive to ask questions
  › Intelligent – note, not the same as well-educated
  › Umpire – capable of making calls on the field, not just citing rules

• Most everything else can be taught...
Training Auditors

• An effective auditor training program combines both formal training and field experience

• Formal training:
  › Always include a company-specific component covering the internal procedure, even for new auditors that have prior auditing experience
  › More general GMP/auditing training may either be given internally or through various seminars / classes
  › Refresher courses on the internal procedure should be given periodically
  › Include a “continuing education” component and encourage attendance at outside seminars / classes
Training Auditors: Field Experience

• The amount of field experience required varies based on:
  › the amount of prior auditing experience, and
  › the need to get the auditor started as quickly as possible

• Field experience involves three stages...
  › First, the new auditor shadows an experienced auditor during one or more supplier or internal audits
    – The new auditor should assist the experienced auditor during the audit with some record review and/or interviewing tasks
    – These shadow audits should occur at or around the same time as the formal training to help drive the points of the formal training home
Training Auditors: Field Experience (cont.)

- Field experience involves three stages...
  - Second, the new auditor takes the lead during an audit while accompanied by an actively participating experienced auditor
    - The experienced auditor may provide advice to the new auditor, assist during the audit (document review / interviewing), and take over if requested
  - Third, the new auditor takes the lead during an audit monitored by an experienced auditor
    - The experienced auditor only takes over if required to under the circumstances
    - Audits that require a team to accomplish are generally not appropriate for this stage
Audit Types

• Consider the different types of audits that are done when training auditors:
  › New supplier audits
  › Existing supplier audits for different materials or service
  › Time cycled audits
  › For cause audits
  › Internal audits

• More complex supplier audits (new suppliers, suppliers of critical components, for cause audits) should be reserved for use as first stage field experience

• Internal audits and more basic supplier audits (time cycled audits) should be used as second or third stage field experience

• Existing auditors should also vary the types of audits they routinely conduct to make them more balanced
Pre-Audit Activities

• Training should focus on good audit practices throughout the audit process, including pre-audit activities:
  › Assigning the audit
    – Is an Audit Team necessary?
  › Researching the necessary data:
    – Supplier Questionnaire
    – Supply Agreement
    – History of production issues and incoming sampling
    – Preliminary review of the Quality System documentation
  › Developing an audit plan/agenda
    – Target specific issues/concerns to be covered
    – Identify potential confidentiality concerns
The Audit: Areas of Focus

• Regulatory: Is the documentation / recordkeeping system appropriate?

• Quality: Are the production and design processes sufficient to prevent the production and shipment of nonconforming product and/or services?

• Operational Capability: Is the supplier able to meet the manufacturer’s product and/or service specifications and supply requirements?
  › This includes assessing the adequacy of manufacturing processes or equipment, information technology, system infrastructure, engineering resources, etc.
  › Note that assessing operational capability is just as important as checking the regulatory and quality boxes, because an inability of the manufacturer to meet specifications and/or supply requirements has a direct impact on product quality.
• Business Capability: Is the supplier’s business stable, such that it will be able to provide quality products and/or services long-term?
  › This requires evaluating the supplier’s business conduct, practices, reputation and financial viability by studying:
    – Supplier’s approach to the audit
    – Employee-management relationships
    – Number of temporary employees
    – State of the grounds around the building
    – Whether space is overused or underused
    – General appearance of non-visitor areas
    – Use of temporary structures
  › While less tangible, business capability is an important predictor of a supplier’s commitment to the business relationship, which has an impact on quality and the ability to meet supply requirements
The Audit: Areas of Focus (cont.)

• It is much harder to teach how to assess operational and business capability. It is generally something that comes with time and experience.

• Despite this, the training program should provide methods for assessing operational and business capability, and these topics should be included on the report form.
The Audit Process

• Audits can take two different forms, so it is important to train to both types:
  › Top-down: The ISO-style audit that focuses on the quality system documentation and recordkeeping to verify its overall robustness
  › Bottom-up: The FDA-style audit that examines specific quality deficiencies and traces their cause up through the quality system to find a cause

• Auditors should be trained on both methods, as both are important tools to conducting a good audit
Audit Closeout

- Often the most difficult part of the audit is the presentation of findings
- Auditors should be trained to provide suppliers with notice of a deficiency as soon as it has been verified to avoid any surprises during the close-out
- Deficiencies should be presented along with constructive advice on how to remedy the deficiency. Note that the auditor should never dictate a specific course of action to remedy the deficiency, particularly where other options are possible
- Where appropriate, offer assistance to ensure the continued flow of quality components or services
After the Audit is Over

• Impress upon auditors that the audit system is only as good as the documentation supporting it
• Ensure that auditors file timely reports with sufficient detail
• For significant audits, an internal briefing should be held with management to discuss the results and recommendations
• Instill auditors with confidence that their evaluations are valued, while including an internal supervisory review by the Audit Team Coordinator
Audit Reports

• Audit reports should be designed to require more than just numerical grades with brief two sentence explanations.
• Audit reports should provide the following sections:
  › Purpose of the Audit
  › Recommendations: A brief summation of the appropriate actions that should be taken in light of the auditor’s findings
  › Discussion: A detailed review of the audit that provides the objective details necessary to document the auditor’s grades and recommendations. May also provide information useful for follow-up audits, such as travel information, and areas that were not covered during the audit due to time constraints or confidentiality issues
  › Findings: A discussion of each deficiency, including the specific objective evidence supporting the deficiency finding and the commitments made by the supplier to correct the deficiency.
  › Grade Sheet: Numerical grade sheet with brief explanations for the grades.
Keeping the Audit Team Sharp

• Vary assignments among your experienced auditors
• If staffing allows, ensure that no supplier is audited by the same auditor twice in a row
• Encourage continuing education opportunities, which may bring in new ideas
• Monitor for “rubber stamp” auditors
Questions
Seth A. Mailhot
401 9th Street, N.W.
Washington, D.C. 20004-2128
Phone: (202) 585-8196
smailhot@nixonpeabody.com

Admissions
Seth is admitted to practice in the District of Columbia and Massachusetts, and before the U.S. Patent and Trademark Office.

Education
New England School of Law, J.D., Valedictorian, summa cum laude
University of Massachusetts, B.S.

Experience
Seth Mailhot is the lead attorney for Nixon Peabody’s FDA Regulatory practice, and a member of its Life Sciences and Health Care practices. His 14 years working in the U.S. Food and Drug Administration (FDA) provides a unique perspective in his counseling of clients on a broad range of matters involving the FDA.

While working at the FDA, Seth served in a variety of capacities and oversaw activities of pharmaceutical, biologic, medical device, food, cosmetic, and dietary supplement companies. Seth’s FDA regulatory experience includes enforcement and recall matters, preparation and prosecution of FDA premarket submissions (such as 510(k)s, PMAs, NDAs, ANDAs, INDs, IDEs, pre-INDs and pre-IDEs), product promotion and labeling issues, pharmaceutical exclusivity matters, and compliance with quality, regulatory, and manufacturing requirements.