Leadership Capabilities in a GMP Compliance Environment

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What We Plan to Cover

• Current Challenges: More Than Just a Regulatory Requirement
• Quality and Compliance Excellence: Some Key Considerations
• Critical Success Factors: a High Performance Organization
Leadership: A Regulatory Requirement

• MANAGEMENT RESPONSIBILITY
  
  – Leadership is essential to establish and maintain a company-wide commitment to quality and for the performance of the pharmaceutical quality system.

2.1 Management Commitment

(a) Senior management has the ultimate responsibility to ensure an effective pharmaceutical quality system is in place to achieve the quality objectives, and that roles, responsibilities, and authorities are defined, communicated and implemented throughout the company.

• Quality should be the responsibility of all persons involved in manufacturing.


• “Modern robust quality systems models call for management to play a key role in the design, implementation, and management of the quality system. For example, management is responsible for establishing the quality system structure appropriate for the specific organization. Management has ultimate responsibility to provide the leadership needed for the successful functioning of a quality system”
The Leadership Challenge...

- Role of the global leader in GMP manufacturing is evolving
  - Ensuring medicines are safe, effective, and available for the consumer
  - Embedding a quality culture
  - Raising the bar on innovation, science and technology
  - Leadership in regulatory science and good manufacturing practices is essential
  - Globalization adds to leader complexity
Merck Operates Globally With A Broad Base Of Suppliers And Sites

North America Manufacturing Sites

EMEA Manufacturing Sites

Latin America Manufacturing Sites

Asia Pacific Manufacturing Sites

A Global Network of 67 Manufacturing Sites Under a Global Quality System
Key Quality/Compliance Expectations

• Compliance/Quality is a top priority
• Be proactive and fix problems before they occur
• A Company’s reputation is on the line every day with:
  • Patients and Physicians who expect it
  • Regulators who demand it
  • Employees who are committed to it
Quality Culture: Key Drivers

- Every person is a Quality Leader
- “Safe to speak up” environment
- Make problems visible and solve them once
- Execution is key
- Institutionalization of a culture/attitude in which all employees, regardless of level or function, have ownership and accountability for Quality and Compliance
An ounce of prevention is worth a pound of cure.
-- Benjamin Franklin
Quality Strategy: Transformational Journey

- Focus on Customers
- Make Problems Visible
- Strengthen Process Stability and Flexibility
- Optimize Value Stream
- Develop People to Lead, Teach, & Coach

Quality Strategy

- Built-in Quality / Right First Time
  - Quality & Compliance Excellence
  - Talent Readiness
  - Everyone is a Quality Leader
  - Regulatory Advocacy

Integrated, Accountable Compliance Minded Leaders At All Levels

Reliable Compliant Product Supply Realize HPO

Inclusive Behaviors / Leadership Behaviors

2011

Pfizer Pharmaceutical Industry Association

2015+

INDUSTRY THAT CARES
What Is Needed to Ensure Quality and Compliance Excellence?

- Permanent Inspection Readiness
- Strong Systems
- Good Processes
- Right People
- Strong Compliance Culture
### Some Foundational Characteristics for Success

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<tr>
<th>Robust Quality Systems and Compliance Culture</th>
<th>Strong Leadership</th>
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<tr>
<td>Compliance must be the top priority</td>
<td>Strategic and tactical agility</td>
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<td>GMP continuum supports flexible approaches to execute development, clinical, and commercial activities across the Quality System</td>
<td>Provide a clear vision and mission, simple messages, and motivation to affect change</td>
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<td>Focus on developing next level of leaders, culture, and capabilities</td>
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<th>Compliance Culture: Collaboration and Continuous Improvement</th>
<th>Global Point of View</th>
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<tr>
<td>Commitment and willingness to change</td>
<td>Collaboration with all groups within company to leverage all expertise and knowledge</td>
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<td>All colleagues in all groups on board, engaged, and focused</td>
<td>Understanding of global regulatory expectations</td>
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<td>Effective governance and metrics</td>
<td>Alignment on quality expectations with suppliers, customers, and overall business</td>
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<td>Well-developed scientific, technical, manufacturing expertise and problem-solving skills</td>
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High Performance Organization

Inputs Into A High Performance Organization (HPO)

- People
- Materials
- Workplace Environment
- Measures
- Robust Processes, Methods & Procedures
- Reliable Equipment & Facilities
Merck’s Competency Model: 4 Categories

Leadership Behaviors define the principles and characteristics that all employees are expected to demonstrate every day. They can help us set the standard for integrity in healthcare around the world, and work together far more efficiently and productively.

Professional Competencies have been created to make our business even stronger by helping us to develop core business skills and abilities.

Functional Core Competencies were developed per function with training and development resources that are tailored to the business needs.

Sub-Function Competencies were developed per key role with training and development resources that are tailored to the business needs.
Competency Model: How it Fits Together

- Leadership Behaviors and Professional Competencies apply across the company

- Functional Competencies are applied only across the function

LEADERSHIP BEHAVIORS
(All Employees)

PROFESSIONAL COMPETENCIES
(All Employees)

FUNCTIONAL COMPETENCIES

- Core Functional Competencies
- Sub-Functional Competencies
- Sub-Functional Competencies

PIA INNOVATION THAT CARES
Some Key Take Aways....

- Everyone is responsible for quality and compliance
- Management commitment to the Quality System is essential
- Ensuring a quality culture where it is safe to speak up
- Leaders who are coaches and teachers (and learners)
- Anticipating and meeting the customer’s needs is paramount
- Execution is key: collaboration and working across boundaries