The Impact of Quality Culture on Quality Risk Management

FDA Perspective on Quality Culture; how it Impacts Risk Management

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Compliance Architects
Agenda

• The WHAT
  Definitions
  – culture
  – risk management
  FDA expectations and what FDA expects to see

• The HOW
  How to create a Quality Culture that enables ROBUST Quality Risk Management

• The Impact of Quality Culture on Risk Management and the Business
Culture and Risk Management Defined

Culture

**Pronunciation:**  cul·ture ˈkəlCHər/

**noun:** culture

“the attitudes and behavior characteristic of a particular social group”

Risk Management

**Pronunciation:**  risk man·age·ment

**Noun:** risk management

“(in business) the (forecasting) and evaluation of (financial) risks together with the identification of procedures to avoid or minimize their impact”
FDA Perspective

Guidance for Industry
Quality Systems Approach to Pharmaceutical CGMP Regulations
September 2006

• Intended to help Industry bridge the gap between US 21CFR Parts 210 and 211 and FDAs CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS
• Not legally enforceable; represents FDAs current thinking on the topic
  – Based upon FDAs 2002 Pharmaceutical CGMPs for the 21st Century Initiative
• Intended to help manufacturers implementing quality systems and risk management approaches to meet the requirements of FDA CGMP regulations
FDA Perspective cont..

• A quality system meets the expectations of the public and private sector to provide high quality products to patients and health care professionals.
  – A well built quality system should reduce risk (recalls, defective products, etc., in the marketplace)

• Modern quality systems coupled with manufacturing process and product knowledge and effective risk management practices enable effective change management (product, process, test method, etc.) and implementation of improvements.

• An effective quality system can lower the risk of manufacturing problems and errors.

• Effective management and allocation of finite resources.
FDA Perspective cont..

• A quality system can provide the framework for implementation of *Quality by Design*, continual improvement, and risk management throughout the supply chain, end-to-end.

• Attempts to harmonize global requirements
  – ISO
  – Device QSR

EX: Harmonization of Regulations and Standards

<table>
<thead>
<tr>
<th>Drugs/Biologics</th>
<th>Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Quality by Design</em></td>
<td>Design Control Regulations</td>
</tr>
<tr>
<td>“continuous improvement”</td>
<td>CAPA</td>
</tr>
<tr>
<td>“risk management”</td>
<td>ISO14971</td>
</tr>
</tbody>
</table>
FDA Guidance on the Quality Systems Model

- Management Responsibilities
- Resources
- Manufacturing Operations
- Evaluation Activities
Management Responsibilities

I. “Provide Leadership”
Senior Management should **demonstrate commitment** to:

– Quality (product, process, and process execution and output)
– Developing and maintaining their quality system
– Quality Plans (goals and objectives) aligned with (and integrated into) business goals and objectives
– Creating a **proactive** Quality Culture
– Establishing mechanisms to ensure science and risk-based decision making throughout the product lifecycle
– Assuring OPEN and TRANSPARENT communication of risks and issues

What does FDA expect to see evidence of?

– **Actively participating** in quality system design, implementation and monitoring, including system review
– **Advocating** continual improvement of operations of the quality system
– **Committing** necessary resources
Management Responsibilities cont.

II. “Structure the Organization”
Management is responsible to:

- **Ensure assigned responsibilities support the production, quality and management activities needed to produce quality products**

- Ensure **ALL managers have the responsibility to communicate employee roles and responsibilities and authorities within the quality system**; ensure the interactions between groups are defined and understood

- **Give the Quality Unit** the **authority** to detect problems and oversee the implementation of solutions

What does FDA expect to see evidence of?

- **Well defined roles and responsibilities** in Standard Operating Procedures (SOPs)
- An **empowered, independent** Quality Unit
Management Responsibilities cont..

III. Build Your Quality System to Meet Requirements

Management is responsible to:

- Ensure the **quality system built provides clear organizational guidance and facilitates systematic evaluation of issues**.

What does FDA expect to see?

- **Scope of the quality system**, including outsourcing
- **Specified Quality Standard(s) to be followed (not the MINMUM)**
- **Policies** to implement the quality system criteria and supporting objectives
- **Procedures** needed to document the quality system
Management Responsibilities cont..

IV. Establish Policies, Objectives and Plans

Management is responsible to:

- **Establish policies, objectives and plans** that articulate the VISION and COMMITMENT they have to quality
- **Establish a MISSION** which incorporates a **strong commitment to QUALITY**
- **Define Quality Objectives** at the top level of the organization to be cascaded down into the organization across all functions and levels in the organization
- Communicate the policies, objectives and plans to all functions and levels in the organization
- **Use the quality plan and objectives to establish priorities and assign resources in the organization**

What does FDA Expect to see?

- **VISION, MISSION, QUALITY GOALS integrated into BUSINESS GOALS**
- Employees **understanding and held accountable for** executing their roles and responsibilities in alignment with the VISION, MISSION and QUALITY GOALS
Management Responsibilities cont..

V. Review the Quality System
Management is responsible to:
– Review the performance of the quality system and planned intervals
– Ensure the review includes assessments of the process, product and customer needs

What does FDA expect to see:
– Quality Management Review with Executive/Senior Management should include (at minimum):
  • Appropriateness of quality policy and objectives
  • Results of audits and other assessments
  • Customer feedback, including complaints
  • Analysis of data trending results
  • Status of actions to prevent a potential problem or recurrence
  • Follow-up action items from previous management reviews
  • Changes in business practices or environment that may after the quality system
  • Product characteristics meeting the customer’s needs
Quality Risk Management

• Effective decision-making in a quality systems environment is based upon an informed understanding of the quality issues.

• Elements of risk should be considered relative to the intended use of the product, and in the case of pharmaceuticals and biologicals, patient safety and ensuring availability of medically necessary drug products.

• Risk should be assigned considering the probability of occurrence of harm and on the severity of the harm.

• Engage the appropriate parties in assessing the risk.
Quality Risk Management cont..

Risk management is an iterative process and should be repeated when new information is presented the changes the need for, or the nature of, the risk(s).

Key elements of Risk Management include:

- Assessing Risks
- Selecting and implementing risk management controls commensurate with the level of risk
- Evaluating the results of risk management efforts

What does FDA expect to see?

- A risk management process and procedure in place
- Evidence of risk management controls
- A process to re-evaluate risks as new information becomes available
- RISKS BEING REDUCED!!!
Key Quality Systems Which Provide “THE RISKS”

- Deviations/Non-Conformances
  - Laboratory Out of Trend or Specification Results
  - Out of Calibration Results
  - Environmental Monitoring Out of Trend of Specification Results
  - Etc.
- Product Stability Testing (“Marketed Product Stability”)
- Annual Drug Product Reviews
  - Annual Examination of GMP Retention Samples
- Product Quality Complaints
- Product Adverse Events
- Internal Audit Findings
- External (Health Authority, Notified Body, or Third Party) Audit Findings
- Outputs of Quality Management Review on the efficacy/health of the Quality System
So… What are some of the Key Elements to Developing a Quality Culture?

- Have a Quality Strategy that enables your business
- Develop the Quality System Architecture based upon your business model
- The Power of Management/Leadership attitudes and behaviors
  - Metrics and Management Review
    - What do you measure?
    - Who do you report results to?
- Accountability
  - What are Executives, all levels of Leaders, and Employees held accountable for?
Key Elements of a Relevant and Executable Quality Strategy

• An understanding of the elements of the Quality System that will *enable* the business strategic plan

• An understanding of the *product risks, Quality System risks, and compliance risks* that will *disable* the business strategic plan

   **NOTE:** The Quality Systems risks includes risks identified in the design, implementation and/or execution of the Quality System

• A methodology and capability to collect, aggregate, quantify and communicate the risks
“the **attitudes** and **behavior** characteristic of a particular social group”

How does culture within an organization impact Quality Risk Management?

- Leadership/Management **attitudes** towards quality from the top down
- Leadership/Management **behavior** towards quality from the top down
behavior

What do employees see?

Daily LEAN walk-about

Time Spent (Minutes)

- Quality Metrics
- Unit Fill Rate
- Plan Adherance
- Line Turn Over Time

FPY on Documents
attitudes

What do employees hear?
“(in business) the (forecasting) and evaluation of (financial) risks together with the identification of procedures to avoid or minimize their impact”

• “That is the decision of our Quality Unit”; I value and respect their decision…
  OR
• That is a compliance issue and the product is safe…
  OR
• You (QA VP) are killing our numbers this quarter…
What Quality Metrics do you Measure and Monitor?

Compliance Metrics
Are we in Compliance?

<table>
<thead>
<tr>
<th>QS</th>
<th>Metrics</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Recalls</td>
<td>How Many?</td>
<td>How Severe?</td>
</tr>
<tr>
<td>Field Alerts</td>
<td>How Many?</td>
<td>On Time?</td>
</tr>
<tr>
<td>Complaints</td>
<td>How Many?</td>
<td>On Time?</td>
</tr>
<tr>
<td>Deviations Non-Conformances</td>
<td></td>
<td></td>
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<tr>
<td>CAPAs</td>
<td>How Many?</td>
<td>On Time?</td>
</tr>
<tr>
<td>Training</td>
<td></td>
<td>On Time?</td>
</tr>
<tr>
<td>Etc.</td>
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Quality System Metrics
Is my Quality System effective?

<table>
<thead>
<tr>
<th>QS</th>
<th>Metrics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Recalls</td>
<td>Root Cause?</td>
<td>Repetitive?</td>
</tr>
<tr>
<td></td>
<td>Design, MFG,</td>
<td>CAPAs in place”</td>
</tr>
<tr>
<td></td>
<td>Supplier, End-User?</td>
<td>CAPAs completed?</td>
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<tr>
<td></td>
<td></td>
<td>Effective?</td>
</tr>
<tr>
<td>Deviations Non-Conformances</td>
<td>Root Cause?</td>
<td>Repetitive?</td>
</tr>
<tr>
<td></td>
<td>Fishbone Results;</td>
<td>Training as root cause?</td>
</tr>
<tr>
<td></td>
<td>5 Why Results,</td>
<td>Quality of Investigation Report?</td>
</tr>
<tr>
<td></td>
<td>etc…</td>
<td></td>
</tr>
<tr>
<td>CAPA</td>
<td>Root Cause?</td>
<td>Effective?</td>
</tr>
<tr>
<td></td>
<td>Fishbone Results;</td>
<td>Quality of CAPA Report?</td>
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<tr>
<td></td>
<td>5 Why Results,</td>
<td></td>
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<tr>
<td></td>
<td>etc.</td>
<td></td>
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<tr>
<td>Training</td>
<td>Effective?</td>
<td>Repeat Deviations for a given product, process or SOP?</td>
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# Meaningful Management Review Presentations

<table>
<thead>
<tr>
<th></th>
<th>Q1</th>
<th>Q2</th>
<th>YTD</th>
<th>Goal</th>
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<tbody>
<tr>
<td>Recalls</td>
<td>1</td>
<td></td>
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<tr>
<td>Field Alerts</td>
<td>2</td>
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<tr>
<td>Deviations</td>
<td>241</td>
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<tr>
<td>CAPAs</td>
<td>15</td>
<td></td>
<td></td>
<td>90% on time</td>
</tr>
<tr>
<td>% on time = 85%</td>
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<tr>
<td>Complaints</td>
<td>945</td>
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<td></td>
<td>95% on time</td>
</tr>
<tr>
<td>% &lt; 45 days</td>
<td>94%</td>
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What a Good Management Review Looks Like

Recommended Actions:
- Facility for Products C and D
- Process Capability for Products B and C

Detail Specific Actions and Resources Required

Develop Ways to Look at Risk
EX: Product, Process and Facility Risks
Develop Ways to Look at Risk

EX: Corporate Quality System Audit Findings

Focus on the urgent and critical risks only

Anticipated FDA Response

5 - Systemic Deficiencies Leading to Warning Letter
4 - Major FD 483 Observation
2 - Single, minor FD 483 Observation
1 - Closeout Recommendation
0 - No comment

Number of Gaps/Observations

0 20 40 60 80 100 120
How do you hold EVERYONE at ALL LEVELS up to the CEO Accountable?

<table>
<thead>
<tr>
<th>CEO</th>
<th>VP Ops/Mfg</th>
<th>Plant Manager</th>
<th>VP QA</th>
<th>Site QA Director</th>
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</thead>
<tbody>
<tr>
<td>Sales Growth</td>
<td>Unit Fill Rate</td>
<td>Unit Fill Rate</td>
<td>Recalls</td>
<td>Recalls</td>
</tr>
<tr>
<td>Income Growth</td>
<td>Cost of Goods</td>
<td>Cost of Goods</td>
<td>Health Authority Audit Results</td>
<td>Health Authority Audit Results</td>
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<tr>
<td></td>
<td></td>
<td>Plan Attainment</td>
<td>Compliance Metrics</td>
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Is anyone responsible for Quality Outcomes?
How do you hold EVERYONE at ALL LEVELS up to the President Accountable?

<table>
<thead>
<tr>
<th>President</th>
<th>VP Ops/Mfg</th>
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<td>Health Authority Audit Results</td>
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<tr>
<td>Profitability</td>
<td></td>
<td>Plan Attainment</td>
<td>Compliance Metrics</td>
<td>Compliance Metrics</td>
</tr>
</tbody>
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- Cost of Non-Conformance Reduction

- Effective, timely, robust CAPAs that reduce Risks and improve Patient and Customer Satisfaction Metrics

- Patient and Customer Satisfaction Metrics
So… What is the Impact of Quality Culture on Risk Management

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- Develop the Quality System Architecture based upon your business model
- The Power of Management/Leadership attitudes and behaviors
- Metrics and Management Review
  - What do you measure?
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Enables a Robust Quality Risk Management Process
How does Quality Culture Effect Quality Risk Management and the Business?
Questions?