Risk-Based Thinking in Quality Management Systems:
How to Incorporate Risk into Your Processes

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Agenda

• Understanding Operational Risk Management
• How Risk Management processes drive new ways of looking at compliance in operations
• ISO 9000:2015 and Risk Management
• Common tools for leveraging risk in compliance
Increasing Rate of Change
There is an Increasing Rate of Change

• **We are more complex**
  – Global Scale of Production, Design, Sourcing
  – More Mergers, Acquisitions
  – Growing Supply-Chain

• **There is more competition**
  – Competition leads to shorter product lifecycles
  – Increases in product complexity
  – More variety of goods in more areas

• **Companies need to maintain compliance AND keep up with the pace of business!**
Time to shift our mindset?

• **How compliance keeps up with change**
  – Automation of compliance processes
  – Integration with business systems
  – Harmonization of compliance processes

• **Cost of compliance is skyrocketing**
  – Cost of systems, people and time
  – Cost of holding back operations
  – Cost of holding back inventory

• **Quality and Compliance need to expand!**
  – We must think beyond Quality silo
  – From audit results to risk assessments
  – Risk is a more efficient measure of compliance

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Risk Management: Hazard vs Risk

- The terms "hazard" and "risk" are often used interchangeably. However, in terms of risk assessment, these are two very distinct terms.
Risk Management: Hazard

1. **Insurance**: Condition or situation that creates or increases chance of loss in an insured risk, separated into two kinds (1) Physical hazard: physical environment which could increase or decrease the probability or severity of a loss. It can be managed through risk-improvement, insurance policy terms, and premium rates. (2) Moral hazard: attitude and ethical conduct of the insured. It cannot be managed but can be avoided by declining to insure the risk.

2. **Workplace safety**: Dangerous event or situation that may lead to an emergency or disaster. It could also be a biological, chemical, or physical agent in (or a property of) an environment that may have an adverse health effect, or may cause injury or loss. As such, a hazard is a potential and not an actual possibility.

Read more:
http://www.businessdictionary.com/definition/hazard.html#ixzz3miUj2jq1
Risk Management: Risk

- Risk is defined as the probability that exposure to a hazard will lead to a negative consequence, or more simply:

\[
\text{Risk} = \text{Hazard} \times \text{Exposure} \quad \text{Probability of}
\]

- Thus, a hazard poses no risk if there is no exposure to that hazard.
Consider the following example from David Okrent's 1980 article, "Comment on Societal Risk":

3 in a boat

Three people crossing the Atlantic in a rowboat face a hazard of drowning...

300 in a ship

Three hundred people crossing the Atlantic in an ocean liner face the same hazard of drowning...
Risk Management: Hazard vs Risk

Consider the following example from David Okrent's 1980 article, "Comment on Societal Risk":

The risk to each individual per crossing is given by the probability of the occurrence of an accident in which he or she drowns.

RISK = probability of accident occurring x hazard

High Probability = equipment, # of people, environment

Low Probability = equipment, # of people, environment
Risk Management: Hazard vs Risk

Consider the following example from David Okrent's 1980 article, "Comment on Societal Risk":

The hazard [drowning] is the same for each individual, but the risk [probability of drowning] is greater for the individuals in the rowboat than in the ocean liner.

\[
\text{Hazard} = \text{Hazard} \\
\text{Probability} > \text{Probability}
\]

MORE RISK

LESS RISK
Risk Management: the Process

- Risk Management is a broad standard (ISO 31000)

- Identify all relevant risks (e.g., hazard analysis)
- Quantify the risk (e.g., probability and severity)
- Implement a process
- Use objective and proven tools
- Accept (worth it), reduce (mitigate), compensate (insure), transfer (partner), avoid (stop)
- Change management to introduce or improve controls
Risk Management: Areas of Coverage

- Enterprise Risk Management
  - Quality
  - Regulatory
  - Environmental
  - Safety
  - Financial
  - Commercial
Risk Management: Rationale for Risk

Risk Management is the Core Methodology

- Easy to understand for the uninitiated
- Drives short term and long term change
- A way to evaluate risk in an operational context
- Beware a false sense of security

Repeatable and objective methods

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ISO 9000:2015....it’s not just requirements,

It’s a company mindshare of Quality.

There should be a company-wide commitment/leadership around Quality
ISO 9000:2015 view on risk

**Section 5: Leadership**
Provide leadership by encouraging a focus on quality

Promote the use of risk-based thinking.

**Section 6: Planning**
Consider risks and opportunities when you plan your QMS
Plan how you’re going to manage risks and opportunities

DISCLAIMER: The ISO view on risk is SIMPLY STATED. “Use Risk-based thinking” to manage and plan.... But what does that really mean? Broad, and simple – lots of interpretation!
Planning your QMS with risk in mind

- Identify risks and opportunities to influence QMS performance
- Determine how you’re going to measure those risks
- Build risk treatment options
- Define actions to address these risks
Planning your QMS with risk mind

- How to start Identifying risks?
  - Survey your operations
  - Audit, Survey, collect, analyze

Diagram:
- Hazard
  - Operational
    - Severity
    - Frequency
  - Financial
    - Severity
    - Frequency
  - Environmental
    - Severity
    - Frequency
  - Manufacturing
    - Severity
    - Frequency
Planning your QMS with risk in mind

• **Evaluate How to handle the risk**
• **Risk Assessment**
  – Should be repeatable, objective
  – Should be backed by REAL-WORLD DATA
• **Quantitative means to build a risk assessment**
Planning your QMS with risk in mind

- We know the risk….how do we handle it?

Acceptance: “Worth it”
Reduction: “Mitigation”
Compensation: “Insurance”
Transference: “Move it”
Avoidance: “Stop it”
Planning your QMS with risk in mind

- **Take Action:** Create Visibility and Control the Risk

  - Corrective/Preventive Action
  - Controls/Action Plans
  - Reporting/Trending

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Planning your QMS with risk in mind

- **Identify Risks**
- **Evaluate Risks**
- **Treatment of Risks**
- **Take Action**

**DOCUMENT YOUR ACTIVITIES**

- How? Audit Findings, Survey Results, Report on Findings
- Document your Evaluation: Control your methods, tools, processes
- Document the treatment, the overall decision factors
- Link Assessments to Actions taken, improvements made

- Document the process in order to have traceability.
Planning your QMS with risk in mind

- It’s not all for just the Risks! Identify Opportunities too!
Common Tools for Risk Management Treatment

- Decision Tree
- Risk Matrix
- Risk Register
Decision Tree Analysis

Easy to integrate with everyday processes

- Did the employee experience an injury or illness?
- Is the injury or illness work-related?
- Is the injury or illness a new case?
- Does the injury or illness meet the general recording criteria or the application to specific cases?

- Do not record the injury or illness
- Record the injury or illness

Updated the previously recorded injury or illness entry if necessary.

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Decision Tree Example

- **When to report to the FDA**
  - Medical device manufacturer
  - Reporting decision embedded in complaint handling process
  - Filled out by analysts for every potential adverse event
  - Drives decision to report (Yes/No) and acceptable delay (when?)

- **Prioritize internal notification**
  - Global Utilities company
  - Automated determination of who needs to be notified of incidents based on risk level
  - Immediate initial risk assessment determines risk level
  - Risk level determines email distribution list, including SMS (text) alerts for highest level
  - Follow up risk assessment performed after investigation is completed (for long term trend analysis)
  - Take immediate action on critical issues, and implement long term improvements on unacceptable trends
## Risk Matrix

Quick, easy, colorful

Quantifies the risk level using tested assumptions

<table>
<thead>
<tr>
<th>Probability</th>
<th>Minor (1)</th>
<th>Negligible (2)</th>
<th>Marginal (3)</th>
<th>Critical (4)</th>
<th>Catastrophic (5)</th>
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</thead>
<tbody>
<tr>
<td>Frequent (5)</td>
<td></td>
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<tr>
<td>Probable (4)</td>
<td></td>
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<tr>
<td>Occasional (3)</td>
<td></td>
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<tr>
<td>Remote (2)</td>
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<tr>
<td>Improbable (1)</td>
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</tbody>
</table>

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Risk Matrix Example

Identify potential adverse events
- Medical device manufacturer (a different one)
- Customer complaints routed for investigation
- Subject matter experts perform risk assessment (meeting)
- Risk levels drive decisions for recalls, notifications, CAPA

Survey of known and unknown threats
- Services organization
- Periodic survey to all business functions
- Managers re-calculate risk levels for known threats and suggest new threats
- Prioritization of compiled risk levels drives strategic risk mitigation initiatives (managed through CAPA process)
Risk Register

• **Monitors risk levels over time**
  – Library of hazards (typically known for each industry)
  – Collects risk assessment data from many processes
  – Provides visibility into critical events and data for trend reporting
Summary

• Complexity and scale breeds the need for change
• Risk is a universal compliance constant
• ISO 9000:2015 is about enrolling everyone in Quality
• Risk in ISO 9000:2015 is simply stated, but maps well to the risk methodology
• Figure out your path to risk, and leverage tools to expand to a risk-based QMS
• There are tools to help ease this transition!
Thank you! Questions?

**EtQ**

**Traqpath**

Designed for small workgroups in Quality, EHS and Compliance looking to track events, issue action items and launch corrective actions.

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