How to Apply Risk to your Quality Management System: Defining and Building a Risk Management Strategy for Quality and Compliance Management Systems

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Agenda

• Objectives
  o How to measure compliance in the complexity of business today
  o How Risk Management processes drive new ways of looking at compliance
  o Understand the relationship between Risk Management and Risk Assessment
Increasing Rate of Change...
Increasing Rate of Change...

- More complex organizations
  - Design and production facilities are worldwide
  - Mergers and acquisitions introduce cultural differences
  - Suppliers are providing more of the product

- More intense competition
  - Competition leads to shorter product lifecycles
  - New technology increases product complexity
  - Globalization introduces local differences
  - Better marketing data expands product selection

- Companies need to maintain compliance AND keep up with the pace of business!
... makes Compliance More Difficult

• How compliance keeps up with change
  o Software automation of compliance processes
  o Integration with business systems
  o Harmonization of compliance processes

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

• Time for compliance objectives to change?
  o From 100% to Acceptable
  o From audit results to risk assessments
  o Risk is a more efficient measure of compliance
Compliance Standards are Catching On

Meeting the standards of compliance

ISO 31000
Guidance for risk management in any organizations

ISO 14000 (environment) & OHSAS 18000 (safety)
Identify and assess every risk

ISO 13485/14969 (medical device), ICH Q10/Q9 (pharma)
Explicit reference to risk management

ISO 27000 (information security)
Primary focus is risk, taking into account threats, vulnerabilities and impacts

ISO 9000:2008
No direct reference, but stay tuned for 2015!

14 CFR Part 5 (air transportation)
Primary focus is risk assessment, control and overall management

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Risk Management Process

- Risk Management is a broad standard (ISO 31000)

Risk Analysis

1. Risk Identification
2. Risk Evaluation
3. Development and evaluation of risk assessment methods
4. Risk management decisions
5. Implemented solution

- 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 Terminology

• Hazard
  - A situation that poses a level of threat to life, health, property or environment (an undesired event)

• Risk
  - The potential that a chosen action or activity will lead to an undesirable event

• Control
  - A method of evaluating potential losses and taking action to reduce or eliminate the potential for an undesired event
Risk Management, Many Applications

Quality, Safety, Environmental, Financial, Regulatory, Commercial
Challenges with Risk Management

From “A Transformational Approach to Safety Risk Management” Bob Dodd, Aloft

• Lots of Focus on Process, but Content is Key
  o How to manage unidentified hazards?
  o How to calibrate risk levels?

• Understand the Limitations of the Process
  o We are not good at assessing risk
    • We don’t expect the unexpected
    • We reconstruct instead of replay
    • We see patterns in random events
    • We confuse understanding with knowledge
    • We group think
  o Prediction is hard (experts are no better)
  o Dealing with very small sample sets (single occurrence)

• Use a Structured Approach: Risk Models

• Collect Lots of Data
  o Roll out models everywhere
  o Monitor near misses in addition to recording critical events
Risk Assessment is the Core Methodology

- A way to evaluate risk in an operational context
- Repeatable and objective methods
- Easy to understand for the uninitiated
- Drives short term and long term change
- Beware a false sense of security
Where to Assess (Operational) Risk

**Product and Process Design**
- Change Management
- Production Part Approval Process (PPAP)
- Failure Mode Effects Analysis (FMEA)
- Job Safety Analysis

**Manufacturing and Delivery**
- Nonconforming Reports and Planned Deviations
- Incident and Accident Reporting

**Post-Production**
- Complaints Handling
- Supplier Performance Rating
- Internal Audits
- Corrective /Preventive Actions (CAPA)
How to Assess Risk (only a sample)

- Risk Matrix
- Failure Modes and Effects Analysis
- Decision Tree
- HACCP
- Bowtie
- Risk Register
## Risk Matrix

**Quick, easy, colorful**

**Quantifies the risk level using tested assumptions**

### SEVERITY

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

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Risk Matrix Example

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

• Monitor occupational injuries
  o Global facilities management company
  o Incident reports submitted by safety professionals
  o Perform initial risk assessment on submission, using detailed guidelines (over 30 options divided into 5 categories)
  o Risk levels drive alerts, immediate actions and trend reports
Risk Matrix Example

- 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)

- Identify job hazards
  - Power utility serving 7 countries
  - Analysis performed for every job position, periodically reviewed
  - Initial risk assessment of each job step
  - Mitigate risk through protective equipment and process change until residual risk is acceptable
# Failure Modes and Effect Analysis

For design of products and processes

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**FMEA**

**Revision 6.0 2/11/98**

### Part Name
Filter

### Core Team
Brad Anderson, Jerry Benware, Lisa Brown, Ken Caracci, Bill Cox, Fred Jordan, Ken Kratz

### Designer/Model Year
Brad Anderson, Sedan / 1998

### Action Results

<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Occurrence</th>
<th>Detection</th>
<th>R. P. N.</th>
<th>Recommended Action(s)</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter for assembly with B44 to firewall</td>
<td>Insufficient wax coverage over specified surface</td>
<td>Deteriorated life of door leading to: Unsatisfactory appearance due to rust through paint over time, impaired function of interior door hardware</td>
<td>4</td>
<td>4</td>
<td>Supplier certification</td>
<td>1</td>
<td>16</td>
<td>None</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>set up set up</td>
<td>4</td>
<td>80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Corroded interior lower door panels</td>
<td>Improper oxide coating</td>
<td>Entrapped air prevents wax from entering corner/edge access</td>
<td>6</td>
<td>6</td>
<td>Test spray pattern at startup and after idle periods, and ...</td>
<td>5</td>
<td>180</td>
<td>Add team evaluation using production spray equipment and specified wax</td>
<td>Engineering and Assembly Operations 2/18/98</td>
</tr>
<tr>
<td>Spray heads clogged: Viscosity too high, Temperature too low, Pressure too low</td>
<td></td>
<td></td>
<td>4</td>
<td>4</td>
<td>Incomming audit per 200-16 certification, SPC Lot/Qtr</td>
<td>2</td>
<td>48</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory test using “worst case” wax and application hole size</td>
<td></td>
<td></td>
<td>3</td>
<td>72</td>
<td>Add laboratory accelerated corrosion testing</td>
<td>3</td>
<td>72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conduct DOE on wax thickness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Engineering Associates 2/18/98</td>
<td></td>
<td></td>
<td></td>
<td>DOE shows 25% variation in specified thickness is acceptable</td>
</tr>
<tr>
<td>Feeder not properly or</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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FMEA Process

Planning Stage

1. Develop and Execute FMEA Strategic Plan
2. Develop and Execute FMEA Resource Plan

Analysis Stage

3. Develop Program-Specific FMEAs

Review Stage

4. Management Review
5. FMEA Quality Audit
6. Supplier FMEAs

Implementation Stage

7. Execute Actions to Reduce or Eliminate Risk
8. Linkage to Other Processes

9. Test and Field Failures
### Sample FMEA Form

**Revision 6.0 2/11/98**

<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Class</th>
<th>Potential Cause(s) / Mechanisms of Failure</th>
<th>Occur</th>
<th>Design Controls</th>
<th>R. P. N.</th>
<th>Recommended Action(s)</th>
<th>Responsibility &amp; Target Completion Date</th>
<th>Action Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter for assembly with B44 to firewall</td>
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<td>4</td>
<td>4</td>
<td>Insufficient wax thickness specified</td>
<td>4</td>
<td>Supplier certification</td>
<td>1 16</td>
<td>None</td>
<td>N/A</td>
<td>2/11/98</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Inappropriate wax specified</td>
<td>5</td>
<td>Set up</td>
<td>4 80</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Five piece setup, in-process, end of run study</td>
<td>2</td>
<td>40</td>
<td>None</td>
<td>N/A</td>
<td>2/11/98</td>
<td></td>
</tr>
<tr>
<td>Corroded interior lower door panels</td>
<td>Improper oxide coating</td>
<td>Entrapped air prevents air from entering corner edge access</td>
<td>8</td>
<td>6</td>
<td>Test spray pattern at startup and after idle periods, and ...</td>
<td>5</td>
<td>180</td>
<td>Add team evaluation using production spray equipment and specified wax</td>
<td>Engineering and Assembly Operations</td>
<td>Based on test results (Test #90890) spray head modified to ...</td>
<td>6 2 5 60</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Spray heads clogged: Viscosity too high. Temperature too low, Pressure too low</td>
<td>4</td>
<td>2</td>
<td>Incoming audit per 200-16 certification, SPC Lot/Qty</td>
<td>2</td>
<td>48</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Laboratory test using “worst case” wax and application hole size</td>
<td>3</td>
<td>72</td>
<td>Add laboratory accelerated corrosion testing</td>
<td>3</td>
<td>2/27/98</td>
<td>ABC Labs</td>
<td>Test results show specified ...</td>
<td>6 3 3 54</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Conduct DOE on wax thickness</td>
<td>2</td>
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<td></td>
<td>6 2 2 24</td>
<td></td>
</tr>
</tbody>
</table>

**Feeder not properly or** | 3 | | | | | | | | | | | | |
FMEA Example

- Demonstrate acceptable quality to customer
  - Global engineering company
  - Uses PPAP to coordinate design changes with parts suppliers
  - FMEA submitted by supplier and evaluated by engineers
  - Risk Priority Number (RPN) drives remedial actions and general acceptability
Decision Trees

Easy to integrate with everyday processes

1. Did the employee experience an injury or illness?
   - Yes → Is the injury or illness work-related?
   - No → Is the injury or illness a new case?

2. Is the injury or illness work-related?
   - Yes → Is the injury or illness a new case?
   - No → Does the injury or illness meet the general recording criteria or the application to specific cases?

3. Does the injury or illness meet the general recording criteria or the application to specific cases?
   - Yes → Record the injury or illness
   - No → Do not record the injury or illness

Updated the previously recorded injury or illness entry if necessary.
Decision Tree Example

• When to report to the FDA
  o Medical device manufacturer (a different one)
  o Reporting decision embedded in complaint handling process
  o Filled out by analysts for every potential adverse event
  o Drives decision to report (Yes/No) and acceptable delay (when?)
# Hazard Analysis (HACCP)

## Preventive approach to safety

<table>
<thead>
<tr>
<th>Step</th>
<th>Hazard</th>
<th>Preventive Measures</th>
<th>GMP/SSOP</th>
<th>Risk Assessment</th>
<th>CCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>B: C: P: Biological Chemical Pathogens</td>
<td>Steps taken to mitigate hazard</td>
<td>Standard Procedures related GMP</td>
<td>Q1 Q2 Q3 Q4</td>
<td>No - -</td>
</tr>
<tr>
<td>3.2</td>
<td>B: C: P: Biological Chemical Pathogens</td>
<td>Steps taken to mitigate hazard</td>
<td>Standard Procedures related GMP</td>
<td>Q1 Q2 Q3 Q4</td>
<td>No - -</td>
</tr>
<tr>
<td>3.3</td>
<td>B: C: P: Biological Chemical Pathogens</td>
<td>Steps taken to mitigate hazard</td>
<td>Standard Procedures related GMP</td>
<td></td>
<td>Yes Yes Yes</td>
</tr>
</tbody>
</table>
Hazard Analysis (HACCP) Example

• Determine inspection level for incoming materials
  o Large food manufacturer
  o HACCP created to identify CCPs in manufacturing process, including incoming food products from vendors
  o HACCP used by control manufacturing and inspection steps
  o Dictates amount of monitoring required for each step and product
Bowtie Model

For low-occurrence events that are catastrophic

- Threat
  - Preventive Controls
  - Preventive Controls
  - Preventive Controls

- Undesired Event (Hazard)
  - Preventive Controls
  - Preventive Controls
  - Preventive Controls

- Recovery Controls
  - Recovery Controls
  - Recovery Controls
  - Recovery Controls

- Consequence
  - Consequence
  - Consequence
  - Consequence

- Frequency
- Likelihood
- Likelihood
- Severity

For low-occurrence events that are catastrophic
Bowtie

For low-occurrence events that are catastrophic
Bowtie Example

• Analyze flight safety reports
  o Worldwide commercial airline
  o Safety reports submitted by any of the 60,000 employees and subcontractors
  o Safety analysts use Bowtie model consisting of thousands of threats and controls, with only 9 possible consequences
  o Automatic calculation of risk level for each threat based on historical frequency data, and estimated likelihood and severity
  o Risk levels drive alerts, immediate actions and trend reports
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
Risk Register is the New Center
Risk Register Example

- Promote high risk events across the organization
  - Worldwide commercial airline (a different one)
  - Events from flight crew, ground crew, airport security, auditors
  - Uses 4 different risk matrices, but harmonized risk levels
  - Automatically displays highest risk events on employee portal
Risk Technology from Start to Finish
Risk Management Starts Now!

- **Risk Technology is NOT automatic**
  - Tools support decision-making process, but people (experts) make the final decision
  - Use a Risk Team to increase visibility and education
  - Vet your risk assessment methods using historical examples to ensure accurate results

- **Risk offers a common language for compliance**
  - Risk assessment is applicable to many operational areas
  - It provides an objective way to prioritize adverse events
  - Known risk models improve speed/quality of decision making
  - Risk terminology offers a common understanding of complex operational issues

Ένα πρόβλημα που πραγματοποιήθηκε στο λεβητοστάσιο, που έκλεισαν την παραγωγή και προκάλεσε μείωση κατά 10% στις αποστολές. Ερευνούμε την αιτία, αλλά μοιάζει με τη διαδικασία όπτησης είναι ξεπερασμένη και των επιχειρήσεων δεν είχαν επαρκή εκπαίδευση.
Thank You! Questions?

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