Risk Management outside Your Four Walls: Implementing Risk Strategies for the Supply-Chain

Tim Lozier, EtQ, Inc.
Agenda

• Looking at the challenges surrounding the Supply-Chain
• Understand the risks associated with Supply-Chain Compliance
• What is the Supplier Network and how does it impact operations?
• Identify the Gaps and Fillers the Supplier Network can control
• Understanding the Risk Management dynamic in the Supply Chain
• Tools for assessing risk in the Supply-Chain
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!
Challenges in the Supply Chain

• Outsourcing On the Rise

Just 25% of a typical company’s end-to-end supply chain is being assessed in any way for risk.

17% of companies have true end-to-end visibility into supplier operations.

53.5% of companies are planning to invest in additional IT to improve supply chain visibility by 2018.
Challenges in the Supply Chain

• Factors driving these trends
  - Greater flexibility in the Supply Chain
  - Specialized knowledge and skills in Suppliers
  - Leverage new technology faster
  - Focus on brand owner core competencies
  - Transfer risk
  - Reduce Costs
  - Time to Market

• Challenge: increased outsourcing creates new risks!
Challenges in the Supply Chain: Trends

- The Internet of Things (IoT)
- Digitization of Data
- Shift to Big (but Usable) Data
- SCM Organizations Will Begin to Adopt Application Convergence Strategy
- Risk Management Comes to the Forefront
- Operations Planning and Inventory Optimization Go Under the Microscope
Challenges in the Supply Chain

- Risks Associated with the Supply Chain

- Dependence on Suppliers
- Different Visions
- Cultural Differences
- Loss of IP & Counterfeiting
- Loss of Critical Skills
- Loss of Operational Control
- Lower Visibility in Performance and Quality
Challenges in the Supply Chain

- How can we mitigate Risk?

Supply Chain Risk

- Dependence on Suppliers
- Different Visions
- Cultural Differences
- Loss of IP & Counterfeiting
- Loss of Critical Skills
- Loss of operational Control
- Lower Visibility in performance/quality
Challenges in the Supply Chain

How can we mitigate Risk?

- **Disaster recovery plan** for supply chain interruptions, Contingencies in the Supply Chain
- **Risk Management plan** to protect IP
- **Supplier selection based on more than specs and cost**, Move from Supply Chain to **Supplier Network**
- **Promote industry groups and standards adoption**, Invest in Track-and-Trace technologies, Integrate business systems
- **Implement an automated Supplier Quality Network**
- **Different Visions**

What skills should we retain? What are the core activities?
Challenges in the Supply Chain

- Top risk mitigating strategies

Source: Aberdeen Group
How your QMS Supports the Supply Chain

- Change control
- Supplier performance
- Out-of-specification management
- Complaints handling
- CAPA program
- Specification management

- Culture?
- Processes?
- Quality system?
- Sub-contractors?

- Define acceptable level
- Real time monitoring
Filling the Gap: Automating Supplier Approval

1. URL Supplier Clicks on Link
2. Register (Enter Registration Information, Address Contacts, etc.)
3. Submit Registration Form & Sends a Notification to Internal Person
4. Supplier & Contact Info. Reviewed Supplier & User Profiles Created

- Access provided to relevant modules
- Dashboard assigned to the Supplier
- Allow the supplier administrator to build their profile
- Filters applied to the User’s profile to show only the relevant data
Current Gaps: Existing Supplier Collaboration

Manual or Offline process

Approved Supplier

Send to Supplier

Specification

Supplier Confirms by providing prototype
The Supplier signs off on the Specification.

If the Supplier cannot deliver to the specification, it is sent back and forth till a version is agreed upon.
Current Gaps: Annual Supplier Audits

Audit

Sent to Supplier

Self Assessment

Supplier Performs Self Assessment

Audit Performed

At the Supplier Site

Follow-up verification
Audit for Effectiveness Check

SCAR Issued

Audit Results Reviewed with the Supplier

Supplier

Manual or Offline process
A Planned Supplier Audit is scheduled. It is sent to the supplier to provide Self-Assessment information.

The supplier does a self assessment and sends the results back.
Supplier Audit (cont.)

The Results of the Audit are reviewed with the supplier. The Supplier has an opportunity to provide additional feedback or agree to Nonconformities.

The Supplier signs off on the agreed Audit results and SCARs/Actions are Issued as necessary.

If Major Nonconformity

SCAR
Current Gaps: Receiving Shipments

Supplier

Receive Shipments & Inspection Performed

Nonconformance

Contact Supplier

Supplier provides response with suggested disposition

Investigate

Issue SCAR

Execute the Disposition

Manual or Offline process
Filling the Gaps: Resolving Material Nonconformance

A nonconformance with batch/lot information is sent to Supplier along with the nonconformance information. The Supplier investigates the issue and recommends a disposition. This Information is then sent to the Internal Rep for Review.
Current Gaps: Supplier Corrective Actions

1. SCAR
   - SCAR
   - Sent to Supplier

2. Supplier
   - Supplier Responds with Suggested Corrective Actions
   - Review of SCAR
   - UNDER REVIEW

3. SCAR Verified & Completed
   - Supplier provides evidence of completion
   - SCAR Implemented

4. Manual or Offline process
   - Mutually Agreed Upon Actions
A SCAR is sent to the Supplier. This record is assigned to a Supplier contact, and is assigned a due date.

The Supplier performs Root Cause analysis, determines corrective action, and due dates and sends it back.
The SCAR is approved and sent back to the Supplier. It is assigned to the Supplier contact with respective due date.

The Supplier Implements the SCAR, provides evidence of completion and sends it back.
Filling the Gap: Supplier Deviations/Waivers

The Supplier sends a Waiver request to deviate from the Approved specification.

Internal Systems

Review of Deviation UNDER REVIEW

The Deviation is reviewed and approved Internally and upon receiving internal Approvals, is sent back

Supplier Network Solution

Supplier Network Solution

Routed to Internal Representative

Deviation is Approved
Risk Management Process

- Risk Management is a broad standard (ISO 31000)

1. **Risk Identification**
   - Identify all relevant risks (e.g., hazard analysis)

2. **Risk Evaluation**
   - Quantify the risk (e.g., probability and severity)

3. **Development and evaluation of risk assessment methods**
   - Implement a process
   - Use objective and proven tools

4. **Risk management decisions**
   - Accept (worth it), reduce (mitigate), compensate (insure), transfer (partner), avoid (stop)

5. **Implemented solution**
   - Change management to introduce or improve controls
Common Tools for Risk Management Treatment

(a sample)

- Decision Tree
- Risk Matrix
- Failure Modes and Effects Analysis (FMEA)
- Bowtie
- Risk Register
Decision Tree Analysis

Easy to integrate with everyday processes

1. Did the employee experience an injury or illness?
   - Yes
   - Is the injury or illness work-related?
     - Yes
     - Is the injury or illness a new case?
       - Yes
       - Updated the previously recorded injury or illness entry if necessary.
       - No
       - 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
   - No
   - Do not record the injury or illness
# Risk Matrix

Quick, easy, colorful

Quantifies the risk level using tested assumptions

## Table of Risk Matrix

<table>
<thead>
<tr>
<th>Probability</th>
<th>Severity</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>
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<tr>
<td>Probable (4)</td>
<td></td>
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<tr>
<td>Occasional (3)</td>
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<td></td>
<td></td>
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<tr>
<td>Remote (2)</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Improbable (1)</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
# Failure Modes and Effect Analysis

For design of products and processes

<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Effect(s) of Failure</th>
<th>Severity</th>
<th>Potential Cause(s) / Mechanisms of Failure</th>
<th>Occur</th>
<th>Current Design Controls</th>
<th>Dete.</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>Insufficient wax thickness specified</td>
<td>4</td>
<td>Supplier certification</td>
<td>1</td>
<td>16</td>
<td>None</td>
<td>N/A</td>
<td>2/11/08</td>
</tr>
<tr>
<td>Corroded interior lower door panels</td>
<td>Improper oxide coating</td>
<td></td>
<td>6</td>
<td></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 2/18/08</td>
<td>Based on test results (Test #9989) spray head modified to ...</td>
</tr>
<tr>
<td>Spray heads clogged. Viscosity too high. Temperature too low, Pressure too low</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>Incoming audit per 200-10 certification, SPC Lot/Qtr</td>
<td>2</td>
<td>48</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory test using &quot;worst case&quot; wax and application hole size</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
<td>Add laboratory accelerated corrosion testing</td>
<td>72</td>
<td></td>
<td>ABC Labs 2/27/08</td>
<td></td>
<td>Test results show specified ...</td>
</tr>
<tr>
<td>Feeder not properly or</td>
<td></td>
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**Part Name:** Design Responsibility
**Supplier:** Any Company, Inc.
**Customer:** Chrysler Motors Corporation
**Customer Part No.:** DC-7723-XYZ
**Supplier Part No.:** ACI-001
**Org. Date:** 2/11/08
**Dwg. Rev.:** 8
**Key Date:** 2/11/08
**FMEA No.:** DFMEA-001

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

**Prepared By:** Brad Anderson
**Date:** 2/11/08
FMEA Process

Planning Stage
- Develop and Execute FMEA Strategic Plan
- Develop and Execute FMEA Resource Plan

Analysis Stage
- Develop Program Specific FMEAs
- Test and Field Failures

Review Stage
- Management Review
- FMEA Quality Audit
- Supplier FMEAs

Implementation Stage
- Execute Actions to Reduce or Eliminate Risk
- Linkage to Other Processes
**Sample FMEA Form**

**Design FMEA**

**Revision 6.0 2/11/98**

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<th>Occurrence (O)</th>
<th>Current Design Controls</th>
<th>Detectability (D)</th>
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<td></td>
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<td>Setup</td>
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<td>Improper oxide coating</td>
<td>Entrapped air prevents wax from entering corner edge access</td>
<td>8</td>
<td>Spray heads clogged: Viscosity too high. Temperature too low, Pressure too low</td>
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<td>Incoming audit per 200-16 certification, SPC Lot/Qtr</td>
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</tbody>
</table>

**Part Name**

Filter

**Design Responsibility**

Brad Anderson

**Application/Model Year**

Sedan / 1998

**Prepared By**

Brad A. Anderson

**Date**

2/11/98
Bowtie Model

For low-occurrence events that are catastrophic
Bowtie Example

For low-occurrence events that are catastrophic
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

PDCA Cycle
Summary

• Supply Chain is Becoming More Complex
  • Many risks associated with growing supply chain
  • Mitigating risks is primarily a strategic initiative

• Supplier Quality Network Cornerstone of Compliance
  • Comprehensive, standardized

• QMS extends to Supply Chain through the This network
  • Key quality processes encompass supplier operations
  • Risk management is critical to maintaining compliance

• Apply Risk Management to the supply-chain
  • Use a objective and repeatable risk management tools
  • Integrate risk assessment into the compliance processes

• Risk Management is also a Strategic Initiative
Thank you! Questions?

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

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