Advanced Quality Auditing

An Auditor’s Review of Risk Based Thinking,
Lean Improvement and Data Analysis

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**audit** (ˈɔːdɪt) n. Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Audit Program

The audit program can be thought of as a performance platform that rests on the three pillars of

- Compliance
- Improvement
- Risk Management
There are 4 phases through which a quality management system may evolve:

- Precertification
- Newly Certified
- Beyond Certification
- World Class
# Audit Program Evolution

<table>
<thead>
<tr>
<th>Phase 3 – Beyond Certification</th>
<th>Phase 4 – World Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Starting to talk to other systems</td>
<td>• Fully integrated with other systems</td>
</tr>
<tr>
<td>• Beginning to shift focus from compliance based to integrated system</td>
<td>• All three pillars of auditing clearly evident</td>
</tr>
<tr>
<td>• Action planning based on data analysis</td>
<td>• Clearly defined and appropriate reporting strategy</td>
</tr>
<tr>
<td>• Higher visibility of audit results</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phase 1 – Precertification</th>
<th>Phase 2 – Certified</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Seeking structure and control</td>
<td>• Compliance and correction driven</td>
</tr>
<tr>
<td>• Backward facing</td>
<td>• Fleshting outôthe system</td>
</tr>
<tr>
<td>• Reactive</td>
<td>• Data collection and reporting</td>
</tr>
</tbody>
</table>

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Defining Risk

Risk – combination of the probability of occurrence of harm and the severity of that harm.

ISO 14971:2007

Risk – the effect of uncertainty on objectives

ISO 31000:2009

Risk – the effect of uncertainty on desired results

ISO 9001:2015 DIS
Where does risk lie in our process?

1. Complexity of the process
2. Complexity of the product
3. Criticality of the product
4. Process location of the product
5. Newness of the product
6. Newness of employees
7. History of the process
How do audits help manage risk?

1. Audit frequency
2. Sample size
3. Complexity of audit plan
4. Containment
5. Corrective action plans
6. Effectiveness verification
7. Special training
## Applying Risk Based Thinking

<table>
<thead>
<tr>
<th>Minor</th>
<th>Major</th>
<th>Critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Violation of internal procedure or work instruction; Current practice that meets requirement is not accurately documented. Could lead to failure of part attributes</td>
<td>Violation of customer requirement or internal requirement. Systemic or chronic failure of QMS requirement. Multiple related minor violations. Issue that could lead to failure of either part function or part variables. Ethical violations. Or issue that could cause great harm to other operations.</td>
<td>Noncompliance that is itself a hazard or may lead to hazardous condition. Direct violation of ISO standards or cGMP. Issue that could directly lead to field failure of finished good. Legal violations. Lost required record or procedure. Zero documented evidence of compliance.</td>
</tr>
</tbody>
</table>
Risk Based Quality Auditing

- Level 1 – plan and report based on QMS process
- Level 2 - Evaluate degree to which RM is used within each QMS process
- Level 3 - Determine enterprise-level risks related to QMS processes
RBQA Types

- Directly audit the risk management (RM) program itself (Level 3)
- Conduct RBQA of aspects of the QMS or of the QMS as a whole
  - Standalone risk management audit of QMS elements (Level 2)
  - Incorporate risk management into existing audits (Level 1)
Risk Management Program Auditing

1. Confirm that results from the risk management program are reported as necessary to appropriate levels of management.
2. Confirm that existing risk management procedures and work instructions are followed.
3. Ensure that organizational training supports the risk management program.
4. Confirm that adequate resources are supplied to meet the goals of the risk management program.
5. Confirm that risk models are periodically reviewed and assessed to determine the need for update.
Scenario

An auditor visits a machine shop and witnesses a welding operation where sparks are flying in the immediate vicinity. The operator is following their instructions and wearing the appropriate PPE, but the auditor notices a small puddle of oil on the floor nearby.

Discuss potential findings from both a compliance and risk based perspective.
Risk is the Compass™ Model

- **Enablers** – Activities or controls such as clear work instructions, operator training program, calibrated/maintained equipment instituted in order to insure that a process is carried out properly.

- **Risks** – those hazards or conditions such as newness of the product, complexity of the process, and poor lighting that work against successful implementation of a process

1 – Developed by Denis Devos of Devos & Associates

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# Risk is the Compass™ Model

<table>
<thead>
<tr>
<th>PROCESS STEP</th>
<th>RISKS</th>
<th>ENABLERs</th>
<th>ADEQUACY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Step 1 Risks</td>
<td>Step 1 Enablers</td>
<td>Are the process step 1 enablers adequate to overcome associated risks</td>
</tr>
<tr>
<td>Step 2</td>
<td>Step 2 Risks</td>
<td>Step 2 Enablers</td>
<td>Are the process step 2 enablers adequate to overcome associated risks</td>
</tr>
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Risk Management

How do we formally integrate risk management into the audit program?

- By tying finding classification to risk assessment
- Let finding risk dictate actions taken
- Let finding risk dictate report distribution
- Establish feedback loop to risk management program
RBQA Review

- Risk based thinking evaluates and responds to occurrences based on risk using risk management tools
- RBQA can be incorporated into existing audits or conducted as standalone audits
- It is important that once process risks are identified that enablers are developed as countermeasures
Lean and Six Sigma tools can be integrated into current audit methodology in order to develop a more robust, value added, and continuous improvement driving internal audit program.
Lean *drives improvement by reducing process waste and production cycle time*

Six Sigma *drives improvement by reducing overall process variation and eliminating special cause variation*
Tool Deployment

Three opportunities to incorporate Lean and Six Sigma tools into auditing

- SIPOC Diagrams
- Value Stream Mapping
- Control Charts
Tool Deployment

Value Stream Mapping
• Value add vs non-value add activities
• Potential process bottlenecks
• Opportunities to match cycle to takt time

SIPOC Diagrams
• Identify implicit needs
• Identify input value streams

Control Charts
• Trending
• Training
• Equipment Discrimination
## SIPOC Diagram

### SIPOC

<table>
<thead>
<tr>
<th>Suppliers (Providers of the required resources)</th>
<th>Inputs (Resources required by the process)</th>
<th>Process (Top level description of the activity)</th>
<th>Outputs (Deliverables from the process)</th>
<th>Customers (Stakeholders who place the requirements on the outputs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirements</td>
<td>Inputs</td>
<td>Process</td>
<td>Requirements</td>
<td>Requirements</td>
</tr>
<tr>
<td>Output</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Facilitated By:

### Notes:

### Input Provided By:

### Process Name:

### Process Owner:

### SIPOC Date:

### SIPOC Rev:

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1. Identify the process and its boundaries

2. Identify the customers for each output

3. Identify the customers for each output

4. List the requirements for each output

5. List the inputs

6. Identify the supplier for each input

7. List the requirements for each input

8. Analyze SIPOC (Scope, Team, Data & Gaps)
Traditional Receiving Audit

Receiving Process Flow

General Inquiries
- How are incorrect counts handled?
- How are other discrepancies processed?
- On new parts, how do you know which ones go to QA?
- How are parts labeled and status identified?

Hard Document Requirements
- Verification purchased product procedure ISO 13485 : 7.4.3
- 21PART820 : 820.50

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Control Charts

Why do we use control charts?

• Monitor a process
• Assess process control
• Assess process capability
Special Cause Variation

![Graph showing Special Cause Variation with control limits UCL and LCL.](image-url)
Trending

$20,000+
scrap
SPC Questions to Ask

- Auditors seeing similar trends in data that they are reviewing should inquire as to if the trend was investigated?
- Also, under what circumstances would process data cause an investigation to be launched?
- How do you respond to an out of control condition?
- Tell me about your SPC training
Recap of Key Thoughts

- Risk based thinking is the review, evaluation and response to audit findings from the perspective of risk.
- The three tiers of a robust audit program are compliance, continuous improvement and risk management.
- Audit program goals should be aligned with the site/company goals.
- Lean six sigma tools as well as data and trend analysis are important skills to master.
Reference

http://asq.org/quality-press/display-item/?item=H1487

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QUESTIONS???

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