A Risk Assessment-driven Quality Management System

A way forward to ISO 9001:2015

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A Risk Assessment-driven QMS

0. Introduction

- With the release of the new ISO 9001:2015 standard, QMS in all kinds of organizations are going to face several changes.

- This presentation intends to assess in one methodology in order to accomplish with the new ISO requirements.
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1. ISO 9001:2015 Requirements

- Determine external and internal issues that affect its ability to achieve the intended result(s) of its QMS.

- Identify the processes needed and their interactions
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1. ISO 9001:2015 Requirements

- Processes identification needs:
  - Inputs and Outputs
  - Sequence and interactions
  - Measuring methods
  - Resources
  - Responsibilities and authorities
  - Risk and opportunities
  - Methods of monitoring
  - Opportunities of improvement
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1. ISO 9001:2015 Requirements

- Risk and opportunities in Processes
  - Identify the Risk and opportunities in process
  - Plan actions to address them
  - Implement the actions

Identify (Risk) → Plan (Actions) → Implement (Actions)
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1. ISO 9001:2015 Requirements

- Identification of Risk related to the QMS

  - Give assurance that the QMS can achieve the intended result
  - Prevent or Reduce, undesired effects (Non-conformities)
  - Achieve continual improvement
Planning actions to address risk

- integrate and implement the actions into its QMS processes
- evaluate the effectiveness of these actions.

This actions shall be proportionate to the potential impact on the conformity of products and services.
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2. Process Management

- A process consists of a set of activities that are performed in coordination.
- They are set in an organizational and technical environment.
- Each process can stand by itself but they can interact each other.
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2. Process Management

S  I  P  O  C

Supplier
- Person / Organization that provides Input

INPUT
- Resource needed

PROCESS
- Steps to convert an Input into an Output

OUTPUT
- Resource created

Customer
- Person / Organization that receives product or services
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2. Process Management

- Market Analysis
- Promotions Planning
- Sales Planning
- Assortment Planning
- Vendor Planning

- Private Brands Introduction
- Product Idea
- Product Design

- Vendor Management
- Assortment Management
- Pricing
- Merchandise Planning
- Purchase Order Processing
- Vendor Settlement
- Import Processing

- Goods Receipt
- Goods Distribution
- Goods Issue
- Export Processing
- Transportation Execution
- Inventory Management
- Warehouse Management

- Customer Management
- Sales Processing
- Sales Support
- Billing

Supportive Processes:
- Master Data Management
- Financials
- Human Resources
- Real Estate Management
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3. Risk Management

- Risk: The combination of the probability of an event and its consequence
- Consequences can be positive or negative
- Risk management: systematic process of understanding, evaluating and addressing these risks to maximize the chances of objectives being achieved
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3. Risk Management

- Identify Risk and their causes
- Continuous monitoring of risk and actions
- Estimate Likelihood and impact of the risk
- Identify Risk and their causes

1. Identification
2. Analysis
3. Treatment
4. Monitoring
3. Risk Management

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Acceptable risk (Medium)</th>
<th>Unacceptable risk (High)</th>
<th>Unacceptable risk (Extreme)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very likely</td>
<td>2</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Likely</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Unlikely</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

What is the chance it will happen?

- Minor
- Moderate
- Major
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4. Integrating Risk into Process Management

- Identify in each process (input / output) the hazards and the harms
- Assess the consequence and the probability
- Define an acceptance criteria
- Define the acceptance or the mitigation
- Identify the cost of mitigation and control
- Monitor new harms for the process
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4. Integrating Risk into Process Management

- Examples of Risk in process

<table>
<thead>
<tr>
<th>Risk</th>
<th>Effectiveness</th>
<th>Productivity</th>
<th>Time</th>
<th>Efficiency</th>
<th>Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Things are done right</td>
<td>Employees are doing more tasks</td>
<td>Reducing throughput time</td>
<td>Employees are doing tasks</td>
<td>Reducing transaction cost</td>
</tr>
</tbody>
</table>
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4. Integrating Risk into Process Management

- Use several methodologies to implement, audit and report potential Risk into the organization QMS process
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4. Integrating Risk into Process Management

- Turtle Diagram Methodology

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Measure(s)</th>
<th>Outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplier</td>
<td>Process</td>
<td>Customer</td>
</tr>
<tr>
<td>Materials / Equipment</td>
<td>Process Support</td>
<td>Competence/ Skills Training</td>
</tr>
</tbody>
</table>
4. Integrating Risk into Process Management

- Turtle Diagram Methodology
  - Advantage
    - Quick identification of process inputs / outputs, controls and resources.
    - High level of detail
    - Ease identification of interactions between process
    - Accomplish with the new ISO 9001:2015 standard
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4. Integrating Risk into Process Management

- Identification of mayor risk in process
  - Is the organization accomplishing with:

<table>
<thead>
<tr>
<th>Mayor Risk</th>
<th>Key process Inputs</th>
<th>Key process Outputs</th>
<th>Key process Activities</th>
<th>Key personnel involved</th>
<th>Process effectiveness measurement</th>
<th>Process Objectives</th>
</tr>
</thead>
</table>
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4. Integrating Risk into Process Management

- Process Risk Assessment:
  - Identify the activity, the potential Hazard and the undesired Outcome
  - Assess the risk (Likelihood and impact)
  - Set a control measure
  - Set a responsible
  - Define a due date
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4. Integrating Risk into Process Management

- Process Risk Assessment matrix:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Hazard Identified</th>
<th>Undesired Outcome</th>
<th>Risk Assessment</th>
<th>Control Measure</th>
<th>Responsible</th>
<th>Due Date</th>
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4. Integrating Risk into Process Management

- Risk Management Plan
  - Once the organization has set the Process Risk Management it should develop a risk management plan for those potential risk that can affect its QMS intended results
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4. Integrating Risk into Process Management

- Risk Management Plan

1. Select the Intended QMS outcome (Conformity)
2. Define the hazard and the potential non-desired outcome (Non-Conformity)
3. Define other areas to be affected
4. Assess the risk
5. Define the risk treatment actions in place
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4. Integrating Risk into Process Management

- Risk Management Plan

6. Identify the residual risk
7. Identify the potential residual non desired outcomes
8. Define additional actions to be taken
9. Identify the recourses required to assess the risk
10. Define the risk owner
4. Integrating Risk into Process Management

- Risk Management matrix:

<table>
<thead>
<tr>
<th>Desired Outcome</th>
<th>Hazard Identified</th>
<th>Undesired Outcome</th>
<th>Risk Assessment</th>
<th>Primary Action plan</th>
<th>Residual Risk</th>
<th>Potential Undesired Residual Outcome</th>
<th>Additional actions</th>
<th>Resources</th>
<th>Risk Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Likelihood</td>
<td>Impact</td>
<td></td>
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</table>
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5. Benefits of Risk Assessment

- **Benefits**
  - Helps to set the strategic and business planning;
  - Makes the use of resources effective;
  - Reduces the undesired outcomes;
  - Can improve the possibility of finding new opportunities in the QMS;
  - Enhance communication between processes;
  - Holds Stakeholders;
  - Helps focus internal audit programme.
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6. Challenges

- Challenges to be faced are
  - Actual QMS are based in “heavy” documentation
  - Few organizations know the risk assessment methodology
  - Fewer organizations are prepared to change their actual QMS
  - Identify the degree of “depth” of the risk assessment
  - New changes in the ISO 9001:2015 final standard
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Move Forward with Confidence
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- Thanks for your attention

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