Presentation Overview

- What Is Risk and How Is It Reduced
- Definition of Risk-Based Thinking
- Standard Requirements for Risk-based Thinking
  - ISO 9001:2015
  - IATF 16949:2016
  - ISO 13485:2016
- Seven Key Elements of Risk Management
- Common Risk Management Tools Used and Mistakes Made When Using
  - Design Failure Modes Effects Analysis (Design FMEA)
  - Process Failure Modes Effects Analysis (Process FMEA)
- What Sources of Risk Must Be Worked On
- How Much Risk Is Acceptable
- Risk-Based Thinking Implementation Example
- Risk-Based Thinking and Plan-Do-Check Act
What Is Risk and How Is It Reduced?

- Two Components of Risk
- How Risk Is Reduced
Definition of Risk-based Thinking

- Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (ISO 9001: 2015 01.d).
- Risk-based thinking allows companies to optimize the use of their available resources through risk-based targeting.
ISO 9001:2015 Requirements for Risk-based Thinking

- The standard in non-prescriptive on where risk-based thinking must be applied (4.4.1).
- Organization must determine processes required for QMS (4.4.1).
- Organization shall determine inputs, outputs, interaction and risks of QMS processes (4.4.1).
- The organization shall plan actions to address the risks of the required processes to confirm the QMS can achieve its intended results, enhance the probability of desirable process outputs and prevent/reduce the probability of undesirable outputs (6.1.1).
- Actions taken to reduce risks shall be proportionate to the potential impact on the conformity of products and services (6.1.1).
- The standard does not define the elements that must be present in system used to manage risk (A.4).
ISO 9001:2015 Requirements for Risk Based Thinking

- The standard does not require formal methods for risk management (A.4).
- The standard does not require a documented risk management process (A.4).
- Organizations can determine whether or not they want to develop a more extensive risk management methodology than required by the standard (A.4).
IATF 16949:2016 Requirements for Risk Based Thinking

- Requires compliance with but not registration to ISO 9001:2015 (0.3.3).

![ASQ Logo]
ISO 13485:2016 Requirements for Risk Based Thinking

- When the term “risk” is used it pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements (0.2).
- Risk is defined as combination of the probability of occurrence of harm and the severity of that harm (3.17).
- Risk management is the systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk (3.18).
- The organization shall apply a risk based approach to the control of the appropriate processes needed for the quality management system (4.1.2).
ISO 13485:2016 Requirements for Risk Based Thinking

- The standard requires risk-based thinking be used for control of the following specific processes:
  - process outsourcing (4.1.5);
  - validation of software used by QMS system (4.1.6);
  - definition of design requirements (8.2.1);
  - worker training (6.2);
  - product realization (7.1, 7.33);
  - product design changes (7.3.9);
  - purchased product (7.4.1, 7.4.3);
  - manufacturing processes (7.5.6);
  - control of monitoring and measurement equipment (7.6);
  - QMS feedback systems (8.2.1).
Seven Key Elements of Risk Management

- Objectionable Incident Definition
- Severity of Harm Definition
- Root Cause Definition
- Risk Control Definition
- Probability of Incident Due to Cause Definition
- Root Cause Priority
- Risk Reduction Activity Tracking
# Design FMEA and Common Mistakes When Using

<table>
<thead>
<tr>
<th>Column Headings</th>
<th>Design FMEA Content</th>
<th>Risk Element</th>
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<tbody>
<tr>
<td>Item/Requirement</td>
<td>Design Requirement</td>
<td>Objectionable Incident</td>
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<td>Potential Failure Mode (FM)</td>
<td>Failure to Meet Design Requirement</td>
<td>Severity of Harm Description</td>
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<tr>
<td>Potential Effect(s) of Failure (FE)</td>
<td>Description of Harm Due To FM</td>
<td>Root Cause Definition</td>
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<td>Risk Control Definition</td>
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<tr>
<td>Potential Cause(s) of Failure (FC)</td>
<td>Improperly Defined Design Specification</td>
<td>Probability of Incident Due To Cause</td>
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<td>Design Prevention Controls</td>
<td>Method of Determining Probability of FM due to FC</td>
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<td>Design Detection Controls</td>
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<tr>
<td>Changes to Design to Reduce Risk</td>
<td></td>
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</tr>
</tbody>
</table>

- **Common Mistakes When Using Design FMEA**
  - Component Design Requirements in Item/Requirements Column
  - Non-Verifiable Design Requirement in Item/Requirements Column
  - Objectionable Incident in Potential Cause(s) of Failure (FC) Column
  - Use of RPN to Determine What to Work On
### Process FMEA and Common Mistakes When Using

<table>
<thead>
<tr>
<th>Column Headings</th>
<th>Process Step/ Purpose</th>
<th>Potential Failure Mode (FM)</th>
<th>Potential Effect(s) of Failure (FE)</th>
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<th>Class</th>
<th>Potential Cause(s) of Failure (FC)</th>
<th>Occ</th>
<th>Process Prevention Controls</th>
<th>Process Detection Controls</th>
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<th>RPN</th>
<th>Risk Reduction Action Tracking</th>
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<tbody>
<tr>
<td>Process FMEA Content</td>
<td>Process Step/ Purpose</td>
<td>Defect</td>
<td>Impact of Defect On Product and Process</td>
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<td>SC</td>
<td>Thing Gone Wrong In Process To Cause FM</td>
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<td>Failure Cause (FC) Prevention Method</td>
<td>Failure Mode (FM) Detection Method</td>
<td>3</td>
<td>84</td>
<td>Changes to Process to Reduce Risk</td>
</tr>
</tbody>
</table>

- **Risk Element**: Objectionable Incident, Severity of Harm Description, Root Cause Definition, Risk Control Definition, Probability of Incident Due To Cause, Root Cause Priority, Risk Reduction Activity Tracking

- **Common Mistakes When Using Process FMEA**
  - Defect Impact on Product Incorrect or Missing
  - Non-Root Cause in Failure Cause Column
  - Risk Controls Too General
  - Use of RPN to Determine What to Work On
Risk-Based Thinking Implementation Example

- Where Risk Must Be Managed
- What is Risk Based PLM®
- Risk Based PLM® Is Not The Only Compliance Solution
- Core Tools Of Risk Based PLM® - RRA®, DFMEA, PFMEA, URA™ and PFMEA
Define Core Processes, Inputs and Outputs

“Define Customer Requirements” Process

- Objectionable Incident
  - Customer Requirements Are Not Optimized
- Potential Harm
  - Market Share
  - Redesign
  - Returns
  - Safety
- Potential Root Cause of Risk
  - Customer Requirement Not Specified Correctly
- Risk Management Tool
  - Requirements Risk Assessment® (RRA®)
  - Customer Requirements Design Review
Voice of Customer

Define Customer Rqmts

Define Design Rqmts

Define Design

Define Usage Controls

Define Process and Controls

Customer Rqmts Review

RRA® (Part 1)

Risk Ok?

No

Yes

Release Customer Requirements
“Define Design Requirements” Process

- Objectionable Incident
  - Customer Requirement Not Met
- Potential Harm
  - Market Share
  - Redesign
  - Returns
  - Safety
- Potential Root Cause of Risk
  - Design Requirement Not Specified Correctly
- Risk Management Tool
  - Requirements Risk Assessment® (RRA®)
  - Design Validation Plan
Risk Based PLM RRA® Part 2

1. Define Customer Rqmts
   - Customer Rqmts Review
     - Risk Ok? Yes: Release Customer Requirements
     - No: Design Validation Plan

2. Define Design Rqmts
   - Design Validation Plan
     - Risk Ok? Yes: Release Design Requirements
     - No: RRA® (Part 2)

3. Define Design
   - RRA® (Part 2)
     - Risk Ok? Yes: Release Design Requirements

4. Define Usage Controls

5. Define Process and Controls
“Design Product” Process – Risk Sources

- Objectionable Incident
  - Product Failure To Meet Design Requirement
- Potential Harm
  - Market Share
  - Redesign
  - Returns
  - Safety
  - Manufacturing Process Redesign
  - Manufacturing Scrap Loss
- Potential Root Cause of Risk:
  - Incorrect Hardware Design Specification
  - Incorrect Software Code
- Risk Management Tool
  - Design FMEA
  - Design Verification Plan
Risk Based PLM – Design FMEA and Design Verification Plan

Voice of Customer

1. Define Customer Rqmts
   - Customer Rqmts Review
     - Risk Ok?
       - No
         - Define Design Rqmts
           - Design FMEA
             - Risk Ok?
               - Yes
                 - Release Design
               - No
                 - Design Validation Plan
                   - Risk Ok?
                     - Yes
                       - Release Design Requirements
                     - No
                       - Define Design
                         - Design FMEA
                           - Risk Ok?
                             - Yes
                               - Release Design
                             - No
                               - Define Usage Controls
2. Define Design Rqmts
   - RRA® (Part 1)
     - Risk Ok?
       - Yes
         - Release Design Requirements
       - No
         - Define Design
           - Design FMEA
             - Risk Ok?
               - Yes
                 - Release Design
               - No
                 - Define Usage Controls
3. Define Design
   - Design Verification Plan
     - Risk Ok?
       - Yes
         - Release Design
       - No
         - Define Usage Controls
“Design Usage Instruction” Process

- Objectionable Incident
  - Product Failure To Meet Design Requirement
- Potential Harm
  - Product Damage
  - Reduced Product Life
  - Returns
  - Safety
- Potential Root Cause of Risk:
  - Incorrect Install and/or Usage Instructions
- Risk Management Tool
  - Usage Risk Assessment (URA™)
  - Usage Verification Plan
“Design Manufacturing Process” Process (Quality Emphasis)

- Objectionable Incident
  - Out of Specification Product Produced
- Potential Harm
  - Product Damage
  - Reduced Product Life
  - Scrap/Rework
  - Returns
  - Safety
- Potential Root Cause of Risk:
  - Out of Spec Purchased Item
  - Process Sources of Produced Product Variation
- Risk Management Tool
  - Process FMEA
# What Sources of Risk Must Be Worked On – Automotive Design

## Risk Matrix (Auto Industry Design Process)

<table>
<thead>
<tr>
<th>SEV/OCC</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
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</tr>
</tbody>
</table>

#### Class Symbols

- **CC**: Safety/Legal
- **SC**: Return/No Buy

Symbol is assigned based on SEV and Occ.
### What Sources of Risk Must Be Worked On – Medical Device

#### Severity Rating

<table>
<thead>
<tr>
<th>Severity Rating</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Death</td>
</tr>
<tr>
<td>4</td>
<td>Permanent Injury</td>
</tr>
<tr>
<td>3</td>
<td>Injury Requires Medical Attention</td>
</tr>
<tr>
<td>2</td>
<td>Injury Does Not Require Medical Attention</td>
</tr>
<tr>
<td>1</td>
<td>Inconvenience or Temporary Discomfort</td>
</tr>
</tbody>
</table>

#### Occurrence Rating

<table>
<thead>
<tr>
<th>Occurrence Rating</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Likely to happen, often, frequent.</td>
</tr>
<tr>
<td>4</td>
<td>Can happen but not frequently.</td>
</tr>
<tr>
<td>3</td>
<td>Unlikely to happen, rare, remote.</td>
</tr>
<tr>
<td>2</td>
<td>Likely to happen, often, frequent.</td>
</tr>
<tr>
<td>1</td>
<td>Can happen but not frequently.</td>
</tr>
<tr>
<td>SEV/OCC</td>
<td>Unlikely to happen, rare, remote.</td>
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</tbody>
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#### Risk Symbol

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<th>Risk Symbol</th>
<th>Effect</th>
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<tr>
<td>D</td>
<td>Death</td>
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<tr>
<td>II</td>
<td>Permanent Injury</td>
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<tr>
<td>RIMA</td>
<td>Injury Requires Medical Attention</td>
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<tr>
<td>RI</td>
<td>Injury Does Not Require Medical Attention</td>
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<tr>
<td>NI</td>
<td>Inconvenience or Temporary Discomfort</td>
</tr>
</tbody>
</table>

#### Risk Matrix - Medical Industry

```
  5   D   D
  4   II  II
  3   RIMA RIMA
  2   RI  
  1   NI  
SEV/OCC 1  2  3
```
What Is Acceptable Risk – Automotive Design Risk Policy

- Areas of acceptability in Risk Table for release of Design and Manufacturing Processes (aka Risk Policy).
- Different products can use same Risk Matrix but have different Risk Policies.

<table>
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<tr>
<th>SEV/OCC</th>
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* = Do Not Release
### What Is Acceptable Risk – Medical Device Risk Policy

#### Severity Rating vs. Effect

<table>
<thead>
<tr>
<th>Severity Rating</th>
<th>Effect</th>
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<tr>
<td>5</td>
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<tr>
<td>1</td>
<td>Inconvenience or Temporary Discomfort</td>
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</tbody>
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#### Occurrence Rating vs. Effect

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#### Risk Symbol vs. Effect

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<th>Risk Symbol</th>
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<td>D</td>
<td>Death</td>
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<tr>
<td>II</td>
<td>Permanent Injury</td>
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<tr>
<td>RIMA</td>
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**Risk Policy (\* = Do Not Release)**

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**Late Stage Cancer Treatment**

**Spinal Implant**
Plan-Do-Check-Act Without Risk-Based-Thinking

- **Plan**: Define what the organization wants to accomplish and how the organization is going to accomplish it.
- **Do**: Implement Plan.
- **Check**: Measure results of implementation the plan.
- **Act**: If desired results are not achieved, modify plan.
Plan-Do-Check-Act With Risk-Based-Thinking

- **Plan**: Define what the organization wants to accomplish and how the organization is going to accomplish it. Assess risk of plan.
- **Do**: If risk acceptable, implement Plan.
- **Check**: Measure results of implementation the plan.
- **Act**: If desired results are not achieved, modify plan. Assess risk of plan modification. If risk acceptable, implement plan modification.
Questions?

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Email: Richard.harpster@harpcosystems.com