Case for Quality
Company C

Risk Management
Topics

• Overview of the Risk Management Process and Activities

• Risk Analysis Architecture : Pre-Market Activity
  • Process to systematically analyze and control risk
  • Risk Analysis (Hazard Analysis)
  • Cross functional interaction and timing during Product development

• Post market Risk Management Overview

• Issue Impact Assessment (HHA) - A Post Market Activity
Product risk management

Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk

Process governed by ISO 14971- “Application of Risk Management to Medical Devices Risk Management Process

PROCESS MAP IN EVERY PROCEDURE
Closed loop Risk management activities/process

Pre-Market
- Risk controls driving product requirements
  - Risk Management Plan and Report
    - Compare and update
      - Product Issues (Field)

Post-Market
- Feedback learning
  - Risk assessment (HHA)
    - Post-Market Surveillance
      - NCRs
        - Lifetest results
        - Service Records
        - Literature Review
        - Clinical Trials
    - CAPA decisions
    - PHO, FCA,
Performing Risk Analysis during development

Risk Analysis must identify **known and foreseeable hazards** in both normal and fault conditions. It requires more than Failure Mode Effects Analysis (FMEA)

- Standardized list of Hazards and Harms
- Sources of Hazards/initiating events and their likelihood of occurrence.
  - *Ex: Design/process FMEAs, Use-error, cyber security analysis*
- Risk matrix to categorize/classify the Risk

**Requirements from ISO 14971**

- **Intended use of the medical product**
- **Product characteristics impacting safety**
- **Known/Observe d/Reported Risks** (ex: CAPA, field complaints etc.)
- **Foreseeable/ Potential risks**
- **Use conditions/use-error but medical device functions normally “Normal condition”**
- **Failure of product design-process “Fault Condition”**
Risk Analysis Architecture is a pre-market process to develop a structured risk analysis approach considering risks from design, use conditions and manufacturing

- Comprehensive risk analysis - Avoids Silos
- Prevents inconsistent estimation of patient harms by ensuring only qualified personnel assess patient harm
- Traceability between different analysis and to product requirements
- Enforces common understanding & ownership at the various levels of risk analysis
- Enforces the need to understand system interactions that impacts risk
- Assists post market risk analysis comparison
- 1 Stop shop to demonstrate compliance

Risk Analysis Architecture Process Steps

1. Plan Risk Analysis Architecture
2. Assess Hazard Sources
3. Perform Product Risk Analysis
Risk analysis architecture process

Risk analysis architecture requirements - Requires more than a FMEA
(FMEA as it is not the Product Risk Analysis but an input to the risk analysis)

- Inputs to Product Risk Analysis (Hazard Sources/Initiating Events)
  - System Safety Characterization
  - Product Design Failure Analysis
  - Use-Error Analysis
  - Product Security Analysis

- Product Process Failure Analysis

Next level /safety hazard from Hazard Source = Hazard in Hazard analysis
A tongue depressor is a simple device that allows a clinician to hold a patient’s tongue in place to visualize the throat. A tongue depressor needs to be able to perform that function without harming the patient. A shipping/handling issue was identified that could damage the curved edges of the depressor.

**Hazard sources/Initiating event:**
Shipping/handling issue damages tongue depressor

**Hazard:**
Sharp edge on tongue depressor

**Hazardous Situation:**
Use of a tongue depressor with a sharp edge by a physician on a patient

**Harm:**
Cut on patient’s tongue

**Severity of the Harm:**
Minor: Temporary injury or impairment

**Probability of Occurrence of the harm:**
\[ P1 \times P2 \]

**Risk:**

**P1:** Probability of a physician using the sharp edge on a patient considering the probabilities of:
- Shipping/Handling issue
- Physician not noticing the sharp edge before using it on the patient

**P2:** Probability of a sharp edge cutting a patient’s tongue
**Risk Management**

Risk Or Hazard analysis form for comprehensive coverage of risks and controls

Risk Analysis considering Normal/Fault; Known/ Foreseeable per ISO 14971

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Known or Foreseeable</th>
<th>Operational Lifecycle Phase</th>
<th>Hazard Source(s)</th>
<th>Normal or Fault Condition</th>
<th>Sequence(s) of events</th>
<th>Hazardous Situation</th>
<th>Harm (Effects)</th>
<th>Risk Estimation</th>
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Risk Control Selection and Traceability to product Requirements/Validation

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Risk Management

Risk Controls and Product Requirements

Role: Reduces/eliminates risks using all the 3 Risk Control options in the priority order listed below and traces to product requirements

1. Safety by Design and Construction
   Ex: Designing for inherent safety by
   - eliminating hazard OR
   - reducing the probability of occurrence of the harm

2. Protective Measure
   Ex: Adding protective measures by using visual or acoustic alarms to alert the operator to hazardous conditions.

3. Information for Safety
   Ex: Providing information for safety by:
   - placing warnings in the labelling of the medical device

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“6.2 of ISO 14971 obliges the manufacturer to "use one or more of the following risk control options in the priority order listed: (a) inherent safety by design; (b) protective measures in the medical device itself or in the manufacturing process; (c) information for safety"”
Risk Management during Product Development

A cross functional activity

Cross functional responsibilities are defined in the Risk Management Plan

Roles

- Product Development
- Personnel with Clinical knowledge
- Human Factors; Cyber Security risk Eng.
- Reliability Eng.
- Manufacturing Eng.

Product Risk or Hazard Analysis

- Intended use and Systems safety characteristics
- Risk Controls Selection
- Risk Control Implementation Verification
- Risk Control Verification of effectiveness

Use-Error Analysis; Security Risks

Device/System fault analysis/FMEA

Medical device Process FMEA

Design Input Phase

Design Output Phase

Process Validation Phase

Design Verification & Validation Phase
Post market Risk Management
**PRODUCTION AND POST PRODUCTION**

- Assessment of Production and Post-Production Information for new hazards or increased risks from existing hazards
- Evaluation of any new or increased risks
- Control of any new or increased risks not deemed acceptable
- Evaluation of overall residual risk
- Update of Risk Management documentation
Product Impact Assessment (PIA/HHA) form

- Primary tool used to assess the risk of issues impacting product in the field
  - Analyzes and Evaluates the risk of the issue
    - Uses ISO 14971 flow for assessing risks to allow comparison against pre-mkt.
  - Recommends whether additional actions or controls are needed, including field corrective actions
    - Based on benefit-risk analysis
    - Cross-functional approval including clinical expertise
- Determines whether additional updates to risk management files are needed
Important aspects of assessing field issues (HHA)

**Identifying population/sub populations**

- Total number of Impacted Devices:
  - Are any subpopulations of devices at higher risk?
    - Yes, Subpopulations:
    - No
  - Rationale:
  - Predicted rate of occurrence of this issue and number of occurrences

**Drives actions to mitigate risk in field based on benefit-risk analysis**

- Initiate Actions to Manage issue/mitigate risk in the field?
  - Yes
  - No, Rationale:

**Setting a threshold to revisit using complaint monitoring process**

- HIA Reassess Threshold

**Risk Analysis consistent with ISO 14971/pre-market**

- Section 2.1: HHA Section: Hazard / Harm / Other Factors
  - Hazard and Hazardous situation:
  - Harm(s):
  - Exacerbating Factors:
  - Mitigating Factors:
  - Severity of Harm:
  - Occurrence of Harm:

**Closing the loop-updating Risk mgmt. files**

- Update of Risk Management Files (if applicable) recommended?
  - System that will contain evidence of completion: