Case for Quality
Company A

Risk Management

AdvaMed
Advanced Medical Technology Association

Purpose and Benefits of Risk Management

- Risk Management Program
  - establishes a process to **identify** risk, **evaluate** risk, and **reduce risk** to an acceptable level

- Risk Management is performed:
  - to ensure our products and processes are **safe** and **effective**
  - throughout the **entire** product lifecycle
  - with consideration of product **use**, **design** and **manufacturing**

- Risk Management is an integral part of the Quality System:
  - Non-Conformances
  - CAPA
  - Complaints
  - MDRs
  - Recalls

Regulatory Requirements for Risk Management

USA – Food and Drug Administration (FDA):

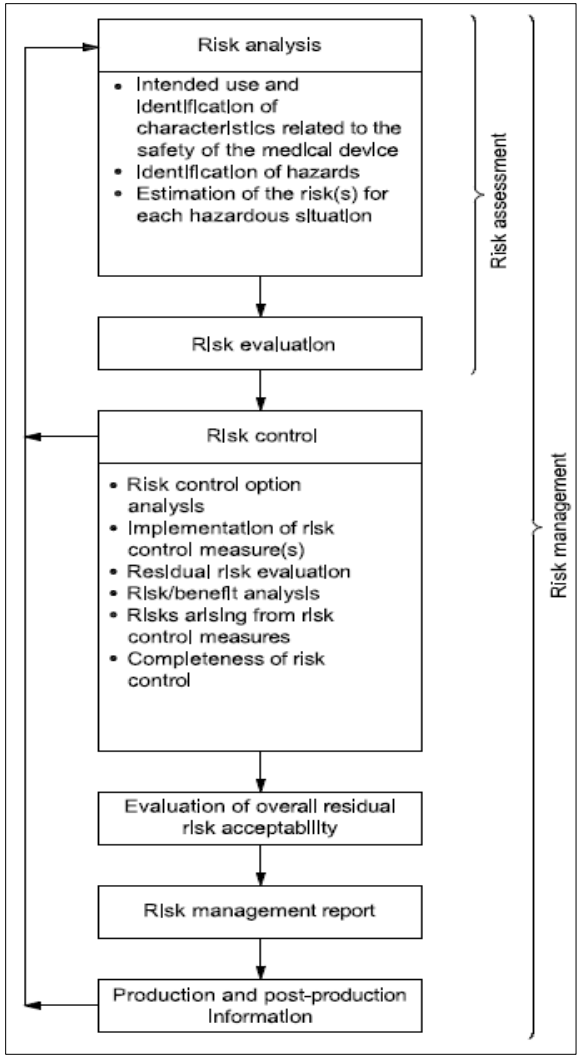
- 21 CFR 820 Preamble
- 21 CFR 820.30(g) Design Validation:
  - **European Union – Medical Device Directive (98/79/EC):**
- "Risk" referred to in 24 separate essential requirements.

EN ISO International Standard 13485:2012 – Medical Devices - Quality Management Systems:

- Section 7.1:
  - The organization shall establish documented requirements for risk management throughout product realization. See ISO 14971 for guidance related to risk management.
- Section 7.3.2:
  - Inputs relating to product requirements shall be determined. These inputs shall include output(s) of risk management.

Risk Management

Risk Management Process (14971)



Preliminary Hazard Analysis- Identify Hazards

- Potential hazards which may occur during normal use, foreseeable misuse, installation and disposal of the product are considered taking into account the intended use
  - Based on EN ISO 14971:2012, Annexes C & E

Template :

Identification of Product Characteristics Related to Safety:

System Component	Product Characteristic Question	Yes	No	Guidance for Further Consideration	Comments

Preliminary Hazard Analysis – List of Hazards, Annex E

Hazard Category	Hazard	Hazard ID	Comments/Examples/Helper Text	Does this hazard apply to the product?
Physical (P)	Line Voltage			
	ElectroMagnetic Interference			
	Laser Energy in Excess of Class I			
	Radio Frequency Radiation			
	Stored Eletrical Energy			
	High Temperature			
	Low Temperature			
	Uncontrolled airborn particles			
	Fire			
	Falling Mass			
	Suspended Mass			
	Vibration			
	Stored Mechanical Energy			
	Moving Parts			
	Sharp Edges			
	Ultrasonic Energy			

Risk Analysis: Relationship between Hazard, Hazardous Situation and Harm

- Example 1
  - Hazard is electricity
  - Hazardous situation is frayed wire, short circuit
  - Harm is electric shock causing second degree burns

- Example 2
  - Hazard is cross contamination
  - Hazardous situation is reusing pipet for multiple samples
  - Harm is false result (false positive/false negative) that causes misdiagnosing patient leading to no treatment and early death

Risk Analysis

- **Risk Analysis** involves the evaluation of risk on two dimensions:
  - Severity of the harm should the harm actually occur
  - The probability of the harm occurring

Risk= Severity x Occurrence

- **Severity** ratings are related to harms
- The severity of a harm cannot be affected by a risk mitigation
- experience provided from post-launch surveillance activities

Occurrence ratings are related to the probability of a harm occurring
The probability of occurrence of a hazard can be affected by a risk mitigation
Occurrence ratings should be updated based on device field

See: 61 Fed. Reg. 52620, Oct. 7, 1996

Risk Assessment: Determine Risk Controls

Risk Controls are developed in the following priority	Example for Sharp edge hazard
1st Inherently safe design and construction	Design out sharp edge
2nd Protective measures	Provide physical shield from sharp edge
3rd Information for safety	Warning label for sharp edge

- All possible risk controls must be employed (per EN ISO 14971:2012)

Risk Assessment: Implement and Verify Risk Controls

- Risk controls focus on:
  - Elimination of the hazard
  - Prevention or detection of the events leading to the hazardous situation
- All risk controls are themselves assessed for risk
- All risk controls have traceable evidence documented for:
  - Implementation
  - Verification of effectiveness (design V&V, process validation, engineering studies)

Residual Risk Evaluation

- The probability of occurrence of harm is **re-estimated** for each failure mode/fault after risk controls are **implemented**
  - Consider effectiveness of the implemented risk controls
  - Consider available information (design V&V studies, process validation, engineering studies)

Risk Management Report

- **Upon completion of activities, a Risk Management Report (RMR) is created to show that:**
  - **The Risk Management Plan was appropriately implemented**
  - **The Overall Residual Risk is acceptable**
    - **The cumulative residual risk for all failure modes/faults is determined, including "Acceptable" risks**
    - **A Risk/Benefit Analysis is documented based on the cumulative residual risk and overall benefit of the product**
    - **Disclosure requirements for residual risk are defined**
  - **Appropriate methods are in place to obtain relevant production and post-production information**

Active Risk Monitoring

- Production and post-production monitoring of risk is required for the lifetime of the product
- A product's Risk Management File is a living assessment of risk
- Risks are re-assessed for product/process changes, non-conformances, CAPA, field issues
- RMFs updated if:
  - New or unrecognized hazards or failure modes/faults/events are identified
  - Severity or occurrence estimates have changed