



# **RISK MANAGEMENT INDUSTRY PERSPECTIVE**

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# Risk Management

Design Control

Production

Purchasing Controls

Service/Install

Complaints/MDR

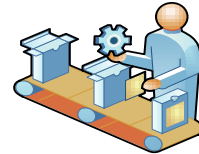
CAPA

Management Controls

Risk Management activities are integrated throughout the Quality System

# DYNAMICS OF RISK MANAGEMENT...

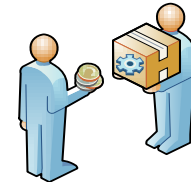
## WHERE ARE RISK DECISIONS BEING MADE?



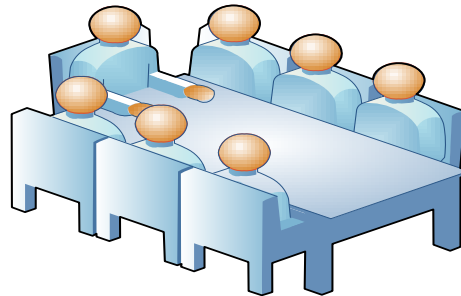
Production/Mfg



Design & Development



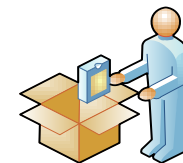
Purchasing



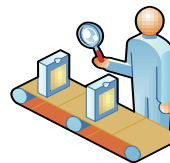
Management Controls



Post Market Monitoring



Service/Install



Quality Control

Risk –based decisions are made throughout the lifecycle of the product

# RISK MANAGEMENT AREAS OF FOCUS

- Must ensure the terminology is used consistently across the quality system...
- Must use consistent processes (incl. people and tools) when assessing risk...
- Must ensure that that risk criteria and risk acceptability is agreed upon across all functions...
- Risk activities must be used throughout the lifecycle...

# RISK MANAGEMENT TERMS

## Key definitions (per ISO14971)

- Hazard – potential source of harm
- Hazardous Situation – circumstances in which people, property or the environment are exposed to one or more hazards
- Harm – physical injury or damage to the health of people, or damage to property or the environment
- Risk Analysis – systematic use of available information to identify hazards and to estimate the risk
- Risk Evaluation – process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk
- Risk Assessment – overall process comprising a risk analysis and risk evaluation

# RISK MANAGEMENT RELATIONSHIPS

**Table E.3 — Relationship between hazards, foreseeable sequences of events, hazardous situations, and the harm that can occur**

Hazard	Foreseeable sequence of events	Hazardous situation	Harm
Electromagnetic energy (Line voltage)	(1) Electrode cable unintentionally plugged into power line receptacle	Line voltage appears on electrodes	Serious burns Heart fibrillation Death
Chemical (Volatile solvent)	(1) Incomplete cleaning of volatile solvent used in manufacturing (2) Solvent residue converts to gas at body temperature	Development of gas bubbles in the blood stream during dialysis	Gas embolisms Brain damage Death
Biological (Microbial contamination)	(1) Inadequate instructions provided for decontaminating re-used anesthesia tubing (2) Contaminated tubing used during anesthesia	Bacteria released into airway of patient during anesthesia	Bacterial infection Death
Electromagnetic energy (ESD)	(1) Electrostatically charged patient touches infusion pump (2) ESD causes pump and pump alarms to fail (3) Insulin not delivered to patient	Failure to deliver insulin unknown to patient with elevated blood glucose level	Minor organ damage Decreased consciousness Coma, death
Function (No output)	(1) Implantable defibrillator battery reaches the end of its useful life (2) Inappropriately long interval between clinical follow-up visits	Device cannot deliver defibrillation shock when an arrhythmia occurs	Death

# Risk Management

Design Control

Production

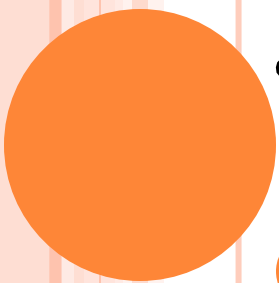
Purchasing Controls

Service/Install

Complaints/MDDI

CAPA

Management Controls



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# RISK MANAGEMENT IN CAPA

- How to use Risk Management in CAPA?
  - Monitor your “listening systems” for issues...
  - Establish trend triggers based on Risk File...
  - Not all issues are equal, so establish a risk-based approach...
  - Level of investigation should be commensurate with the risk...
  - Use your risk files to determine if immediate corrections are warranted...



# RISK MANAGEMENT IN COMPLAINTS

- How to use Risk Management in Complaint process?
  - Establish trend triggers based on Risk File...
  - Evaluate complaint to determine if issue exists...
  - Investigate complaint commensurate with risk...
  - Establish a process to assess MDR reportability based on your risk file...
  - Continually review/update your Risk File based on the information received from complaints

# SAMPLE CASE STUDY

A 10% increase in the number of complaints received for a “bursting” (rupturing) balloon on a catheter...  
The ruptures led to medical intervention by the clinicians...

What do you need to know?

What questions should you ask?

# SAMPLE CASE STUDY



- ❑ Is this a new or unknown hazard?
- ❑ What is the severity of this issue? Has it changed?
- ❑ Is the 10% increase within the estimated rate?
- ❑ Has the issue been confirmed?
- ❑ What immediate actions are needed?
- ❑ What failure mode can lead to this issue?

- ❑ Were there new failure modes which could have contributed to the issue?
- ❑ What did my trend analysis show me?
- ❑ Is this a systemic or lot specific issue?
- ❑ Were there any changes made?
- ❑ Why am I seeing this now?

# WHAT DOES “GOOD” LOOK LIKE?

- Use of consistent terminology/definitions
- Use of consistent risk methodologies and tools
- Use of an agreed upon/consistent level of risk acceptability
- Ensure the proper functions are engaged in the risk activities...including management
- Continuously update risk management files as more data is gathered from your data sources

# Questions?

