Medical Device – Risk Management

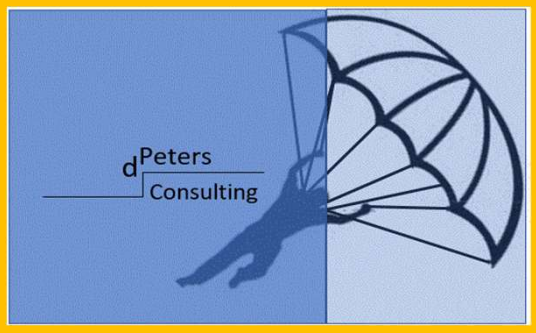
<*Brief*>

Safety:

Freedom from *un-intentional* harms

Security:

Freedom from *intentional* harms

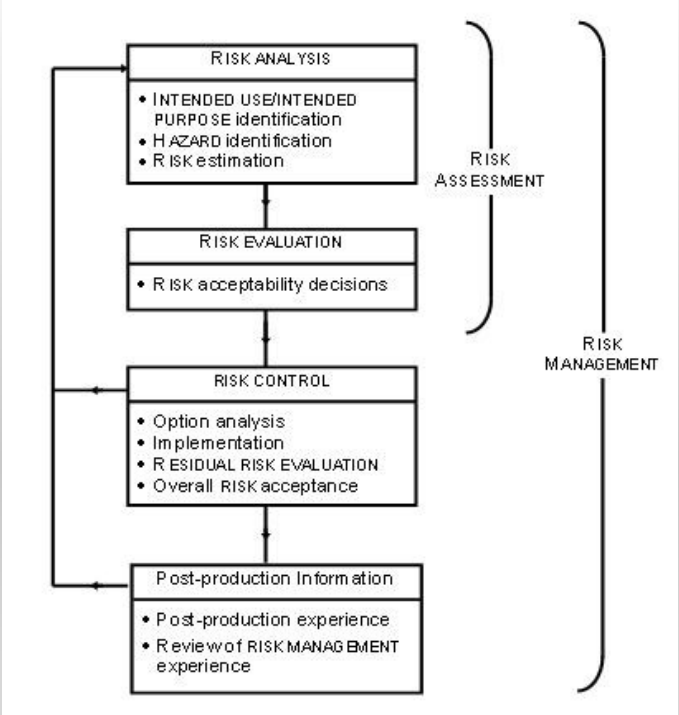


Risk Management

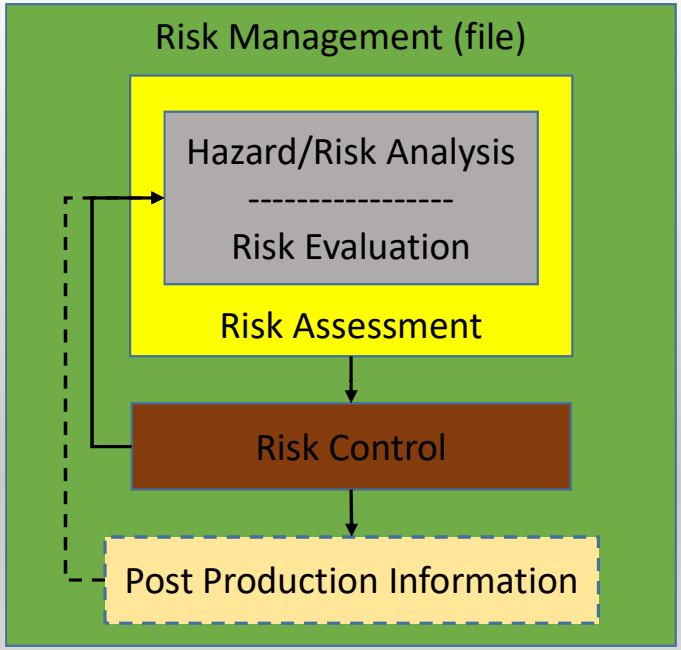
- Safety:
  - Freedom from *un-intentional* harms
- Security:
  - Freedom from *intentional* harms

ISO 14971 – Risk Management

Figure Used in ISO 14971

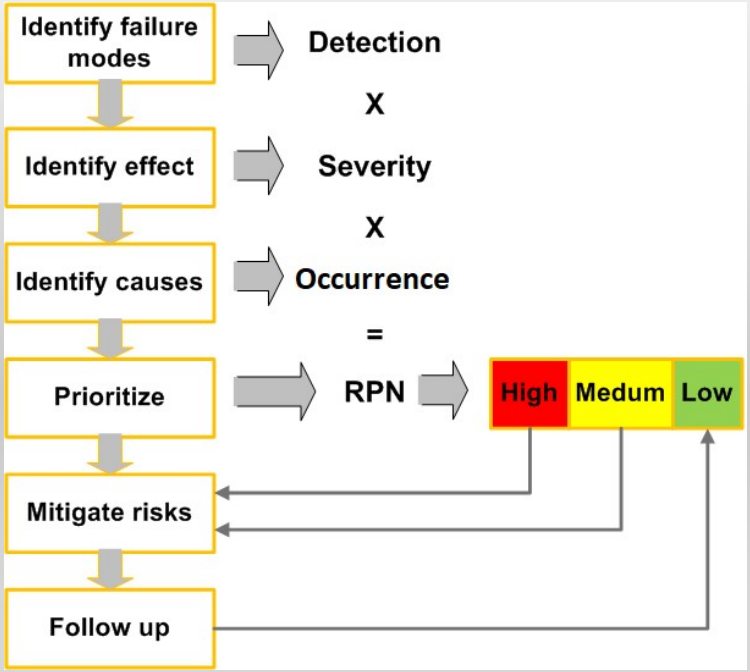


Simplified Illustration

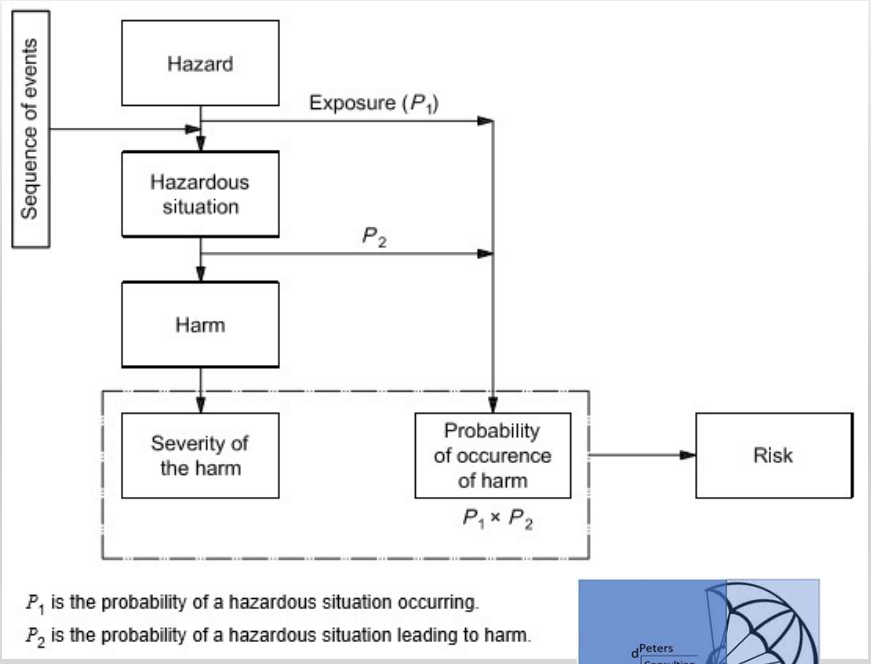


These are NOT the same procedural steps

FMEA Risk Analysis Process Steps



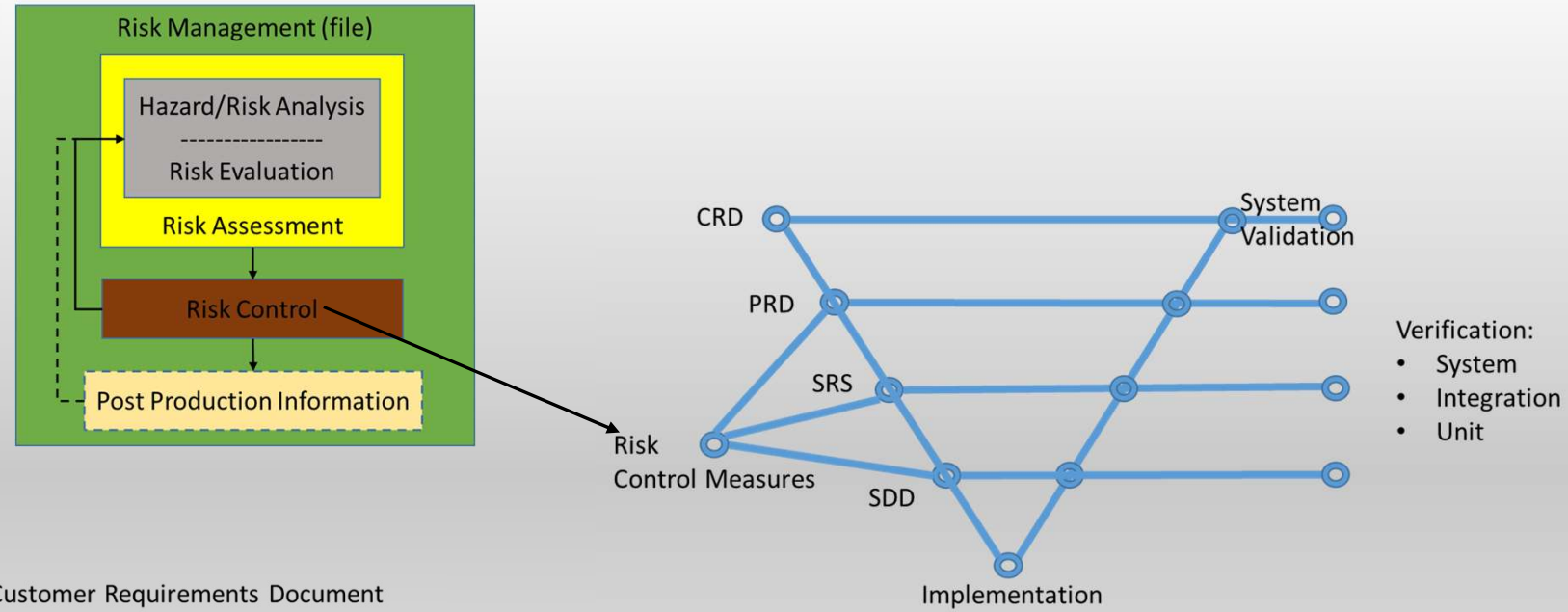
ISO 14971 Risk Analysis Process Steps



This is a Hazard (Threat)

This is a Hazardous Situation (Threat Event)

Risk Controls Must Be Traceable & Verified



CRD: Customer Requirements Document
PRD: Product Requirements Document
SRS: Software Requirements Specification
SDD: Software Design Document

U.S. FDA Medical Device Quality System Regulation:

- *Code of Federal Regulations* (CFR), Title 21, Part 820, Quality System Regulation

FDA Guidance:

- *General principles of software validation; Final guidance for industry and FDA staff,* 2002
- *Guidance for the content of premarket submissions for software contained in medical devices,* 2005
- *Guidance for industry, FDA reviewers and compliance on off-the-shelf software use in medical devices,* 1999
- *Guidance for industry and FDA premarket and design control reviewers: Medical device use-safety: Incorporating human factors engineering into risk management,* 2000
- *Applying human factors and usability engineering to optimize medical device design,* draft 2011
- *Design Control Guidance for Medical Device Manufacturers*, 1997

Industry Standards:

- IEC 62304 *Medical device software – Software lifecycle processes*
- ISO 14971 *Medical devices – Application of risk management to medical devices*
- ISO 13485 *Quality management systems – Requirements for regulatory purposes*

Technical Reports:

- IEC/TR 80001 *Application of risk management for IT-networks incorporating medical devices*
- IEC/TR 80002 *Guidance on the application of ISO 14971 to medical device software*