Risk Management in the Quality System Regulation

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Introduction

- Risk Management Requirements
  - ISO 13485
  - ISO 14971
  - Quality System Regulation (21 CFR 820)
- Risk Based Decisions
  - Quality System Regulation
  - Preamble

Introduction

- Similarities between ISO and FDA Risk Management Requirements
- Evaluation of Risk Management Systems in a Quality System/GMP Inspection
- Summary

Risk Management Requirements: ISO 13485

- 7.1 Planning of Product Realization

  The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained.

  Note 3 See ISO 14971 for guidance related to risk management.

Risk Management Requirements: ISO 14971

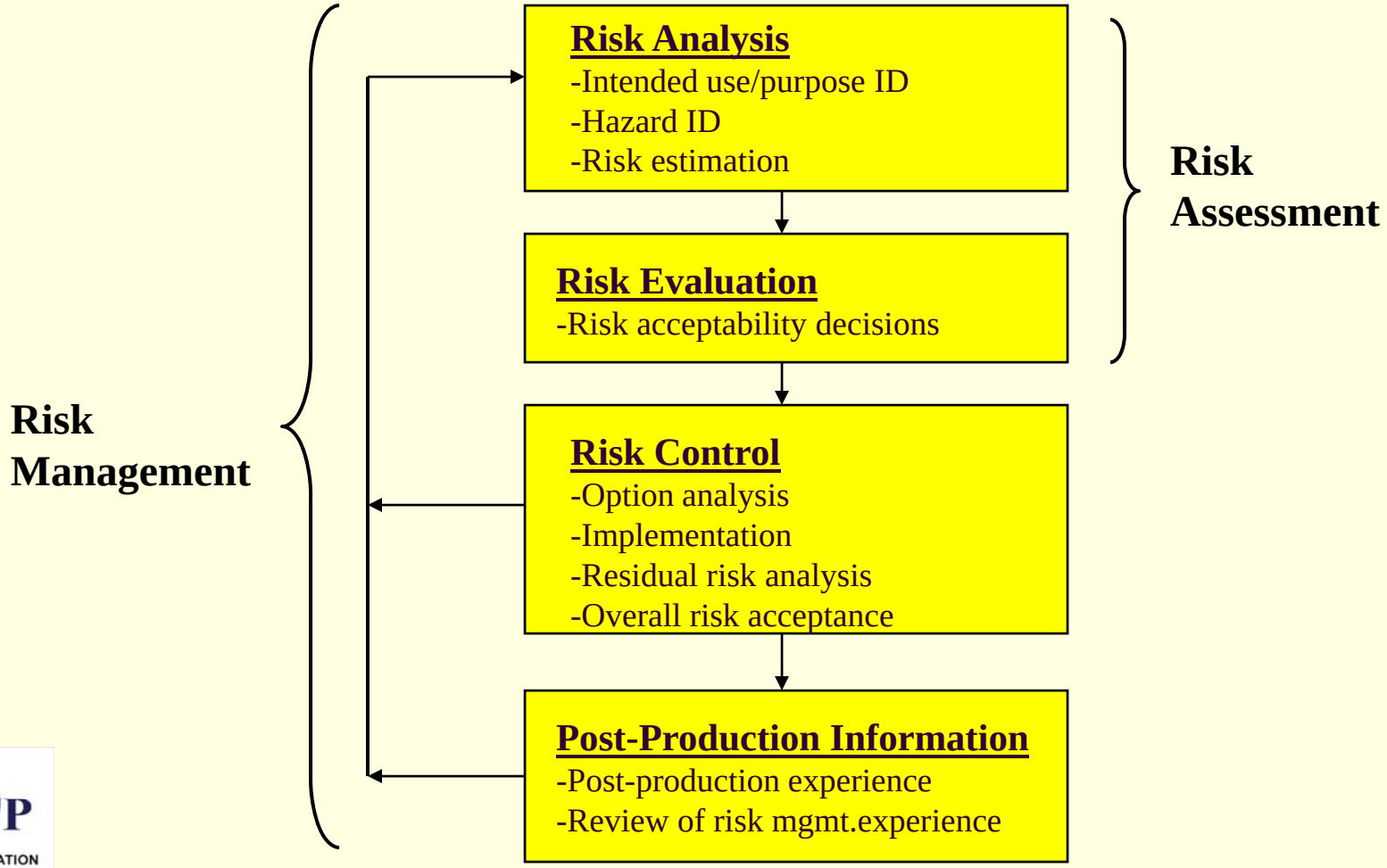
1 Scope

This International Standard specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.

The requirements of this International Standard are applicable to all stages of the life-cycle of a medical device. …

This International Standard does not require that the manufacturer have a quality management system in place. However, risk management can be an integral part of a quality management system.

Risk Management Process: ISO 14971



Risk Management Requirements: Quality System Regulation

- 21 CFR 820.30(g) Design Validation

*… The results of design validation shall include software validation and **risk analysis** …*

- Risk Based Decisions to Implement Quality System Requirements
  - Preamble comments

Risk Management Requirements: Quality System Regulation

Risk Analysis includes:

- Identification of possible hazards
  including use error
- Risk Calculate
  normal and fault conditions
- Risk Acceptability Determination
- Risk Reduced to Acceptable Level
- Evaluation of changes for introduction of new hazards

Preamble Comment 83

Risk Management Requirements: Quality System Regulation

- Risk Based Decisions in the QS Regulation Preamble
  - 820.1 Scope
  - 820.30 Design Controls
  - 820.50 Purchasing Controls
  - 820.65 Traceability
  - 820.70 Production and Process Control
  - 820.90 Non Conforming Product
  - 820.100 CAPA
  - 820.200 Servicing

Risk Management Requirements: Quality System Regulation

- 820.30(i) Design Changes

… Manufacturers must also conduct such tests when they make changes in the device … The extent of testing conducted should be governed by the risk(s) the device will present if it fails …

Preamble Comment 81

Risk Management Requirements: Quality System Regulation

- 820.50 Purchasing Controls

…. the need for specifications should be based on the criticality of and risk associated with the use of the specific manufacturing material.

Preamble Comment 115

Risk Management Requirements: Quality System Regulation

- 820.50 Purchasing Controls (Continued)

  …. The extent of the specification detail necessary to ensure that the product or service purchased meets requirements will be related to the nature of the product or service purchased, taking into account the effect the product or service may have on the safety or effectiveness of the finished device …

Risk Management Requirements: Quality System Regulation

- 820.90 Non Conforming Product

  The requirement in this section … requires that nonconforming product discovered before or after distribution be investigated to the degree commensurate with the significance and risk of the nonconformity.

  Preamble Comment 161

Risk Management Requirements: Quality System Regulation

- 820.100 Corrective and Preventative Action

… FDA agrees that the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered …

Preamble Comment 159

820.100 CAPA Continued

- 820.100 CAPA (Continued)

  … FDA does expect the manufacturer to develop procedures for assessing the risk, the actions that need to be taken for different levels of risk, and how to correct or prevent the problem from recurring, depending on that risk assessment …

Risk Management Requirements: FDA vs. ISO

- FDA & ISO Quality Management System Requirements
  - Require risk management activities
  - Point towards ISO 14971's process
  - Do not mandate ISO 14971

Risk Management Requirements: FDA vs. ISO

- FDA Risk Analysis vs ISO 14971 Risk Management
  - Intentional Similarities in objectives and process
  - Terminology Differences
    - FDA Preamble: risk in terms of patient & user
    - ISO 14971: risk applies to people, property & environment
  - FDA Risk Analysis ≈ ISO Risk Analysis + ISO Risk Evaluation + ISO Risk Control
  - Feedback Loops
    - FDA – CAPA
    - ISO 14971 – Clause 9 Production & Post Production

Evaluation of Risk Management During an FDA Inspection

Design Controls

- Procedures document a repeatable, well defined risk analysis process
- Risk Analysis procedure has been implemented
- Design Output Requirements
- Design Validation
- Links to other subsystems

Evaluation of Risk Management During an FDA Inspection

Production & Process Controls

- Review methods for controlling & monitoring the process

Purchasing Controls

- Ensure the role of risk to the patient/user is documented in procedures for evaluation and control of suppliers, and procedures are implemented
- Ensure there are links to other subsystems

Evaluation of Risk Management During an FDA Inspection

Corrective and Preventive Action

- Ensure procedure(s) document how risk to the patient/user is used to:
  - Prioritize CAPA items
  - Determine the degree to which a CAPA item is investigated
  - Determine depth of root cause investigation
  - Determine the verification and validation activities
- Ensure procedures are fully implemented
- Ensure there are links to other subsystems

Summary

- FDA Quality Management System
  - Risk management* in Design Controls
  - Risk based decision in the rest of the Quality System
- ISO 13485 Quality Management System
  - Risk management in Product Realization
- ISO 14971
  - Applies to all aspects of device lifecycle
  - Effective for meeting FDA and ISO Quality Management System Requirements