Risk Management & the Total Product Life Cycle (TPLC)

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June 23, 2021
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Objectives

1. Applicable Regulations, Standards, & Guidance Documents
2. The Important of Risk Management
3. Key Risk Management Terms & Definitions
4. Risk Management Process
Applicable Regulations, Standards, & Guidance Documents

- 21 CFR 820, Quality System Regulations
- ISO 13485:2016, Medical devices – quality management systems
- ISO 14971:2019, Medical devices – Application of risk management to medical devices
- *Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions*
Applicable Regulations, Standards, & Guidance Documents

• Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications
• Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics
• Factors to Consider When Making Benefit-Risk Determinations for Medical Device Investigational Device Exemptions
• Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions
Why should I conduct risk management activities?
The Importance of Risk Management

- Regulatory Requirement
- Required for Regulatory Submissions
- Good Business Practice & Cost Efficiency
- Safety
Key Risk Management Terms:

- **Risk**
  - The combination of the probability of occurrence of harm and the severity of that harm

- **Benefit**
  - Positive impact or desirable outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health

- **Harm**
  - Injury or damage to the health of people, or damage to property or the environment

- **Hazard**
  - Potential source of harm
Hazard

Probability of a hazardous situation occurring ($P_1$)

Sequence of events

Circumstances affecting severity

Hazardous situation

Probability of a hazardous situation leading to harm ($P_2$)

Circumstances affecting severity

Probability of occurrence of harm ($P = P_1 \times P_2$)

Risk

Harm

Severity of harm

Source: ISO 14971:2019 Annex C
Key Risk Management Terms:

• 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 a risk evaluation

• Risk Management
  – Systemic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk

• Life Cycle (TPLC)
  – Series of all phases in the life of a medical device, from the initial conception to final decommissioning and disposal.
Risk Management

Implementing a Process & Plan
Risk analysis
- Intended use and reasonably foreseeable misuse
- Identification of characteristics related to safety
- Identification of hazards and hazardous situations
- Risk estimation

Risk evaluation

Risk control
- Risk control option analysis
- Implementation of risk control measures
- Residual risk evaluation
- Benefit-risk analysis
- Risks arising from risk control measures
- Completeness of risk control

Evaluation of overall residual risk

Risk management review

Production and post-production activities
- General
- Information collection
- Information review
- Actions

Source: ISO 14971:2019
Risk Analysis

• Intended use & reasonably foreseeable misuse
• Identification of characteristics related to safety
• Identification of hazards and hazardous situations
• Risk Estimation
Risk Evaluation
Risk Control

• Risk control option analysis
• Implementation of risk control measures
• Residual risk evaluation
• Benefit-risk analysis
• Risks arising from risk control measures
• Completeness of risk control
Evaluation of Overall Residual Risk
Risk Management Review
Production and Post-Production Activities
A.2.10 Production and post-production activities

It cannot be emphasized too often that risk management does not stop when a medical device goes into production. Risk management often begins with an idea, before there is any physical manifestation of the medical device. Manufacturers collect information from many sources, including experience with similar medical devices and technologies. Risk estimation is refined throughout the design process and can be made more accurate when a functioning prototype is built. However, no amount of modelling can substitute for an actual medical device in the hands of actual users.

Source: ISO 14971:2019 Annex A
Production and Post-Production Activities

• General
• Information Collection
• Information Review
• Actions
Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 27, 2016.

The draft of this document was issued on June 16, 2016

For questions about this document regarding CDRH-regulated devices, contact the Office of Compliance at 301-796-5900.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Summary

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• The Important of Risk Management
• Key Risk Management Terms & Definitions
• Risk Management Process
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Questions?