1. Purpose

The purpose of this SOP is to define the process for risk management in the development and lifecycle of infusion pumps, ensuring compliance with FDA 21 CFR 820 and ISO 14971. This SOP aims to systematically identify, evaluate, control, and monitor risks associated with infusion pumps throughout their lifecycle.

2. Scope

This SOP applies to all design and development activities, manufacturing processes, and post-market surveillance of infusion pumps at ABC Medical.

3. Responsibilities

3.1 Risk Management Team

- Oversee the entire risk management process.
- Conduct risk assessments.
- Ensure compliance with relevant regulations and standards (e.g., FDA 21 CFR 820, ISO 14971).
- Maintain the Risk Management File (RMF).

3.2 Project Manager

- Coordinate risk management activities within project timelines.
- Ensure integration of risk management with the design and development process.
- Facilitate communication between different teams involved in risk management.

3.3 R&D Team

- Identify potential risks associated with design and development activities.
- Participate in brainstorming sessions to identify hazards.
- Provide technical input for risk analysis and control measures.

3.4 QA Team

- Responsibilities:
- Ensure that risk management activities align with quality assurance processes.
- Validate the completeness and accuracy of risk analysis and evaluations.
- Monitor the effectiveness of risk control measures.

3.5 Regulatory Affairs

- Ensure adherence to applicable regulations regarding risk management.
- Keep the risk management process updated with any changes in regulatory requirements.

- Assist in the documentation and reporting of risk management activities.

3.6 Cross-Functional Teams

- Participate in risk identification and analysis sessions.
- Provide input from various perspectives (e.g., design, manufacturing, user experience).
- Collaborate to develop and implement effective risk control measures.

3.7 Definitions

- Risk: The combination of the probability of occurrence of harm and the severity of that harm.
- Hazard: A potential source of harm.
- Risk Management File (RMF): A compilation of documents that describes the risk management process, including risk analysis, evaluation, and controls.

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5. Procedure

5.1 Risk Management Process Overview

The risk management process will consist of the following stages:

1. **Risk Identification**
2. **Risk Analysis**
3. **Risk Evaluation**
4. **Risk Control**
5. **Risk Monitoring and Review**
6. **Risk Management File Maintenance**

5.2 Risk Identification

Objective: Identify potential hazards associated with infusion pumps.

Procedure:

1. Conduct brainstorming sessions with cross-functional teams to identify hazards.
2. Review design inputs, user needs, and applicable standards.
3. Utilize historical data, complaint records, and feedback from previous designs.
4. Document identified hazards in the Risk Management File (RMF).

Key Decisions:

- Validate that all significant hazards have been identified.

Exit Criteria:

- A comprehensive list of hazards documented in the RMF.

5.3 Risk Analysis

Objective: Analyze identified hazards to determine their associated risks.

Procedure:

1. For each identified hazard, assess the severity of potential harm.
2. Estimate the likelihood of occurrence (probability) of each hazard.
3. Calculate the risk level by combining severity and probability.
4. Document findings in the RMF.

Key Decisions:

- Determine acceptable levels of risk based on predefined criteria.
- Validate the completeness and accuracy of risk analysis.

Exit Criteria:

- Completed risk analysis for all identified hazards documented in the RMF.

5.4 Risk Evaluation

Objective: Evaluate whether risks are acceptable based on the risk analysis.

Procedure:

1. Compare calculated risk levels against established acceptable risk criteria.
2. Prioritize risks for further action based on their significance.
3. Document evaluations and justifications in the RMF.

Key Decisions:

- Confirm that all risks have been evaluated against acceptable criteria.

Exit Criteria:

- Documented evaluation results in the RMF, including prioritization of risks.

5.5 Risk Control

Objective: Implement measures to control identified risks.

Procedure:

1. Determine appropriate risk control measures (e.g., design modifications, warnings, training).

2. Assess the effectiveness of the implemented risk controls.
3. Document the selected risk control measures in the RMF.
4. Review and update the risk management process as needed.

Key Decisions:

- Approve risk control measures based on effectiveness and feasibility.

Exit Criteria:

- Implementation of risk control measures documented and effectiveness confirmed.

5.6 Risk Monitoring and Review

Objective: Continuously monitor and review risks throughout the lifecycle of the infusion pump.

Procedure:

1. Establish a schedule for regular reviews of the RMF and identified risks.
2. Monitor post-market performance and user feedback to identify new risks.
3. Update the RMF with any new hazards, risks, or changes in risk controls.

Key Decisions:

- Determine the frequency and scope of risk reviews based on product lifecycle stages.

Exit Criteria:

- Updated RMF reflecting current risks, controls, and post-market data.

5.7 Risk Management File Maintenance

Objective: Maintain comprehensive documentation of the risk management process.

Procedure:

1. Ensure all documentation related to risk management activities is up-to-date and accessible.
2. Archive obsolete documents while retaining critical historical data.
3. Review and approve RMF documentation regularly.

Key Decisions:

- Confirm that the RMF is comprehensive and reflects all aspects of the risk management process.

Exit Criteria:

- An updated and approved Risk Management File, readily available for review.

6. References

- FDA 21 CFR 820 (Quality System Regulation)
- ISO 14971 (Application of Risk Management to Medical Devices)

7. Revision History

Version	Date	Description of Changes	Author
01	15-Oct-2024	Initial release	Raj Solai