1. Risk Identification

Objective: Identify potential hazards associated with infusion pumps.

Procedure:

1. **Brainstorming Sessions:**
    - Conduct sessions with cross-functional teams (R&D, QA, Regulatory Affairs).
    - Use techniques like SWOT analysis (Strengths, Weaknesses, Opportunities, Threats) and Fishbone diagrams to identify hazards.
2. **Review Design Inputs and Standards:**
    - Examine design inputs, user needs, and applicable standards (e.g., ISO 14971).
3. **Historical Data Analysis:**
    - Utilize historical data, complaint records, and feedback from previous designs.
4. **Documentation:**
    - Document identified hazards in the Risk Management File (RMF).

Tools Used:

- SWOT Analysis
- Fishbone Diagrams
- Historical Data Analysis Tools (e.g., databases of past complaints)

Example:

- Hazard: Potential for battery failure in the infusion pump.
- Source: Historical data showing previous incidents of battery issues.

Key Decisions:

- Validate that all significant hazards have been identified.

Exit Criteria:

- A comprehensive list of hazards documented in the RMF.

2. Risk Analysis

Objective: Analyze identified hazards to determine their associated risks.

Procedure:

1. **Severity Assessment:**
    - Assess the severity of potential harm for each identified hazard.
2. **Probability Estimation:**

- Estimate the likelihood of occurrence (probability) of each hazard.

3. **Risk Calculation:**
    - Calculate the risk level by combining severity and probability using a risk matrix.
4. **Documentation:**
    - Document findings in the RMF.

Tools Used:

- Risk Matrix
- FMEA (Failure Modes and Effects Analysis)

Example:

- Hazard: Battery failure.
- Severity: High (could lead to device shutdown during critical operation).
- Probability: Medium (based on historical data).
- Risk Level: High (requires immediate attention).

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.

3. Risk Evaluation

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

Procedure:

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

Tools Used:

- Risk Acceptance Criteria
- Prioritization Matrices

Example:

- Risk Level: High (battery failure).
- Action: Prioritize for immediate risk control measures.

Key Decisions:

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

Exit Criteria:

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

4. Risk Control

Objective: Implement measures to control identified risks.

Procedure:

1. **Determine Risk Control Measures:**
    - Identify appropriate measures (e.g., design modifications, warnings, training).
2. **Effectiveness Assessment:**
    - Assess the effectiveness of the implemented risk controls.
3. **Documentation:**
    - Document the selected risk control measures in the RMF.
4. **Review and Update:**
    - Review and update the risk management process as needed.

Tools Used:

- Design of Experiments (DOE)
- Control Charts

Example:

- Risk Control Measure: Redesign battery compartment to prevent failure.
- Validation: Conduct tests to ensure the new design mitigates the risk effectively.

Key Decisions:

- Approve risk control measures based on effectiveness and feasibility.

Exit Criteria:

- Implementation of risk control measures documented and effectiveness confirmed.

5. Risk Monitoring and Review

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

Procedure:

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

Tools Used:

- Post-Market Surveillance Systems
- Risk Review Checklists

Example:

- New Risk: Identified through user feedback indicating a new type of malfunction.
- Action: Update RMF and implement additional 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.

6. Risk Management File Maintenance

Objective: Maintain comprehensive documentation of the risk management process.

Procedure:

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

Tools Used:

- Document Management Systems
- Archiving Tools

Example:

- Regularly updated RMF with all current and historical data accessible for review.

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.

7. Validation of Risk Control Measures (RCM)

Objective: Ensure that implemented risk control measures effectively mitigate identified risks.

Procedure:

1. **Testing:**
    - Conduct rigorous testing of the implemented risk control measures.
2. **Verification:**
    - Verify that the measures effectively reduce the risk to an acceptable level.
3. **Documentation:**
    - Document the validation process and results in the RMF.

Tools Used:

- Verification and Validation (V&V) Plans
- Testing Protocols

Example:

- Risk Control Measure: Enhanced battery design.
- Validation: Conduct battery life cycle tests to ensure reliability.
- Result: Document successful test results in the RMF.

8. References

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

9. Revision History

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