Standard Operating Procedure (SOP) for Design Control of Infusion Pumps

- **SOP Number**: SOP-DC-001
- **Title**: Design Control Procedure for Infusion Pumps
- **Version**: 01
- **Effective Date**: 15-Oct-2024

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1. Purpose

This SOP defines the design control process for infusion pumps in accordance with **FDA 21 CFR 820** and **ISO 13485**. It ensures all design activities are systematically planned, executed, and documented to meet user, regulatory, safety, and performance requirements.

2. Scope

This procedure applies to all design and development activities related to infusion pumps at [Company Name], from initial concept to post-market surveillance.

3. Responsibilities

- **Project Manager**: Oversees the design and development process and ensures compliance.
- **R&D Team**: Responsible for design inputs, outputs, verification, and validation.
- **QA Team**: Ensures that the design meets quality and regulatory standards.
- **Regulatory Affairs**: Ensures compliance with FDA regulations, ISO standards, and global market requirements.
- **Cross-functional Team**: Involved in design reviews and approval stages.

4. Definitions

- **Design History File (DHF)**: A compilation of records that describe the design history of a medical device.
- **Risk Management File (RMF)**: A file documenting all risk management activities, per ISO 14971.

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5. Procedure

Phase 1: Concept Phase

Objective: Define the project's scope, feasibility, regulatory considerations, and identify initial risks.

Key Decisions:

1. **Project Feasibility**: Assess technical and commercial viability of the product concept.
2. **Regulatory Pathway**: Determine whether a **510(k), PMA**, or **CE marking** is required.

3. **Risk Identification**: Identify potential risks associated with the device.
4. **Resource Allocation**: Ensure sufficient resources are available to pursue the project.

Exit Criteria:

1. **Feasibility Study**: Completed and documented feasibility study.
2. **Preliminary Risk Assessment**: Identified risks documented in a **Preliminary Hazard Analysis (PHA)**.
3. **Concept Document**: Initial concept document created, with high-level performance goals.
4. **Approval**: Approval from senior management to proceed.

Phase 2: Design Input Phase

Objective: Convert user needs, safety requirements, and regulatory considerations into detailed and measurable design inputs.

Key Decisions:

1. **User Needs and Regulatory Requirements**: Validate that all critical user needs and regulatory requirements are considered.
2. **Detailed Specifications**: Define critical design inputs such as **performance, safety**, and **usability** specifications.
3. **Risk Management Initiation**: Initiate the formal risk management process based on user needs and regulatory expectations.

Exit Criteria:

1. **Design Input Specification (DIS)**: Complete and documented DIS with measurable performance criteria.
2. **Traceability**: All design inputs traced back to user needs and regulatory requirements.
3. **Risk Management**: Preliminary risk analysis integrated into the design inputs.
4. **Approval**: Cross-functional team approval of design inputs.

Phase 3: Design Output Phase

Objective: Create detailed design outputs that meet the design inputs and are ready for verification, validation, and transfer to manufacturing.

Key Decisions:

1. **Detailed Design**: Verify that the design outputs meet all the specified design inputs.
2. **Manufacturability**: Assess the design for manufacturability and compatibility with current production processes.

3. **Documentation Completeness**: Ensure all design outputs are well-documented (drawings, specifications, test methods).

Exit Criteria:

1. **Design Output Documentation**: Complete documentation of all design outputs, including assembly drawings, specifications, and software descriptions.
2. **Traceability**: Design outputs traced back to design inputs.
3. **Risk Controls**: Risk mitigations integrated into the design outputs.
4. **Approval**: Cross-functional approval of design outputs before moving to the verification phase.

Phase 4: Design Review Phase

Objective: Conduct formal reviews at key stages to verify the design meets the required inputs and identify any issues or corrective actions.

Key Decisions:

1. **Review Participation**: Ensure all relevant stakeholders (engineering, QA, regulatory, manufacturing) are involved.
2. **Design Evaluation**: Evaluate whether the design meets the specified inputs and regulatory requirements.
3. **Risk Reassessment**: Reassess and document any new risks identified during the design review.

Exit Criteria:

1. **Formal Design Review Completed**: All necessary design reviews (concept, detailed design, final design) are completed, and any issues are documented.
2. **Resolution of Action Items**: All open action items are resolved.
3. **Approval to Proceed**: Formal approval to move forward to verification and validation.
4. **Risk Management Updated**: Documented updates to the risk management file.

Phase 5: Design Verification Phase

Objective: Verify that the design outputs meet the design inputs through testing, inspection, or analysis.

Key Decisions:

1. **Verification Methods**: Confirm that verification methods are appropriate and comprehensive.
2. **Test Results**: Ensure that all test results meet the pre-defined acceptance criteria.

3. **Design Modifications**: Determine whether design modifications are necessary based on verification results.

Exit Criteria:

1. **Verification Testing Completed**: All verification tests are completed and documented.
2. **Design Verification Report (DVR)**: Verification results documented and reviewed.
3. **Risk Management Updated**: Update risk management file to reflect any residual risks identified during verification.
4. **Approval to Proceed**: Approval from the verification team to proceed to validation.

Phase 6: Design Validation Phase

Objective: Validate that the infusion pump meets user needs and performs as intended in real-world conditions.

Key Decisions:

1. **Validation Strategy**: Determine the appropriate validation approach (e.g., clinical testing, usability studies).
2. **Real-World Testing**: Assess whether the device performs as intended in actual or simulated use environments.
3. **Acceptance Criteria**: Confirm that the device meets all validation acceptance criteria and regulatory requirements.

Exit Criteria:

1. **Validation Testing Completed**: All validation tests, including usability and clinical testing, are completed.
2. **Design Validation Report (DVR)**: Validation results documented and approved.
3. **Human Factors Validated**: Usability and human factors validated according to FDA guidance.
4. **Regulatory Compliance**: Confirmation that the device complies with all applicable regulations.
5. **Risk Management Finalized**: Any residual risks are documented in the final risk management report.

Phase 7: Design Transfer Phase

Objective: Transfer the final design to manufacturing while ensuring that the product can be consistently produced and tested.

Key Decisions:

1. **Manufacturing Readiness**: Assess whether design outputs are complete and suitable for manufacturing.
2. **Process Validation**: Ensure that the production processes are validated and ready for scale-up.
3. **Supplier and Quality Controls**: Confirm that all suppliers and production processes are qualified and controlled.

Exit Criteria:

1. **Manufacturing Documentation Finalized**: Complete documentation for production, including Bill of Materials (BOM), assembly instructions, and QC procedures.
2. **Process Validation Completed**: Manufacturing processes validated and approved.
3. **Risk Management Finalized**: Risk management activities completed and reviewed.
4. **Approval to Proceed**: Approval to proceed with full-scale production.

Phase 8: Post-Market Surveillance Phase

Objective: Monitor the performance of the infusion pump in the field, capture real-world data, and manage any new risks.

Key Decisions:

1. **Post-Market Monitoring Strategy**: Define how post-market performance will be monitored (e.g., customer feedback, adverse events reporting).
2. **Risk Reassessment**: Identify any new risks based on real-world performance data and plan corrective actions if necessary.

Exit Criteria:

1. **Post-Market Surveillance Plan**: Plan established for ongoing monitoring and data collection.
2. **Regulatory Compliance**: Compliance with post-market regulatory requirements (e.g., FDA adverse event reporting).
3. **Ongoing Risk Management**: Risk management file updated based on post-market data.

6. References

- ISO 13485 (Medical Device Quality Management Systems)
- FDA 21 CFR 820 (Quality System Regulation)
- ISO 14971 (Application of Risk Management to Medical Devices)

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7. Revision History

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