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|---|-------------------------------------|-----------------------|--------------------------|
| <b>Title:</b> Design Input Work Instruction | <b>Standard Operating procedure</b> |                       |                          |
|   | <b>Doc Number</b><br>SOP-001-02     | <b>Revision</b><br>01 | <b>Page No</b><br>1 of 1 |

1. **Purpose:** Ensure design inputs are developed based on user needs, regulatory requirements, and risk analysis.
2. **Procedure:**
  - Gather and document user needs, regulatory requirements, and clinical considerations.
  - Translate these needs into measurable design inputs.
  - Initiate risk management activities related to design inputs.
3. **Key Decisions:**
  - **Completeness of Inputs:** Validate that all critical user needs are addressed.
  - **Performance Specifications:** Establish measurable, testable performance criteria.
4. **Exit Criteria:**
  - **Approved DIS:** The Design Input Specification is complete and approved.
  - **Traceability:** Inputs are traced to user needs and regulatory requirements.
  - **Risk Management Link:** Risks identified at this stage are integrated into the overall risk management process.

5. **Revision History**

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