**[This form may serve as the DHF Table of Contents and should be placed in the front of every DHF binder.]**

**Design History File Verification**

**Project Name:**

**Prepared By**

|  |  |
| --- | --- |
| [Name] | [Role/ Function] |
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|  |  |
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**Approved By**

|  |  |
| --- | --- |
| [Name] | [Role/ Function] |

**Revision**

[V.#]

**Date**

[dd-MON-yyyy]

| **PHASE I – DESIGN AND DEVELOPMENT PLANNING** | | | |
| --- | --- | --- | --- |
| **DOCUMENT LIST** | **NEW DOCUMENT** | **N/A** | **DOCUMENT & REVISION (and location if not in the DHF)** |
| 1. Design and Development Plan, SSI-QF-10A |  |  |  |
| 1. Risk Management Plan, SSI-QF-13A |  |  |  |
| 1. Software Safety Classification, SSI-QF-20A |  |  |  |
| 1. Software Development Plan, SSI-QF-20B |  |  |  |
| 1. Strategy for regulatory compliance; SSI-QF-23A (EU) |  |  |  |
| 1. Design Traceability Matrix, SSI-QF-10D (User Needs) column - Preliminary |  |  |  |
| 1. Preliminary Project Schedule |  |  |  |
| **Comments:** | | | |

Add rows as necessary. Remove/edit blue text as necessary depending on the nature of the project*.*

| **PHASE II – DESIGN INPUTS** | | | |
| --- | --- | --- | --- |
| **DOCUMENT LIST** | **NEW DOCUMENT** | **N/A** | **DOCUMENT & REVISION (and location if not in the DHF)** |
| 1. Use Specification, Design Traceability Matrix, SSI-QF-10D (User Needs) & (Design Inputs) columns |  |  |  |
| 1. Design Traceability Matrix, SSI-QF-10D (User Needs) & (Design Inputs) columns |  |  |  |
| 1. General Safety and Performance Requirement (Applicability, Yes/No, Rationale, References to applicable Harmonized Standards and Common Specifications); SSI-QF-22B (EU) |  |  |  |
| 1. Intended Use and Characteristics, Design and Development Plan, SSI-QF-10A |  |  |  |
| 1. Preliminary ASL (i.e. questionnaire) |  |  |  |
| 1. Design and Development Plan, SSI-QF-10A, as required |  |  |  |
| 1. Risk Management Plan, SSI-QF-13A, as required |  |  |  |
| **Comments:** | | | |

Add rows as necessary. Remove/edit blue text as necessary depending on the nature of the project*.*

| **PHASE III – DESIGN OUTPUTS** | | | |
| --- | --- | --- | --- |
| **DOCUMENT LIST** | **NEW DOCUMENT** | **N/A** | **DOCUMENT & REVISION (and location if not in the DHF)** |
| 1. Drawings(e.g. Assembly, Component, Purchased Parts, Fixtures) |  |  |  |
| 1. Design Traceability Matrix, SSI-QF-10D (Design Outputs) column |  |  |  |
| 1. Product Labels – Preliminary |  |  |  |
| 1. IFU – Preliminary |  |  |  |
| 1. Bill of Materials (BOM) and [Assembly routers- work instructions] – Preliminary |  |  |  |
| 1. Hazards Analysis – Preliminary |  |  |  |
| 1. Process FMEA – Preliminary |  |  |  |
| 1. Test Method Validations |  |  |  |
| 1. Supplier qualification and approval |  |  |  |
| 1. Updated Design & Development Plan, as required |  |  |  |
| 1. Updated Design and Development Plan, SSI-QF-10A, as required |  |  |  |
| 1. Updated Risk Management Plan, SSI-QF-13A, as required |  |  |  |
| **Comments:** | | | |

Add rows as necessary. Remove/edit blue text as necessary depending on the nature of the project.

| **PHASE III – DESIGN VERIFICATION** | | | |
| --- | --- | --- | --- |
| **DOCUMENT LIST** | **NEW DOCUMENT** | **N/A** | **DOCUMENT & REVISION (and location if not in the DHF)** |
| 1. Design Verification  * Usability (formative evaluation) * Print Verification * Ship/Package/Distribution Testing * Software Verification (Product) * Accelerated Aging/Shelf Life * Lifetime verification * Edit list of design verification activities, as appropriate.   Note: Design verification and validation activities can overlap, i.e., same activity can be considered a design verification and design validation. |  |  |  |
| 1. Design Traceability Matrix, SSI-QF-10D (Design Verification) column |  |  |  |
| 1. Hazards Analysis – Preliminary |  |  |  |
| 1. Process FMEA – Preliminary |  |  |  |
| 1. Design and Development Plan, SSI-QF-10A, as required |  |  |  |
| **Comments:** | | | |

Add rows as necessary. Remove/edit blue text as necessary depending on the nature of the project.

| **PHASE IV – DESIGN VALIDATION** | | | |
| --- | --- | --- | --- |
| **DOCUMENT LIST** | **NEW DOCUMENT** | **N/A** | **DOCUMENT & REVISION (and location if not in the DHF)** |
| 1. Design Validation  * Usability (Summative evaluation) * Ship/Package/Distribution Testing * Software Validation (Product) * Accelerated Aging/Shelf Life   Edit list of design validation activities, as appropriate.  Note: Design verification and validation activities can overlap, i.e., same activity can be considered a design verification and design validation. |  |  |  |
| 1. Clinical Evaluation Report (EU) |  |  |  |
| 1. Process Validation  * -IQ * -OQ * -PQ * As applicable. |  |  |  |
| 1. General Safety and Performance Requirement (Methods of conformity and reference to the documents); SSI-QF-22B (EU) |  |  |  |
| 1. Hazards Analysis |  |  |  |
| 1. Process FMEA |  |  |  |
| 1. Design Traceability Matrix, SSI-QF-10D (Design Validation) column |  |  |  |
| **Comments:** | | | |

Add rows as necessary. Remove/edit blue text as necessary depending on the nature of the project.

| **PHASE VI – DESIGN TRASFER** | | | |
| --- | --- | --- | --- |
| **DOCUMENT LIST** | **NEW DOCUMENT** | **N/A** | **DOCUMENT & REVISION (and location if not in the DHF)** |
| 1. Design Transfer Checklist, SSI-QF-10E |  |  |  |
| 2. Device Master Record (DMR)  -Assembly Procedures / Work Instructions  -Inspection Procedures / Work Instructions |  |  |  |
| 1. Assembly routers [work instructions] |  |  |  |
| 1. Finalized Process FMEA |  |  |  |
| 1. Finalized Hazard Analysis |  |  |  |
| 1. Risk Management Report |  |  |  |
| 1. Revised Final Labeling, as required |  |  |  |
| 1. Post Market Surveillance Plan, SSI-QF-17K (EU) |  |  |  |
| **Comments:** | | | |

Add rows as necessary. Remove/edit blue text as necessary depending on the nature of the project.

All Documents for the below Phase(s) are approved with required signatures:

|  |  |  |
| --- | --- | --- |
| Phase I: Design and Development Planning |  |  |
| Phase II: Design Inputs |  |  |
| Phase III: Design Outputs |  |  |
| Phase IV: Design Verification |  |  |
| Phase V: Design Validation |  |  |
| Phase VI: Design Transfer |  |  |
|  |  |  |

# Document Change Control

The following is the document control for revisions to this document.

|  |  |  |  |
| --- | --- | --- | --- |
| **Version**  **Number** | **Date of**  **Issue** | **Author(s)** | **Brief Description of Change** |
| [[###]] | [[###]] | [[###]] | [[###-###]] |