**[This template is intended only as a guide and may be adapted as required to meet specific circumstances.]**

**Design and Development Plan**

**Project Name:**

**Project Type:**

**New Product**

**Portfolio Extension**

**Design Change**

**Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Prepared By**

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

**Revision**

[V.#]

**Date**

[dd-MON-yyyy]

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# Purpose

The purpose of this this document is to:

* Set out an implementation plan and describe the major deliverables for SSI design and development activities for the [name of product and listing of high-level deliverables (product, accessories, packaging, labels]
* ensure that this product designed and developed by SSI is in conformity with regulation and standards.

# Scope

The Design and Development Plan covers the design, design verification and validation, design transfer and design release for [product name] product within [project name/ code]*.*

This plan fulfils the requirements of Design Planning in accordance with regulation and standards; see section 3.2 below.

The activities associated with this plan will be documented in the project Design History File (DHF).

# Reference Documents

## General

### SSI-SOP-10, Design and Development Control

### SSI-SOP-20, Software Development

### SSI-SOP-32, Usability Engineering

### SSI-SOP-25, Clinical Evaluation

### SSI-SOP-13, Risk Management

### SSI-SOP-14, Labelling

### SSI-SOP-22, Creation and Maintenance of Technical Documentation

[Additional references as needed]

## Regulations and Standards

### EU Medical Device Regulation (MDR) 2017/745

### FDA Design Control Guidance for Medical Device Manufacturers

### UK Medical Device Regulations

### SOR/98-282 Canadian Medical Device Regulations

### ISO 13485 Medical Device Quality Management Systems – Requirements for Regulatory Purposes

### ISO 14971 Medical devices – Application of risk management to medical devices

### IEC 62304 Medical Device – Software Lifecycle Processes

[Remove/Add regulations and standards as need. Ensure the standard year and version are specified, as applicable]

# Design Project Description

[Provide a brief high-level description of the design project including scope of the proposed product line and a brief summary of any new features.

Describe the project scope in general, materials required, any additional components required and the general intent of the project. Identify features that the product MUST have. ]

# Product Description

## Intended Use and Intended Users

[Provide a brief high-level description of the proposed intended use and intended users]

## Intended Population

[e.g., adult patients, describe conditions or any other specific characteristics of the patient population]

## Intended Environment

[e.g., home or clinical environments.]

## Intended Markets

[e.g., to be suitable to be marketed globally in highly regulated markets such as EU, USA, Canada, etc.]

## Predicate or Similar Devices

[Describe/ list devices considered predicate or similar to the proposed device. These may be competitor devices or devices within the organization. Where possible, describe anticipated similarities and differences to these.]

|  |  |
| --- | --- |
| **Similar Product(s)** | **Manufacturer of similar product(s)** |
|  |  |
|  |  |

# Design Project Schedule

*[*Describe the method that will be used to manage project schedules. For simpler projects this document, spreadsheets or flowcharts are appropriate.

For larger projects a Gantt chart might be appropriate. If a separate Project Schedule is maintained see below suggested wording]

A schedule baseline is defined in Annex 1 – Schedule, development stages and responsibilities.

# Resources

[Describe the required resources to complete the project. Include 3rd party resources and any equipment or facility needs required for development]

The following personnel are assigned on the project *[*This should cover personnel from each department]:

|  |  |  |
| --- | --- | --- |
| **Name** | **Function/ Role** | **Area/competence** |
|  |  |  |
|  |  |  |

Identified Parties and Associated Roles [List other companies involved in the project.]  N/A

The following 3rd party resources are required for this project:

|  |  |
| --- | --- |
| **Identified Parties** | **Associated Roles** |
|  |  |
|  |  |

[In the following remaining sections, describe or reference key design and development activities that will be carried out, for example: risk management; human factors engineering; design verification; design validation, as determined by the product characteristics, predicate product knowledge, and the regulatory requirements outlined in a documented regulatory plan or in this document. Some examples follow; add or subtract as appropriate.]

# Risk Management Planning

The risk management process will be adhered to by systematically identifying hazards, estimating and evaluating risks associated with these hazards, controlling hazards, and monitoring the effectiveness of the controls throughout the lifecycle of the product.

New Risk Management File [The risk management plan shall be defined per SSI-SOP-XX and SSI-QF-XXA template shall be used]

Update to Existing Risk Management File[Risk Management Plan XXX shall be reviewed and updated to expand the scope associated with this project.]

# Usability Engineering Planning

Usability Engineering process and evaluations in accordance with **SSI-SOP-32, Usability Engineering**, will be established and maintained to ensure that required documents and documented evaluations related to Human Factors are planned and conducted at appropriate stages of product lifecycle as applicable, following best practices, as captured [below/in a separate Usability Engineering Plan/ File. Capture the Usability Engineering Plan here or refer to a separate document.]

# Software Development Planning

The Software development process and lifecycle in accordance with **SSI-SOP-20, Software Development**, as appropriate to the scope, magnitude and software safety classifications of the software system, will be developed [in a separate Software Development Plan in accordance with applicable standards (i.e., IEC 62304 and 21CFR Part 820]. Capture the Software Development plan here or refer to a separate Software Development Plan document]

# Design Review Planning

Review and approval of each design deliverable is undertaken using **SSI-QF-10C Design Review** as detailed in **SSI-SOP-10 Design and Development Control**.

[State the proposed formal documented reviews of the design results, bearing in mind design reviews shall be conducted at appropriate stages of the product development lifecycle. Suggested reviews may include:

|  |  |  |  |
| --- | --- | --- | --- |
| **Design Stage Review** | **Product Lifecycle Phases** | **Required**  **(Y/N)** | **Justification, if (N)** |
| Design and Development Planning Review | Planning & Project Viability |  |  |
| Design Input Review | Inputs |  |  |
| Design Output Review | Development & Specifications |  |  |
| Design Verification Review | Verification |  |  |
| Design Validation Review | Validation |  |  |
| Design Transfer Review | Transfer to Production |  |  |
| Post Project & Commercial Release Review | Release |  |  |

]

Results of all design reviews shall be documented in the project Design History File (DHF).

# Design Verification Planning

Design verification activities are planned, conducted, reviewed and approved for products in development in accordance with **SSI-SOP-10 Design and Development Control** and applicable governing regulations, standards and/or guidance documents.

[Describe the Design Verification plan or refer to a separate Design Verification and Validation Plan document if applicable]

# Design Validation Planning

Design validation activities are planned, conducted, reviewed and approved for products in development at SSI in accordance with **SSI-SOP-10 Design and Development Control** and regulations, standards and guidance documents.

[Refer to a separate Design Verification and Validation Plan document if applicable]

# Design Transfer

Product Design Transfer activities are planned, conducted, reviewed and approved for products in development at SSI in accordance with **SSI-SOP-10 Design and Development Control**.

Product Design Transfer activities include the compilation of records and references that demonstrate that the device design is correctly translated into manufacturing/production specifications.

[Refer to a separate **SSI-QF-10E Design Transfer Checklist** if applicable]

# Regulatory Strategy

[Describe the relevant details of the regulatory compliance strategy for this product, or provide a reference to a separate Regulatory Plan/ Regulatory Compliance Strategy document. For Medical Devices placed in the EU, the regulatory strategy must at minimum address the following aspects:

* identification of relevant legal requirements,
* qualification,
* classification,
* handling of equivalence, if applicable and
* choice of and compliance with conformity assessment procedures.

See Annex 2 of this plan for an example of Regulatory and Submission Strategy Summary, this should be accompanied by a detailed strategy for regulatory compliance document; see **SSI-QF-23A Strategy for Regulatory Compliance** ]

# Clinical Strategy

[Describe whether a clinical investigation will be performed, including a brief discussion of study type/methodology. Describe whether a new clinical evaluation report will be written, or whether an existing clinical evaluation report will be updated.]

[For Medical Device Placed in the EU, capture the details of the Clinical Evaluation Plan (CEP) and/ or Clinical Development Plan (CDP). The CDP can be included in the CEP.]

# Post Market Surveillance

Post Market Surveillance Phase includes production, product sale and distribution. Post Market Surveillance will be conducted per existing procedures for review of non-conformances, complaints, serious incidents/ adverse events, CAPAs.

[For a Medical Device Placed in the EU, capture the details of the Post Market Surveillance Plan (PMSP)]

# Other: Specify

# Annexes

## Annex 1 - Project Schedule, Development Stages and Responsibilities

## Annex 2 - Regulatory Strategy and Submission Summary

# 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** |
| [[###]] | [[###]] | [[###]] | [[###-###]] |
|  |  |  |  |
|  |  |  |  |

**Annex 1 – Project Schedule, Development Stages and Responsibilities**

[This table can be customized based on each individual project, e.g., deliverables can be more specific and granular, Design Reviews can be modified etc.]

|  |  |  |
| --- | --- | --- |
| **Deliverable** | **Description/reference** | **Responsible** |
| **Project Definition Phase** [insert timeline, if required {start week – finish week}] | | |
| Statement of objectives |  |  |
| Reference to related objects |  |  |
| **Planning Phase** [insert timeline, if required {start week – finish week}] | | |
| Staff organization |  |  |
| Staff activity responsibilities |  |  |
| Management and supporting activities |  |  |
| General product description |  |  |
| Intended use and use environment |  |  |
| Intended Markets |  |  |
| Design Project Plan SSI-QF-10A |  |  |
| Design Traceability Matrix SSI-QF-10D | Defines the requirements of the product. Includes intended use, user needs, and design input. |  |
| Risk Management Plan SSI-QF-13A |  |  |
| Regulatory strategy SSI-QF-23A | Required by the MDR. |  |
| Clinical strategy (CEP SSI-QF-25A, CDP as applicable) | Required by the MDR. |  |
| Design review 1 SSI-QF-10C |  |  |
| **Design Inputs Identification Phase** [insert timeline, if required {start week – finish week}] | | |
| Preliminary Hazard Analysis | The first draft version of the hazard traceability matrix which provides input to the requirement traceability matrix. |  |
| Design requirements related to risk:   * Software * Hardware * Overall |  |  |
| As appropriate, information derived from previous similar designs |  |  |
| As appropriate, information derived from management review |  |  |
| Results of contract review activities/customer requirements |  |  |
| Factors outside standard SSI system |  |  |
| Software description |  |  |
| Software Development Plan SI-QF-20A |  |  |
| Usability Engineering Plan SI-QF-32A |  |  |
| Applicable statutory and regulatory requirements, common specifications, Standards and Guidance List |  |  |
| Design Inputs SSI-QF-10A |  |  |
| Design review SSI-QF-10C |  |  |
| **Design Output Documentation Phase** [insert timeline, if required {start week – finish week}] | | |
| Mechanical manufacturing specifications |  |  |
| Electronics specifications |  |  |
| SW specifications |  |  |
| Labelling specifications |  |  |
| Packaging specifications |  |  |
| Assembly instructions |  |  |
| Instructions for use |  |  |
| Formative evaluation |  |  |
| Quality plan | Includes manufacturing flowchart. |  |
| Supplier evaluation records |  |  |
| Equipment requirement specifications |  |  |
| Design review 3 SSI-QF-10C |  |  |
| **Design Verification Phase** [insert timeline, if required {start week – finish week}] | | |
| Master validation plan | A list of all processes that should be validated together with a high-level description of how to do this. |  |
| Process validation plans and records |  |  |
| Verification protocols/records |  |  |
| Pre-production products |  |  |
| Design review 4 SSI-QF-10C |  |  |
| **Design Validation Phase** [insert timeline, if required {start week – finish week}] | | |
| Clinical Evaluation report (CER) | Required by the MDR |  |
| Summative evaluation/ Usability Engineering File |  |  |
| Design validation protocols/records |  |  |
| Risk management report |  |  |
| General safety and performance requirement checklist (GSPR checklist) | Required by the MDR |  |
| PMS Plan | Required by the MDR |  |
| Risk management file |  |  |
| Technical documentation | Required by the MDR |  |
| Design review 5 SSI-QF-10C |  |  |
| **Design Transfer Phase** [insert timeline, if required {start week – finish week}] | | |
| Design transfer checklist |  |  |
| Design review 6 SSI-QF-10C |  |  |
| Declaration of conformity | Required by the MDR |  |
| Product Registration, as applicable |  |  |
| **Commercial Release** [insert timeline, if required {start week – finish week}] | | |
| Design transfer checklist |  |  |
| Design review 6 SSI-QF-10C |  |  |
| Declaration of conformity | Required by the MDR |  |
| Product Registration, as applicable |  |  |

**Annex 2 – Regulatory Strategy and Submission Summary**

[Add as many tables as necessary based on the intended markets. Delete the tables that are not applicable]

|  |  |
| --- | --- |
| **EU Regulatory and Submission Strategy** | |
| **Indications for Use** |  |
| **Classification(s)  and MDR Annex VIII Rules(s)** | Class IIb; Rule \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Class IIa; Rule \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Class I; Rule \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other; specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Conformity Assessment Route(s)** |  |
| **Technical Documentation** | Update Technical Documentation # \_\_\_\_\_\_\_\_\_  New Technical Documentation |
| **Justification for submission type(s)** |  |
| **Projected CE mark date(s)** |  |
| **Known regulatory risks  (including any anticipated notified body questions or discussion points)** |  |

|  |  |
| --- | --- |
| **UK Regulatory and Submission Strategy** | |
| **Indications for Use** |  |
| **Classification(s)  and MDD Annex IXI Rules(s)/ UK MDR 2002 (as amended)** | Class IIb; Rule \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Class IIa; Rule \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Class I; Rule \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other; specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Conformity Assessment Route(s)** |  |
| **Technical Documentation** | Update Technical File # \_\_\_\_\_\_\_\_\_  New Technical File |
| **Justification for submission type(s)** |  |
| **Projected UKCA mark date(s)** |  |
| **Known regulatory risks  (including any anticipated notified body questions or discussion points)** |  |

|  |  |
| --- | --- |
| **US Regulatory and Submission Strategy** | |
| **Indications for Use** |  |
| **Classification(s)** | Class III  Class II  Class I exempt  Other; specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **FDA Product Code(s)  and CFR References** |  |
| **Applicable FDA Guidance Documents** |  |
| **Planned Submission(s)** | 510(k)  Traditional  Special  Abbreviated  Predicate Device: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other (e.g., tissue); specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Justification for submission type(s)** |  |
| **Projected submission date(s)** |  |
| **Estimated time for clearance(s)/approval(s)** |  |
| **Known regulatory risks  (including any anticipated notified body questions or discussion points)** |  |

|  |  |
| --- | --- |
| **ROW Regulatory and Submission Strategy** | |
| **Countries** |  |
| **Indications for Use** |  |
| **Planned Submission(s)** |  |
| **Justification for submission type(s)** |  |
| **Projected submission date(s)** |  |
| **Justification for submission type(s)** |  |
| **Additional Documentation Requirements** |  |
| **Additional Testing Requirements** |  |
| **Additional Labeling Requirements** |  |
| **Product Sample Requirements** |  |
| **Estimated time for approval(s)** |  |
| **Known regulatory risks  (including any anticipated notified body questions or discussion points)** |  |