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

**It is for use in the development of a new software system. Bug fixes and enhancements to an existing system are dealt with using SSI-QF-10P Problem Report as the primary input source.**

**Software 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

This Software Development Plan (SDP) is to be used in conjunction with **SSI-SOP-20 Software Development and Verification** to define the software development plan for the *<project name/ code>*. This plan covers the activities and tasks performed until software maintenance.

# References

## *Doc. Ref. xxxxx: Document title - Requirements Traceability Matrix*

## *Doc. Ref. xxxxx: Document Title - Design & Development Plan*

## *Doc. Ref. xxxxx: Document Title – Risk Management Plan*

## SSI-SOP-20 Software Development and Verification

## SSI-SOP-13 Risk Management

## SSI-SOP-10 Design and Development

# Development Activities

## Development Management

The Software Development process will be managed by *<NAME>*. The main software development shall be carried out by *<NAME/S>*. Quality system personnel *<NAME>* will be involved in reviewing and verifying activities. All software development documents shall be signed off by the project lead *<NAME>* and/or other appropriate individuals. The progress shall be reviewed by the management team on a regular basis.

## Risk Management

The SSI Risk Management Process shall be followed. Assessment of software related risk shall be included in the project risk management plan. IEC TR 80002-1 may be referred to for assistance in the software risk process. The software safety class shall be determined after the assessment of software risk and shall be documented in the Risk Management File.

## Standards

### BS EN 62304:2006+A1:2015, Medical Device Software – Software Lifecycle Process

### EN ISO 14971:2019/A11:2021, Medical devices - Application of risk management to medical devices

### IEC TR 80002-1:2009, Medical Device Software – Part 1: Guidance on the application of ISO 14971 to medical device software

### BS EN 62366-1:2015+A1:2020, Medical devices. Application of usability engineering to medical devices

### *<Additional regulations and standards>*

# Deliverables

The deliverables, including documentation, required for the development of this software system are listed below:

| **Activity** | **Deliverables** | **Milestone** | **Documentation (if applicable)** |
| --- | --- | --- | --- |
| *Requirements Analysis* | *Concept Software Design*  *Software Safety Classification*  *Software System Structure– software item, unit and SOUP identification*  *Software Development Planning*  *Software requirements prepared and reviewed* | *Software Planning Complete* | *Software Safety Classification (SSI-QF-20A)*  *Software Development Plan (SSI-QF-20B)*  *Software Requirements Traceability Matrix (SSI-QF-20C)* |
| *Risk Management* | *Software Risk Assessment*  *Software Requirements update*  *Software Review* | *Software Requirements Baselined* | *Software Risk Assessment (SSI-QF-XX)*  *Software Review Meeting Minutes (SSI-QF-10C)* |
| *Design and Implementation* | *Software Architecture*  *Software Detailed Design*  *Implementation and Coding* | *Software Design Baselined* | *Software Architecture Description (SSI-QF-20D)*  *Software Review Meeting Minutes SSI-QF-10C)* |
| *Software Verification and Configuration Management* | *Software Unit test protocols*  *Software Integration test protocols*  *Software System test protocols*  *Dry run*  *Software Review* | *Software Verification Readiness* | *Software Test Protocols (SSI-QF-20E)*  *Software Review Meeting Minutes (SSI-QF-10C)* |
| *Software Unit testing*  *Software Integration testing*  *Software System testing*  *Software Change Requests*  *Software Problem Resolution* | *Software Approval* | *Software Test Reports (SSI-QF-20F)*  *Nonconformance Reports (SSI-QF-XX) (if applicable)*  *Change Requests (SSI-QF-10G) (if applicable)* |
| *Release* | *Software Review* | *Software Release* | *Software Requirements Specification and Traceability Matrix (SSI-QF-20C)*  *Software Maintenance Plan (SSI-QF-20G)*  *Software Release Review Meeting Minutes (SSI-QF-10C)*  *Software Summary Report (SSI-QF-20I)*  *Software Revision History (SSI-QF-20J)* |
| *Repeat above rows for additional spirals as needed* |  |  |  |

# Configuration Management

Configuration items shall be placed under documented configuration management control before they are verified. The change control and problem resolution process for managing these items is described in SSI-SOP-20.

## Software Items and Units

The software development and maintenance process described in SSI-SOP-20 shall be used to manage the configuration management process (including problem resolution), responsibilities and relationships for this software item.

| **Title** | **Configuration ID** |
| --- | --- |
|  | *Version number* |

## SOUP

The software maintenance process described in SSI-SOP-20 shall be used to manage the configuration management process (including problem resolution), responsibilities and relationships to maintain this software item.

| **Title** | **Configuration ID** | **Manufacturer** | **License type**  **(if applicable)** |
| --- | --- | --- | --- |
|  | *Version, a release date, a patch number or an upgrade designation* |  |  |

## Supporting Items

### Development Tools

| **Title** | **Configuration ID** | **Manufacturer** | **Validation Status** |
| --- | --- | --- | --- |
|  | *Version, a release date, a patch number or an upgrade designation* |  | *Not Required.* |
|  |  |  | *Validation Required. See Doc. Ref. xx for results.* |

### Production Tools

| **Title** | **Configuration ID** | **Manufacturer** | **Validation Status** |
| --- | --- | --- | --- |
|  | *Version, a release date, a patch number or an upgrade designation* |  | *Not Required.* |
|  |  |  | *Validation Required. See Doc. Ref. xx for results.* |

### Verification Tools

| **Title** | **Configuration ID** | **Manufacturer** | **Validation Status** |
| --- | --- | --- | --- |
|  | *Version, a release date, a patch number or an upgrade designation* |  | *Not Required.* |
|  |  |  | *Validation Required. See Doc. Ref. xx for results.* |

## Other Configuration Items

*<* *List other configuration items not noted above. Include as appropriate, descriptions, configuration identifiers, versions, validation status, and other appropriate information. Include as appropriate, descriptions, configuration identifiers, versions, validation status, and other appropriate information>*

# Risk Management

Software risk management (including SOUP) is planned in conjunction with product-level risk activities plan as defined in the Product Design and Development Plan. In addition, during software planning, the Software Safety Classification, see SSI-QF-20A is prepared as applicable. The Project Lead is responsible for coordinating the upper level risk management activities with the software risk management activities, in conjunction with the Software Engineer. The risk management file will be updated by the Project Lead accordingly. Software engineering decisions are risk-based as the design risk assessment is reviewed and updated during the different phases of the software life-cycle. See SSI-SOP-13 for risk management process during planning. The design risk assessment will be reviewed and updated as necessary throughout the lifecycle. See SSI-SOP-13 for specifics on the risk activities.

# Software Unit Implementation and Verification

The software units shall be implemented using the tools and configurations as defined in section 5 above.

File storage and version control shall be carried out as described in **SSI-SOP-20 Software Development and Verification procedure**.

Units may be tested or evaluated informally during the development process (e.g. by inspection of behaviour, or through debug feedback). Any formal testing carried out shall be documented. Code reviews may also be carried out.

*<Describe the methods and criteria for software unit verification. Acceptable methods are analysis, demonstration, inspection and testing. Code reviews will be performed. Once the software architecture and risk assessment is released (software units are defined, and software safety classification can be determined) then it is known what unit verification needs to happen. Discuss and document rationale for any deviations to the plan (e.g., no testing is necessary; however, the following software units will be tested). In addition, the following items shall be addressed:>*

The Software Verification Readiness Review meeting shall verify in the documented meeting minutes that all the required documentation for the execution of verification have been prepared and ensure coverage of the requirements.

# Software Unit Integration and Software Unit Integration Testing

*<Explain integration process for software incorporated in the products, suggested wording below, this may be amended as appropriate>*

The software items, or groups of items, are running on an independent dedicated PIC microcontroller. The software units will be integrated in stages as the units are implemented in order to carry out informal (or formal) testing or evaluation. This occurs when the appropriate code for each unit is included or called from the main.c file and the code is compiled and programmed to a device. If multiple PIC microcontrollers are used, the software items are integrated by the programming of the separate microcontrollers on the same hardware.

Informal testing or evaluation of integrated units may be carried out during the development process.

Formal integration testing shall be carried out as part of system testing. *<Change if separate integration testing is planned.>*

Plans for testing shall include:

* The software units have been integrated into software items and the software system.
* The hardware items, software items and support for manual operations (human-equipment interface) of the system have been integrated into the system.
* The integrated software item performs as intended. (System level testing).

Including:

* The required functionality of the software
* Implementation of risk control measures
* Specified timing and other behaviour
* Specified functioning of internal and external interfaces
* Testing under abnormal conditions including foreseeable misuse

If any changes are made to any software units as a result of the testing process, additional testing shall be carried out as appropriate to test and verify effectiveness of the change in correcting the problem and that unintended side effects have not been introduced. Relevant risk management activities shall be carried out.

*<Explain integration process for medical device software>*

# Software System Testing

A System Testing procedure shall be produced by to establish suitable tests and pass/fail criteria to ensure that all of the requirements of the System Requirements and Software Requirement Specification are met. The tests should also ensure that integrated software items (including soup) are performing correctly.

The test procedure shall be evaluated for correctness (signed off) before tests are carried out.

System testing shall be carried out and documented. Test documents shall document the person conducting the tests, maintain sufficient record to allow the tests to be repeated and document the results (pass/fail and anomalies).

If any changes are made as a result of the testing process, additional testing shall be carried out as appropriate to test and verify effectiveness of the change in correcting the problem and that unintended side effects have not been introduced. Relevant risk management activities shall be carried out.

Verification of the system testing process shall be carried out to ensure that:

* the verification strategies and test procedures used are appropriate
* software system test procedures trace to software requirements
* all software requirements have been tested or otherwise verified
* test results meet the required pass/fail criteria

# Documentation

## Software System, Items and Units

| **Document Type** | **Template** | **Title** | **Document No.** |
| --- | --- | --- | --- |
| Software Safety Classification | SSI-QF-20A |  |  |
| Software Development Plan | SSI-QF-20B |  |  |
| Software Requirement Traceability Matrix | SSI-QF-20C |  |  |
| Software Risk Assessment | SSI-QF-XX |  |  |
| Software Requirements Review Meeting Minutes | SSI-QF-10C |  |  |
| Software Architectural Design | SSI-QF-20D |  |  |
| Software Detailed Design | SSI-QF-20D/ SSI-QF-20C/ As applicable |  |  |
| Code Review Meeting Minutes | SSI-QF-10C |  |  |
| Software Unit Test Protocols | SSI-QF-XX |  |  |
| Software Unit Test Reports | SSI-QF-XX |  |  |
| Software Integration Test Protocols | SSI-QF-XX |  |  |
| Software Integration Test Reports | SSI-QF-XX |  |  |
| Software System Test Protocols | SSI-QF-XX |  |  |
| Software System Test Reports | SSI-QF-XX |  |  |
| Software Release Meeting Minutes | SSI-QF-10C |  |  |
| Software Summary Report | SSI-QF-20I |  |  |
| Software Revision History | SSI-QF-20J |  |  |
| Software System Change Requests | SSI-QF-10G |  |  |
| Software Maintenance Plan | SSI-QF-20G |  |  |
| Software Maintenance Report (if applicable) | SSI-QF-20H |  |  |

## SOUP

*<Add the following table for each SOUP item listed in section 5.2>*

| **Document Type** | **Template** | **Title** | **Document No.** |
| --- | --- | --- | --- |
| Software Maintenance Plan | SSI-QF-20G |  |  |
| Software Maintenance Report (if applicable) | SSI-QF-20H |  |  |
| Software Revision History | SSI-QF-20J |  |  |

# Approvals

|  |  |  |  |
| --- | --- | --- | --- |
| **Role** | **Name** | **Signature** | **Date** |
| **Software Engineer** |  |  |  |
| **Project Lead** |  |  |  |

# Document Change Control

|  |  |  |  |
| --- | --- | --- | --- |
| **Version umber** | **Date** | **Author(s)** | **Brief Description of Change** |
| <<###>> | <<###>> | <<###>> | <<###-###>> |