MEDICAL DEVICE DESIGN AND DEVELOPMENT PLAN

Engagement ID :

Engagement Name :

Client Name :

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1. Purpose

<< This document is intended to describe the design and development plan for newly developed & Modified Medical Device products. >>

2. Scope

<< This document applies to all Medical device product development practices and activities associated with the planning, design, development and transfer of new and modified medical device products, this plan is applicable to all type of medical device projects (End to end , mechanical ,hardware & embedded type of projects) including software as medical device >>

<< This Medical Device software/artefacts in scope Does/ Does not Contains Legacy Software. >>

<<The scope should clearly define whether any legacy software as defined in IEC 62304 i.e. Medical Device Software which was legally placed on the market and is still marketed today but for which there is insufficient objective evidence that it was developed in compliance with the current version (currently 2015) of this standard, is to be included or excluded from the engagement activities. If included, gap assessment as per standard requirement shall be conducted. Else excluded, it shall be deemed that client is responsible and compliant with the use of legacy software in the medical device.>>

<< Define the scope of the activity in the current version/SoW>>

<< Define the periodicity of review of this current document to be conducted>>

3. Risk Management

<<Risk Management is conducted to reduce the risk of medical devices >>

<< Project should maintain risk management plan and entailed risk management activities for each stage and ideally refer to either clients risk management procedure or risk management processes >>

<< Project should establish the risk acceptance criteria in accordance to the risk management procedure considering the classification of similar devices in the existing markets >>

4. Design and Development Stages/Phases

<<Project should define and describe various design and development stages applicable to particular device. This includes initial designs, various prototype levels, final product and projected details around it.>>

<< Mention life cycle model selected for the software development. E.g. – Waterfall, agile, spiral, or iterative if applicable>>

<<Project should record how design and development activities will be conducted including personnel utilized, facilities used, and regulations followed and possibly projected timeline.>>

<< Typical stages in design and development includes: -

Plan (Include Risk Management)

Maintenance plan

Input

Output

Review

Verification

Validation

Design Transfer

Post Market activities

Design Change Control

Maintaining Design and development File >>

<<

Maintenance Plan can include

a) procedures for: – receiving, – documenting, – evaluating, – resolving and – tracking feedback arising after release of the medical device software;

b) criteria for determining whether feedback is a problem;

c) use of the software risk management process;

d) use of the software problem resolution process for analyzing and resolving problems arising after release of the medical device software;

e) use of the software configuration management process for managing modifications to the existing software system; and

f) Procedures to evaluate and implement: – upgrades, – bug fixes, – patches and – obsolescence of soup.

>>

<< Provide details of reference standards as applicable such as Internal Procedure or any Client Specific development procedure>>

<< Clearly define intended deliverables of each of above mentioned and as applicable stages>>

Title of the Document	**Purpose of documents**	**Intended Audience**	**Procedure for documentation control.**

5. Design and Development requirements development

<<Project should record how design and development activities will be conducted including requirements with/without use cases, standards personnel utilized, facilities used, and regulations followed and possibly projected timeline.>>

<< Project should develop requirements which can be verified and document those software requirements considering

a) implementing system requirements including those relating to risk control;

b) do not contradict one another;

c) are expressed in terms that avoid ambiguity;

d) are stated in terms that permit establishment of test criteria and performance of tests;

e) can be uniquely identified; and

f) are traceable to system requirements or other source. >>

<< Provide details of reference standards as applicable such as Internal Procedure or any Client Specific development procedure>>

6. Design and development Output processing

<< Project should include how the outputs such as code repositories, software detailed description, architectures, drawings or gerber files are reviewed and approved >>

7. Design Verification and Validation

<<Project should plan how all the applicable verification and validation activities will be conducted and responsible team/personnel for the same. This includes all applicable testing activities inclusive of clinical, biocompatibility, sterility, EMC, Latex, cleaning validation, disinfection and all applicable certification testing as per regulatory requirements. If third party vendor utilization is needed, project should identify that at the design and development planning level.>>

<< Project shall also have effective plan for software unit, integration and system testing, ideally the verification reports should entail/place in configuration control any source of code prior to verification testing and pass/fail criteria and identification of testing personnel, reviewer and approver >>

<< Provide details of reference standards as applicable such as Internal Procedure or any Client Specific development procedure>>

8. Design Transfer

<<Project should define how design transfer will take place once the final design is frozen. This could include personnel responsible for design transfer, projected manufacturing facility, related detail information as well as design transfer review projections.>>

<< Project can include process for software deployment >>

<< Provide details of reference standards as applicable such as Internal Procedure or any Client Specific development procedure>>

9. Design Stage Reviews

<<Project should conduct design review at completion of every projected stage and reviews should be conducted and signed off by qualified personnel or team. >>

<< Provide details of reference standards as applicable such as Internal Procedure or any Client Specific development procedure>>

A Typical (example) Review Plan can be as shown below. Artifacts for Review.

Phase	Work Product	Type of Review <Peer or Discussion>	Reviewer	Review Technique <Inspection or Walkthrough>

10 . Traceability

<<Project should define traceability between system requirements, software requirements, software system test, and risk control measures implemented in software; this could be achieved via utilization of Requirement Traceability Matrix as well. >>

<< Project shall maintain traceability of SOUP by recording title, manufacturer of SOUP, and unique SOUP designator The unique SOUP designator could be, for example, a version, a release date, a patch number or an upgrade designation.>>

<< Provide details of reference standards as applicable such as Internal Procedure or any Client Specific development procedure>>

11 . Problem resolution

<< Provide reference to problem resolution for problems, defects including defects that may be introduced based on the selected programming technology that are relevant to the software system or anomalies arising during design and development phases. Define threshold for action to be conducted, including updating of risk management documentation/risk controls, triggering of CAPA or reporting to regulatory bodies >>.

<< Define stages where problems may be identified, logged and resolved using techniques such as CAR/5-Why>>

<< For legacy software, the plan shall address the use of the problem resolution process for handling problems detected in the legacy software and deliverables/Artefacts in accordance with applicable problem resolution process.

Changes to the legacy software shall be performed in accordance with applicable software maintenance process. >>

12 . Resources

<<Project should identify all the required resources for design and development activities, skill sets needed for those personnel, required training as applicable and responsibilities of the resources. >>

<<Project can include information such as tool which are used, in case an external testing conducted, and such tool to be validated, any special environment required for design and development>>

<< Project should include information for how the defects are tracked during development and post deployment, such information can be referred to any other procedures which contains such information, for example, usage of JIRA SOP, or post market complaint/feedback analysis>>

<< Project should include guidelines on configuration management such as naming conventions, tools to used, standard operating procedure for operating such tools. >>

<< Note :- The above template provides an overview of design and development planning, in case any specific section needs to be added, such section can be added. >>

Document information

Change history

Revision	Date	Changes	Author	Reviewer	Approver
1.0	Text	Text	Text	Text	Text

Distribution list

Organization	Name and role	Action	Comments

Text	Name, Role	For action or For information	Text

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