# Checklist Content of Software Development Plan

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# 1 Software Development Plan

*IEC 62304: Medical device software — Software life-cycle processes:*

The objective of this activity is to plan the software development tasks to reduce risks caused by software, communicate procedures and goals to members of the development team, and ensure that system quality requirements for the medical device software are met.

The software development planning activity can document tasks in a single plan or in multiple plans. some manufacturers might have established policies and procedures that apply to the development of all their medical device software. In this case the plan can simply reference the existing policies and procedures. Some manufacturers might prepare a plan or set of plans specific to the development of each medical device software product that spell out in detail specific activities and reference general procedures. Another possibility is that a plan or set of plans is tailored for the development of each medical device software product. The planning should be specified at the level of detail necessary to carry out the development process and should be proportional to the risk. For example, systems or items with higher risk would be subject to a development process with more rigor and tasks should be spelled out in greater detail.

Planning is an iterative activity that should be re-examined and updated as development progresses. The plan can evolve to incorporate more and better information as more is understood about the system and the level of effort needed to develop the system. For example, a system's initial software safety classification can change as a result of exercising the risk management process and development of the software architecture. Or it might be decided that a SOUP be incorporated into the system. It is important that the plan(s) be updated to reflect current knowledge of the system and the level of rigor needed for the system or items in the system to enable proper control over the development process.

# 2 Content Checklist

Check that the document contains at least the following information items:

## 2.1 Software Development Life-Cycle

☐ the software development lifecycle model and the processes used for developing the software system shall either be fully defined or be referenced
☐ procedures for coordination with System Development

## 2.2 Software Development Planning

☐ the scope of the development project

☐ the (initial) software safety classification

☐ coding guidelines

☐ software unit acceptance criteria

☐ the deliverables (including documentation) of the activities and tasks

☐ traceability between system requirements, software requirements, software system test, and risk control measures implemented in software.

☐ include or reference standards, methods and tools to be used during development

## 2.3 Planning of Supporting Processes

references to or inclusion of

☐ Software Integration Plan

☐ Software Integration Test Plan

☐ Software System Test Plan

☐ Software Verification Plan

☐ Software Validation Plan

☐ Software Risk Management Plan

☐ Software Documentation Plan

☐ Software Configuration Management Plan

☐ Software Problem Resolution Plan