# Overview

This master plan describes all design and development activities from concept to launch for the [Product Name], serving as the central planning document for the project, per 21 CFR 820.30.

# Purpose

The purpose of this plan is to define all project activities, responsibilities, timelines, major milestones, and required design control procedures to ensure a compliant and successful development process.

# Scope

This plan governs the entire project and is the parent document for all other subsidiary plans (e.g., Software Development Plan, Quality Plan, Risk Management Plan).

# Project Phases

The design and development of the [Product Name] will follow a structured, phase-gated process in accordance with the waterfall model required by 21 CFR 820.30. Each phase concludes with a formal design review to ensure all phase-specific requirements have been met before proceeding to the next phase.

## Phase 1: Design and Development Planning

This initial phase involves the creation of this plan and all other top-level planning documents. It establishes the project's foundation, including the team, schedule, and procedures. Key outputs of this phase include the Quality Plan (QP-001-A1) and the Risk Management Plan (PRA-001-A1).

## Phase 2: Design Inputs

This phase focuses on defining the design inputs. These are the requirements that the device must meet. The primary activities are the development of the Market Requirements Document (MRD-001-A1) and its translation into the detailed, testable engineering requirements found in the Product Design Requirements (PDR-0001-A1) and its subsidiary requirement documents.

## Phase 3: Design Outputs

This phase is where the design inputs are transformed into the actual design of the device. Design outputs are the documents and drawings that describe the device and how to build it, such as the various Architecture Documents (e.g., SAD-0001-A1, SWAD-0001-A1) and the final component specifications.

## Phase 4: Design Verification

This phase ensures that the design outputs meet the design inputs. It involves testing and analysis to confirm that the device was designed correctly. All activities in this phase are governed by the Design Verification Plan (DVEP-0001-A1), and all test results are documented in a final report.

## Phase 5: Design Validation

This phase ensures that the final device meets the user's needs and intended uses. It involves testing on production-equivalent units under actual or simulated use conditions. Activities are governed by the Design Validation Plan (DVAP-001-A1) and include summative usability testing and clinical evaluations.

## Phase 6: Design Transfer

This phase ensures that the device design is correctly translated into production specifications. The key output is a complete and approved Device Master Record (DMR), which contains all information required to manufacture the device. This process is managed according to the Design Transfer Plan (DTP-0001-A1).