Docs-as-Code for Open-Source Medical Hardware & PPE’s

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Stakeholder Needs

The **Docs-as-Code for Open-Source Medical Hardware & PPE's** architecture is guided by a series of stakeholder needs, listed below.

1: Quality System Processes for Medical Device Manufacturers

> Manufacturers of medical devices shall ensure that finished devices will be safe and effective.[1][2]

2: Design & Development Planning

> Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.[3]

Data Structures

This section covers each data structure type in the **Docs-as-Code for Open-Source Medical Hardware & PPE's** architecture.

Design & Development Plan

Purpose: Data structure for a Design & Development Plan (DDP) document

Design & Development Plan Template

```
project_scope: {{project_scope}}
project_cost: {{project_cost}}
project_schedule: {{project_schedule}}
```

Field	Type	Item Type	Description	Source
project_scope	dict	string	A way to set boundaries, goals, deadlines, assumptions, & constraints.	

Field	Type	Item Type	Description	Source
project_cost	string		An amount of money needed to pay or compensate to buy or take a service or good.	
project_schedule	string		Establishes the criteria & activities for developing and monitoring a schedule.	

Table 1. Design & Development Plan Specification

Derived From:

- Design & Development Planning

[1] 21 CFR Part 820 — Quality System Regulation https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820

[2] ISO 13485 - Quality Management for Medical Devices https://www.iso.org/iso-13485-medical-devices.html

[3] 21 CFR Part 820.30 (B) - Design and Development Planning https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820#p-820.30(b)