Project Management Plan

**Project Name**: project-name-here

**Version:** version-here

**Author:** your-name-here

Last-Revision-Date: MM/DD/YY

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# Purpose

[Purpose, introduction, scope of document. Do not extensively describe the purpose of the project itself.]

# Definitions, Abbreviations, Acronyms

| Term | Definition |
| --- | --- |
| Application | The software component of the system |
| SOP | Standard Operating Procedure |
| [ex.] | [these are examples. Remove above, or add below.] |

# References

* FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
* Draft Guidance for Industry and Food and Drug Administration Staff Mobile Medical Devices
* FDA 21 CFR Part 820 Quality System Regulation
* [above are examples. add or remove as needed. Note: all management plans must reference the Project Management Plan. Additionally, the Project Management Plan must reference all other management plans. These references reflect the relationship between the Integration KA and all other KAs]

# Project Organization

[text-here. Summarize the management hierarchy and management methodology.]

# Product or Service Description

[text-here. Describe the product or service- which is the reason the project is being implemented. A paragraph is acceptable. Referencing the Scope Statement is encouraged.]

# Management processes

[text-here. detail management methodologies.]

# Technical Processes

[text-here. Summarize technical processes including designing the project (or service), implementing the product, testing the product, deploying the product.]

# Schedule information

[text-here. Strictly speaking, the project schedule with dates does not belong in the Project Mgmt Plan. Schedule with dates is why we have a Gantt Chart and Project Schedule. Also, dates change, and we don’t want to be required to update this document every time a date changes. A good approach I’ve seen is to include a milestone list with anticipated cumulative durations to each gate. Though, if you feel strongly about adding a draft schedule with dates, that is acceptable. Below is a milestone list. Note: each project has a different milestone list. What are the 6-12 most important events (project gates) to your project?]

| Milestone | Cumulative Duration |
| --- | --- |
| Project Initiation | 0 Days |
| Vendor Contracts Executed and Signed | 45 Days |
| Design Specification Approved | 110 Days… |

# Budget Information

[text-here. For the same reasons in #8 above, we don’t include detailed budget info here- that is what the cost baseline and cost estimate documents are for. It is sufficient to simply reference Business Case document if that financial information included is still current.]

# Revision Procedures

[text-here, describes the procedure that will control revisions to this document. Drafting, reviewing, approving, releasing, distributing. Note, because all management plans require this section, and this section may be similar for all management plans, a highly productive approach to this completing this section is to create a separate SOP document called “Management Plan Revision Procedure”, and in this section for this document and other management plans, just reference that SOP.]