Requirements Management Plan

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

**Version:** version-here

**Author:** your-name-here

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# Purpose

[Purpose, introduction, scope of document.]

# Definitions, Abbreviations, Acronyms

| Term | Definition |
| --- | --- |
| Application | The software component of the system |
| Software | An electronic program consisting of algorithms, control logic, data structures, data sets, operating system, user interface. Software may consist of critical and non-critical components and may be used as a part or as an accessory of a medical device to perform pre-defined and approved operations on medical devices. Software may itself be a medical device. Software may be used in the production of a device (e.g. programmable logic controllers used in the manufacturing of equipment.) Software may be used in implementation of the device manufacturer’s quality system (e.g. Software that records and maintains the device history record. |
| 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* Draft Guidance for Industry and Food and Drug Administration Staff Mobile Medical Devices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]

# Roles & Responsibilities

|  |  |  |
| --- | --- | --- |
| Name | Role | Responsibilities |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

# Planning, Tracking, & Reporting Requirement Activities

[text-here. How will the PMs maintain requirements to ensure their communicated and stay up to date?]

# Defining Requirement Activities

[text-here. How will the PMs and analysts identify requirements? This generally involves research, investigation, and interviews. Formally describe the process.]

# Prioritizing Requirement Activities & Product Metrics

[text-here. Requirements must be prioritized so that they can be allocated the necessary time and resources. How will you prioritize your requirements, and using what metrics? (You can’t do everything under the sun, so you need to prioritize.)]

# Tracing Requirements Activities

[text-here. Requirements have to be identified, designed, implemented, then tested (in a nutshell.) How will you ensure each requirement goes through the necessary processes? Describe the process. It is essential to mention and reference the Traceability Matrix, it’s role and purpose.]

# Revision procedures

[text-here, describes the procedure that will control revisions to this document. Drafting, reviewing, approving, releasing, distributing]