Risk 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.]

# 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* Draft Guidance for Industry and Food and Drug Administration Staff Mobile Medical Devices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 |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

# Risk Management Procedures

[text-here. Describe the activities of Risk Management.]

# Risk Management Deliverables

[text-here. Describe the risk deliverables, in a table or a list, with definitions. Included in this list is the Risk Registry and the Probability Impact Matrix.]

# Risk Probability, Impact, Criteria

[text-here. Describe the Probability and Impact Categories. Usually this is described in a “Risk Matrix”, which can be researched more in the textbook and the internet. In addition to the matrix, provide definition for each category (i.e. what does it mean to be a minor impact), and the criteria for acceptable amount of risk (i.e. which cells of the Risk Matrix are red, and why?)]

# Revision procedures

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