Communication Management Plan

**Project Name**: SAP ERP Implementation

**Version:** 1.0

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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 |
| User Case/Story | A brief description of how the system user will interact with the ERP system |
| User case diagram | A graphical representation of the use case |
| ER Diagram | Entity-Relationship Diagram. A conceptual representation of how the organization’s data will be represented in the data base. |

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* Draft Guidance for Industry and Food and Drug Administration Staff Mobile Medical Devices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

# Stakeholder communications requirements

* Project Steering Committee: Will not talk any form of communications that is outside the allotted time frame
* Sponsors: Have the right to request an meeting once a month if the project is extremely behind schedule

# Communications summary & Responsibilities

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Stakeholders | Communications Name | Delivery Method/Format | Producer | Due/Frequency |
| Project steering committee | Weekly status report | Hard copy and short meeting | Kristin Maur | Wed. mornings at 9 AM |
| Sponsor and champion | Monthly status report | Hard copy and short meeting | Kristin Maur | First Thursday of month at 10 AM |
| Affected employees | Project announcement | Memo, e-mail, intranet site, and announcement at department meetings | Lucy Camerena and Mike Sundby | July 1, 2007 |
| Project team | Weekly status report | Short meeting | All team members | Tues. afternoons at 2:00. |

# Comments & Guidelines

Employees must contact their HR representee if they wish to talk with the project team. The HR representee must approve all communications within three business days or those requests would be voided. Employees can always make a second request.

Only the project manger can contact the steering committee.

Both the Project sponsors and Streeting committee can contact the project manager. Employees will have no contact with the project manager, unless the project manager permits it.

# Escalation procedures for resolving issues

The Escalation procedures is as follows:

* Employees contact their department’s project representative
* If needed, the project representative can request help from other project members or escalate the issue to the project manger

# Revision procedures

The project manger has the sole authority to make any changes to this document. However, 2/3 majority of project sponseros and sterring comitte members can force a revision to this document.