QA Doc

Release 2.0

Validation Plan

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1.0 Purpose

The purpose of this validation plan is to define the validation activities for Release 2.0 for the QA Doc system. The goal of validation is to provide evidence that the system meets intended use.

2.0 Project Scope

The scope of this project is to provide an enterprise-wide, common content management solution to manage Quality Documents and Records for any Medtronic business, facility, or location. This system will be based on the existing QA Doc system. To minimize total cost of ownership, we will utilize a global instance which meets critical requirements, upgrade the solution to a supported version and deploy the web based client. The Key features of this system are:

- Meet compliance requirements requested by Medical Device Industry
- Support document management process needed to achieve business objectives
- Provide accessibility to the approved documents

3.0 Abbreviations Acronyms and Definitions

Refer to the MSVM Glossary for a list of validation terms and definitions. Refer to the ECM Glossary for a list of system and/or project terms.

4.0 References

The following referenced documents are stored in the GBS Quality System.

Documentum ID	Document Title
47860-ECM Glossary	ECM Glossary
MITSS0046-27589	MSVM Process
MITSS0046-26630	MSVM Policy
MITSS0046-27590	MSVM Validation Planning Process
MITSS0046-27591	MSVM Validation Reporting Process
MITSS0046-27593	MSVM Business Impact Analysis
MITSS0046-27594	MSVM Change Management
MITSS0046-27596	MSVM Configuration Management

MITSS0046-27600	MSVM Failure Analysis
MITSS0046-27601	MSVM Phase Review
MITSS0046-27603	MSVM Release Management
MITSS0046-27604	MSVM Requirements Management
MITSS0046-27605	MSVM Support
MITSS0046-27606	MSVM Testing
MITSS0046-27607	MSVM Traceability
MITSS0046-27608	MSVM Training
MITSS0046-27609	MSVM Vendor Management
MITSS0046-27610	MSVM Glossary
MITSS0046-28188	MSVM Assessment
MITSS0003-28757	IT Project Management SOP
MITSS0046-27602	MSVM Project Coordination
MITSS0046-27595	MSVM Code Review
MITSS0046-27597	MSVM Data Management
MITSS0046-27598	MSVM Design
MITSS0046-27599	MSVM Development Standards

5.0 Process

This validation follows the methodology described in the Medtronic System Validation Methodology (MSVM) Process.

6.0 Project Type Definition

This section identifies the project type that was identified for this project. The corresponding MSVM assessment was executed to determine the required and recommended activities.

- QA Doc Release 2.0 is classified as a new system because the software package being used is an upgrade to an existing software package Medtronic currently uses to manage marketing materials. From the vendor perspective the software is an upgrade, but to Medtronic the software is new.

7.0 Validation Activities

The following MSVM Activities are the result of an output from the MSVM Assessment Tool: Tool Version: B1.0.35 2007-02-16; Content Version: MITSS0046-28188 Version 2.0, 2007-06-01. This activities output is attached in Appendix B: MSVM Activities List for QADoc.

The following table describes documented evidence, to be used as proof, of required MSVM activities. The following activities are required and recommended validation activities which may be combined, as needed, into key documents.

Roles and responsibilities for each activity will be provided in the evidence of the activity. If the roles and responsibilities are not included in the evidence they must be documented in the table below with the corresponding activity.

If the activities are not executed in the order listed, rationale will be provided in the validation report.

Order of Execution	Inputs	Activity	Evidence Of Activity	Approvers
1.	Request Business Process Needs	Validation Planning Validation Planning : Approval - Business Unit sponsor or delegate approve validation plan	DOCUMENT: Validation Plan (This Document)	Project Manager Business Sponsor IT Sponsor Quality Representative
2.	Validation Plan	Project Coordination	DOCUMENT: Project Coordination	Project Manager IT Sponsor
3.	Validation Plan	Change Management	DOCUMENT: Approved 49284-CRDM IT ECM Team Org CM Strategy	N/A
4.	MSVM Test Assessment	Testing: Planning	DOCUMENT: Test Plan DOCUMENT: Test Report	Test Lead Technical Lead Quality Representative
5.	Validation Plan	21 CFR Part 11 Questionnaire	DOCUMENT: 21 CFR Part 11 Assessment	Business Sponsor IT Sponsor Part 11 Representative

6.	Validation Plan	Vendor Management	DOCUMENT: DCTM Approved 49291-DCTM Vendor Assess Report DOCUMENT: TSG Vendor Assessment Report	IT Sponsor Quality Representative
7.	21 CFR Part 11 Questionnaire	Requirements Management Requirements Management : for electronic records and/or signatures, based on compliance jurisdiction Requirements Management: Approval – Compliance SMEs for Requirements Requirements Management: Approval – Business Unit Sponsor or delegate approve requirements Requirements Management: Approval – System Architect or Technical Lead approve requirements Phase Review: Analysis	DOCUMENT: System Requirements Specification	Business Sponsor Project Manager IT Business Analyst Quality Representative
8.	System Requirements Specification	Business Impact Assessment	DOCUMENT: Business Impact Analysis	Business Sponsor Project Manager IT Business Analyst
9.	System Requirements Specification	Failure Analysis	DOCUMENT: Failure Analysis	Business Sponsor Project Manager IT Business Analyst

10.	System Requirements Specification Phase Review: Analysis Business Impact Assessment Failure Analysis	Design Design: Approval – System Architect or Technical Lead approve Design Phase Review – Design	DOCUMENT: System Design Document	Project Manager IT Business Analyst Lead Developer Architect
11.	System Design Document	Data Management	DOCUMENT: Migration Plan	Business Sponsor Migration Lead IT Business System Analyst
12.	System Requirements Specification	Configuration Management Release Management	DOCUMENT: Approved System Management Plan (41495-Documentum SMP)	N/A
13.	System Design Document	Development Standards	DOCUMENT: Approved Development Standards (59592-Development Standards)	N/A
14.	System Design Document	Code Review Phase Review: Construction	DOCUMENT: Approved Code Review Plan (59827-Code Review Plan) DOCUMENT: Code Review Report	Lead Developer Quality Representative IT Sponsor
15.	System Requirements Specification	Traceability	DOCUMENT: Traceability Matrix	Test Lead Quality Representative
16.	System Requirements Specification System Design Document	Testing : Unit Test Testing : Integration Test	DOCUMENT: Unit & Integration Summary	Test Lead Lead Developer Quality Representative
17.	Traceability	Testing: System Test	RECORD: Test Results In QC: ECM_QADOC	Test Lead Quality Representative

18.	Test Results In QC: ECM_QADOC	Testing : User Acceptance Test	DOCUMENT: Business Scenarios Executed By Subject Matter Experts – Stored In GBSRCS	Test Lead Business SME
19.	Business Scenarios Executed By Subject Matter Experts – Stored In GBSRCS	Phase Review : Pre-Implementation Phase Review: Approval – Business Unit Sponsors or delegate approve pre-implementation phase review Phase Review: All phases in defined life cycle Phase Review : Approval - Interfacing System representative approve pre-implementation review	DOCUMENT: Pre-Implementation Phase Review	Business Sponsor Project Leader IT Business Analyst IT Sponsor Interfacing System Representative
20.	Implementation Phase Review	Testing : Operability Test	DOCUMENT: Installation Qualification Plan DOCUMENT: Installation Qualification Report	Eapps Enterprise Support Quality Representative
21.	Change Management	Training Training: for electronic records and/or signatures, based on compliance jurisdiction	DOCUMENT: Training Plan	Business Sponsor IT Sponsor Project Leader
			RECORD: Training Records In Saba	N/A
22.	System Requirements Specification	Support	DOCUMENT: Approved 49272-Documentum Systems High-Level Support Plan	N/A
23.	Implementation Phase Review	Validation Report	DOCUMENT: Validation Report	Business Sponsor IT Sponsor Project Leader Quality Representative

7.1 Excluded Activities

The following recommended activities will not be performed for this validation for the reasons indicated:

Recommended MSVM Activity	Rationale for Exclusion
Not applicable	

8.0 Validation Compliance Scope

The following compliance decisions are supported by an output from the MSVM Assessment Tool: MSVM Assessment and Risk, which is attached in the Appendix A: MSVM Assessment and Areas of Risk.

Regulation	Decision	Rationale for Scope Decision
Quality System	In Scope	The system will be used for approving marketing materials. Marketing materials are defined as labeling.
Electronic Records and Signatures (Part 11)		
Privacy / HIPAA	Out of Scope	Privacy/HIPAA data is owned by the Business units and will not be stored in this system. Not Impacted by HIPAA
SOX	Out of Scope	The system does not contain any financial data, nor interface with any Medtronic financial systems.

9.0 Risk Management

Risk management is integrated within each MSVM procedure. The MSVM assessment identified Areas of Risk that will be addressed by performing the validation activities identified by the MSVM Assessment (see appendix A).

The software package being used is an upgrade to an existing software package Medtronic currently uses to manage marketing materials. From the vendor perspective the software is an upgrade, but to Medtronic the software is new, however the technology that the software uses is used widely throughout the world and is considered to be low risk overall.

9.1 Other Risks

This section identifies any areas of validation risk that were not identified by the MSVM assessment.

9.1.1 There are no other areas of validation risk identified.

10.0 Maintaining the Validated State

An MSVM assessment with a Project Type of System Enhancement has been completed for future configuration deployments of the system. If no requirements are added, revised or deleted a Project Type of System Maintenance will need to be executed accordingly.

Review Appendix C: MSVM QADoc Assessment and Areas of Risk- QA Doc Configurations to verify that the answers are valid for the deployment being performed. If there are any differences a new MSVM Assessment with a Project Type of System Enhancement will need to be executed and the results documented in this section and the outputs attached.

The following MSVM Activities are the result of an output from the MSVM Assessment Tool: Tool Version: B1.0.35 2007-02-16; Content Version: MITSS0046-28188 Version 2 2007-06-01. The output of the assessment is attached in Appendix C: MSVM QADoc Assessment and Areas of Risk- QA Doc Configurations. The activities output is attached in Appendix D: MSVM Enhancement Activities.

Roles and responsibilities for each activity will be provided in the evidence of the activity. If the roles and responsibilities are not included in the evidence they must be documented in the table below with the corresponding activity.

If the activities are not executed in the order listed provide rationale in the configuration report.

Order of Execution	Input	Activity	Evidence of Activity	Approvers
1.	Request Business Process Needs	Validation Planning	DOCUMENT: Validation Plan (This Document)	Project Manager Business Sponsor IT Sponsor Quality Representative
2.	Validation Plan	Project Coordination	DOCUMENT: Project Coordination	N/A
3.	Validation Plan	Change Management	DOCUMENT: Approved 49284-CRDM IT ECM Team Org CM Strategy	N/A
4.	Validation Plan	21 CFR Part 11 Questionnaire	DOCUMENT: 21 CFR Part 11 Assessment	Business Sponsor IT Sponsor Part 11 Representative

Order of Execution	Input	Activity	Evidence of Activity	Approvers
5.	Validation Plan	Configuration Management Requirements Management Requirements Management : Approval - Business Unit Sponsor or delegate approve requirements Requirements Management : for electronic records and/or signatures, based on compliance jurisdiction Requirements Management : Approval - Compliance SMEs for Requirements Phase Review : Analysis	DOCUMENT: Configuration Plan	Business Sponsor IT Sponsor Project Manager
6.	Configuration Plan	Business Impact Assessment	DOCUMENT: Business Impact Analysis	N/A
7.	Configuration Plan	Failure Analysis	DOCUMENT: Failure Analysis	N/A
8.	Configuration Plan	Release Management Design Phase Review : Design	DOCUMENT: Configuration Design	Business Sponsor IT Sponsor Project Manager
9.	Configuration Design	Data Management	DOCUMENT: Migration Plan DOCUMENT: Migration Report	
10.	Configuration Plan Configuration Design	Traceability	DOCUMENT: Traceability Matrix	Test Lead Quality Representative

Order of Execution	Input	Activity	Evidence of Activity	Approvers
11.	Configuration Design	Testing: Operability Test	DOCUMENT: Installation Qualification Plan DOCUMENT: Installation Qualification Report	Business Sponsor IT Sponsor Project Manager
12.	Configuration Design	Testing: System Test	RECORD: Test Results In QC: ECM_QADOC	Business Sponsor IT Sponsor Project Manager
13.	Test Results In QC: ECM_QADOC	Phase Review: Pre-Implementation Phase Review : Approval - Business Unit Sponsors or delegate approve pre-implementation phase review Phase Review : Approval - Interfacing System representative approve pre-implementation review Phase Review : All phases in defined lifecycle model	DOCUMENT: Pre-Implementation Phase Review	Business Sponsor IT Sponsor Project Manager
14.	Implementation Phase Review	Testing: User Acceptance Test	DOCUMENT: Business Scenarios Executed By Subject Matter Experts – Stored In GBSRCS	Business Sponsor
15.	DOCUMENT: Business Scenarios Executed By Subject Matter Experts – Stored In GBSRCS	Training Training: for electronic records and/or signatures, based on compliance jurisdiction	DOCUMENT: Training Plan	Business Sponsor IT Sponsor Project Leader
			RECORD: Training Records In Saba	N/A
16.	Implementation Phase Review	Support	DOCUMENT: Approved 49272-Documentum Systems High-Level Support Plan	N/A

Order of Execution	Input	Activity	Evidence of Activity	Approvers
17.	Business Scenarios Executed By Subject Matter Experts – Stored In GBSRCS	Validation Reporting	DOCUMENT: Configuration Report	Business Sponsor IT Sponsor Project Manager

11.0 Validation Planning Evidence

Validation documentation will be stored in the Global Business Solutions Records Control System (GBSRCS) Repository:

- http://gbsrcs.medtronic.com

When this document is imported into GBSRCS and unique identifier was assigned to it:

- **60166-QADoc Validation Plan**

Per the validation performed for the GBSRCS, this document is approved and controlled to prevent changing it without versioning it.

12.0 Approval

The act of approving signifies that the Approver has knowledge of, and agrees with the content of the document. Electronically signed via GBSRCS by the following:

Name	Role	Intent of Signature
Rick Kalgren	IT Sponsor	Understands and agrees with the IT components specified in this document
Dawn Brekke	QA Representative	Document content and the impact of the validation efforts on business and compliance deliverables are understood
Bernard Schmidt	Business Sponsor	Understands and agrees with the business components specified in this document
Sanjeev Bindra	Project Manager	Issuer of document

13.0 Document History

Date	Version	Author	Reason for changes
9/18/2008	2.0	Ben Robbins	Initial document release

Appendix A: MSVM Assessment and Areas of Risk

Project Name	**QADoc Rel 2.0**
Assessment Completed By	**Ben Robbins**
Assessment Completion Date	**2008-09-16**

Project Type
New System Implementation

Unique Question	Project Activity	Response
2	Off the Shelf implementation?	Yes
3	Configuration?	Yes
4	Development?	Yes
5	Infrastructure?	Yes

Unique Question	Compliance - Product	Response
6	Is the system going to be used in the practice of medicine to treat patients?	No
9	Will the system be used to make clinical or medical judgements to treat patients?	No
12	Is the system a medical device or part of a medical device that will be used to treat patients?	No
15	Does the system directly affect any of the following: labeling, manufacturing, release, or distribution of medical product?	Yes
18	Does the system provide evidence of medical product quality (e.g. strength, durability, identity, efficacy, reliability, purity, or sterility) that may be evaluated or required by external bodies?	Yes

Unique Question	Compliance - Training	Response
19	Will the system introduce or change business policies, procedures, or processes?	Yes
20	Are the business policies, procedures, or processes that govern project or system activity new to those that develop, design, deploy, support, maintain, or use the system?	No

Unique Question	Compliance - Electronic Records & Signatures	Response
22	Does the system manage, create, modify, maintain, retrieve or transmit electronic records or use electronic signatures?	Yes
23	Are system records ever submitted to the FDA ?	Yes
24	Are system records used to support compliance to any FDA regulations?	Yes
25	Do system records provide evidence of or support product quality for U.S. Markets?	Yes

Unique Question	Compliance - Privacy	Response
26	Does the system process personal data identifiers? Process means to collect, store, use, disclose, record, organize, adapt, alter, correct, retrieve, combine, block, erase, transfer or destroy.	No

Unique Question	Compliance - Business Conduct	Response
28	Does the system create, manage, record, or use information about relationships with Medtronic Customers ?	No

Unique Question	Compliance - Financial Accountability	Response
30	Does the system interface with the Global Financial System?	No
32	Does the system interface with SAP Financial or any other legacy financial system?	No
34	Is the system or data used to calculate any figures that are manually recorded in MDT's balance sheet or income statement? (e.g. commissions, accruals, allowances, etc.) (Involve local SOX champion to verify answer)	No

Unique Question	Complexity - System	Response
36	Will the system add to, modify, or delete data used by another system?	Yes
37	Will this be a distributed system? A distributed system is defined as several interconnected computers share computing tasks assigned to the system.	Yes
38	Will the system implementation require code or configuration changes in another	No

	system?	
41	Will the system share an environment with another system?	Yes
42	Will more than one Medtronic Business Unit use the system?	Yes
43	Are the system technical requirements complex per the system architect and technical lead?	Yes
45	Is the technology used in the development, design, deployment, support, maintenance of the system new to those involved in those activities?	Yes
46	Will data be converted/migrated from an existing source to this system?	No
51	Is the system intended for use in more than one country?	Yes

Unique Question	Complexity - Business	Response
48	Is the system intended for use by more than one person?	Yes
49	Are the system business requirements complex per the business sponsor ?	Yes
50	Is the purpose of the system critical to business operation per the business sponsor?	Yes

Unique Question	Complexity - Project	Response
52	Will more than one Medtronic Business Unit sponsor the project activity?	Yes
53	Will more than one Medtronic Business Unit validate the system?	Yes
54	Will more than one Medtronic independently-managed team design the system or portions of the system?	No
239	Will more than one Medtronic independently-managed team develop or implement the system or portions of the system?	No
56	Will a non-Medtronic entity design the system or portion of the system?	No
57	Will a non-Medtronic entity develop/construct the system or portion of the system?	No
58	Will a non-Medtronic entity host and/or support the system or portion of the system?	No
59	Will another Medtronic Business Unit host and/or support the system or portion of the system?	No
60	Will a non-Medtronic entity validate the system or portion of the system?	No
61	Will a non-Medtronic entity provide system training or portion of system training?	No

62	Is the project team geographically distributed across multiple time zones or countries?	No

Appendix B: MSVM Activities List for QADoc

Required	Requirements Management
Required	Validation Planning : Approval - Business Unit sponsor or delegate approve validation plan
Required	Validation Planning
Required	Validation Reporting
Required	Change Management
Required	Phase Review : Pre-Implementation
Required	Vendor Management
Required	Release Management
Required	Testing : System Test
Required	Testing : Operability Test
Required	Code Review
Required	Development Standards
Required	Testing : Unit Test
Required	Testing : Integration Test
Required	If this is an Infrastructure project ONLY, the Phase Reviews that may be listed are NOT expected to be performed. This will be performed by the systems using the Infrastructure.
Required	If this is an Infrastructure project ONLY, Testing: User Acceptance Testing is NOT expected to be performed. This will be performed by the systems using the Infrastructure.
Required	Configuration Management
Required	Testing : User Acceptance Test
Required	Requirements Management : Approval - Business Unit Sponsor or delegate approve requirements
Required	Phase Review : Approval - Business Unit Sponsors or delegate approve pre-implementation phase review
Required	Phase Review : Analysis
Required	Phase Review : Design
Required	Business Impact Assessment
Required	Project Coordination
Required	Support
Required	Data Management
Required	Design
Required	Traceability
Required	Training
Required	Failure Analysis
Required	Requirements Management : for electronic records and/or signatures, based on compliance

Required	Requirements Management
Required	Training : for electronic records and/or signatures, based on compliance jurisdiction
Required	21 CFR Part 11 Questionnaire : http://sitebuilder.medtronic.com/ccra/part11/default.aspx
Recommended	Requirements Management : Approval - System Architect and Technical Lead approve requirements
Recommended	Phase Review : Approval - Interfacing System representative approve pre-implementation review
Recommended	Design : Approval - System Architect or Technical Lead approve Design
Recommended	Requirements Management : Approval - Compliance SMEs for Requirements
Recommended	Phase Review : Construction
Recommended	Phase Review : All phases in defined lifecycle model

Appendix C: MSVM QADoc Assessment and Areas of Risk- QA Doc Configurations

Project Name	QA Doc Rel. 2.0 Configurations
Assessment Completed By	Ben Robbins
Assessment Completion Date	2008-09-16

Project Type
System Enhancement

Unique Question ID	Project Activity	Response
65	Off the Shelf implementation?	No
66	Configuration?	Yes
67	Development?	No
68	Infrastructure?	No

Unique Question ID	Compliance - Product	Response
69	Is the system used in the practice of medicine to treat patients?	No
71	Is the system used to make clinical or medical judgements to treat patients?	No
73	Is the system a medical device or part of a medical device that are used to treat patients?	No
75	Does the system directly affect any of the following: labeling, manufacturing, release, or distribution of medical product?	Yes
77	Does the system provide evidence of product quality (e.g. strength, durability, identity, efficacy, reliability, purity, or sterility) that may be evaluated or required by external bodies?	Yes

Unique Question ID	Compliance - Training	Response
78	Will the system enhancement introduce or change business policies, procedures, or processes?	Yes
79	Are the business policies, procedures, or processes that govern project or system activity new to those that develop, design, deploy, support, maintain, or use the system?	Yes

Unique Question ID	Compliance - Electronic Records & Signatures	Response
81	Does the system enhancement affect the requirements for electronic records and signatures?	Yes
82	Are system records ever submitted to the FDA ?	Yes
83	Are system records used to support compliance to any FDA regulations?	Yes
84	Do system records provide evidence of or support product quality for U.S. Markets?	Yes

Unique Question ID	Compliance - Quality System: Electronic Records & Signatures	Response
Unique	Compliance - Privacy	Response
85	Does the system enhancement affect requirements for processing personal data identifiers? Process means to collect, store, use, disclose, record, organize, adapt, alter, correct, retrieve, combine, block, erase, transfer or destroy.	No

Unique Question ID	Compliance - Business Conduct	Response
86	Does the system enhancement affect requirements for creating, managing, recording, or using information about relationships with Medtronic Customers?	No

Unique Question ID	Compliance - Financial Accountability	Response
87	Does the system enhancement affect interface requirements with the Global Financial System?	No
88	Does the system enhancement affect interface requirements with SAP financial or any other legacy financial system?	No
89	Does the enhancement impact financial system or data calculations that are manually recorded in MDT's balance sheet or income statement? (e.g. commissions, accruals, allowances, etc.) (Involve local SOX champion to verify answer)	No

Unique Question ID	Complexity - System	Response
90	Does the system enhancement add to, modify, or delete data used by another system?	Yes

91	Does the enhancement affect the design of a distributed system? A distributed system is defined as several interconnected computers share computing tasks assigned to the system.	No
92	Will the system enhancement require code or configuration changes in another system?	Yes
93	Will the system enhancement affect data exchange with another system?	No
94	Will the system enhancement add to, modify, or delete data used by another system?	Yes
95	Does the system share an environment with another system?	Yes
96	Will more than one Medtronic Business Unit use the system?	Yes
97	Does the system enhancement have complex technical requirements per the system architect and technical lead?	No
99	Is the technology used in the development, design, deployment, support, maintenance of the system enhancement new to those involved in those activities?	No
100	Does the enhancement require data to be converted/migrated from an existing source to this system?	Yes
101	Will the enhancement cause data format changes within the system?	No
105	Is the system intended for use in more than one country?	Yes

Unique Question ID	Complexity - Business	Response
102	Is the system intended for use by more than one person?	Yes
103	Are the system business requirements for the enhancement complex per the business sponsor?	No

Unique Question ID	Complexity - Project	Response
106	Will more than one Medtronic Business Unit sponsor the project activity?	Yes
107	Will more than one Medtronic Business Unit validate the system?	No
108	Will more than one Medtronic independently-managed team design the system enhancement or portions of the system enhancement?	No
240	Will more than one Medtronic independently-managed team develop or implement the system enhancement or portions of the system enhancement?	No
110	Will a non-Medtronic entity design the system enhancement or portion of the system enhancement?	No
111	Will a non-Medtronic entity develop/construct the system enhancement or portion of the system enhancement?	No
112	Will a non-Medtronic entity host and/or support the system or portion of the system?	No

113	Will another Medtronic Business Unit host and/or support the system or portion of the system?	No
114	Will a non-Medtronic entity validate the system or portion of the system?	No
115	Will a non-Medtronic entity provide system training or portion of system training?	No
116	Is the project team geographically distributed across multiple time zones or countries?	Yes
172	Does the System Enhancement Activity involve change of vendor?	No

Appendix D: MSVM Enhancement Activities

REQ/REC	Activity
Required	Requirements Management
Required	Requirements Management : Approval - Business Unit Sponsor or delegate approve requirements
Required	Validation Planning
Required	Validation Reporting
Required	Change Management
Required	Phase Review : Pre-Implementation
Required	Release Management
Required	Testing : System Test
Required	Testing : Operability Test
Required	Configuration Management
Required	Testing : User Acceptance Test
Required	Phase Review : Approval - Business Unit Sponsors or delegate approve pre-implementation phase review
Required	Phase Review : Analysis
Required	21 CFR Part 11 Questionnaire : http://sitebuilder.medtronic.com/ccra/part11/default.aspx
Required	Business Impact Assessment
Required	Project Coordination
Required	Support
Required	Data Management
Required	Design
Required	Traceability
Required	Training
Required	Failure Analysis
Required	Requirements Management : for electronic records and/or signatures, based on compliance jurisdiction
Required	Training : for electronic records and/or signatures, based on compliance jurisdiction
Recommended	Phase Review : Approval - Interfacing System representative approve pre-implementation review
Recommended	Phase Review : Design
Recommended	Requirements Management : Approval - Compliance SMEs for Requirements
Recommended	Phase Review : All phases in defined lifecycle model