Medtronic

	CONFIDENTIAL	DOCUMENT/RECORD

Name	Version	Author
DOC-00000010	3.0	

Title: sdfsadfsdf

QA Type	QA Subtype	Training Type

APPROVALS

Signed By	Meaning of Signature	Date/Time (UTC)
Hanson, Michael	Doc Control Approval	11/26/2008 9:39:31 PM
smoqaapprover1	QA Approval Admin	11/26/2008 9:43:57 PM

QADoc Site specific Requirement Questions

Requirements for the base QADoc system are documented in the QADoc SRS. Several of the requirements will be different based on the decisions made for the specific sites.   Migration will be handled separately for each implementation in a Migration Plan.

GROUPS

What functional groups do you have that will be involved in Approvals? (e.g. Manufacturing Engineer, Quality Assurance, etc).

General Approver
Manufacturing Approver
QA Approver

Who should initially be placed in each group? (may require a spreadsheet)

Test accounts. svc-dctmtest1-svc-dctmtest?

FOLDERS

What is the folder structure that should be in place at migration? (this question may be skipped if it is detailed in the migration plan)

Quality Documents
        POD
        EQP
Quality Records
        Training Records
        Other Records

Who should have access to create folders?
Admins and Authors

DOCUMENTS

What document naming convention should be used?

If Quality Doc Lifecycle is applied, do a QAD prefix + 6 digit sequence. If Quality Record lifecycle is applied, do a QAR + 6 digit sequence.

Is that possible? If not let me know and I'll come up with something else.

Is there any need for supporting documents that have no lifecycle?

Yes. They should be named SUP prefix + 6 digit sequence. No lifecycle should be attached. Admins have DELETE, Authors have VERSION , others have READ.

PROPERTIES

Will different documents in your system require different properties in addition to what is outlined in the SRS?   What additional properties are required? Note: You may have more than one document type here, for example, you may have a 'Policy Document' that has an additional 'Policy ID' property, and you may have a 'Process Document' that has additional 'Input' and 'Output' properties.

What initial values should be populated in the drop down lists for properties?

Process document. Should have "Input Process" (repeating), "Output Process (repeating) and Process Metrics (repeating)

SECURITY

Which groups should have view access to previous versions of effective/approved documents?
Admin and authors – READ, others NONE

Which groups should have view access to obsolete documents?
Admin – READ, others NONE

APPROVALS

What approval types will be used? For each approval type, who/how may approves? What additional property information should be gathered (e.g. justification of change, supporting attachments, etc)? Note: We are currently using a spreadsheet on the support site to capture this detail.

General approval – should allow user to add "Days Until Effective" and "Reason for Change". Should allow any number of approvers to be added from any group.

POD Approval - should allow user to add "Days Until Effective" and "Reason for Change". Should require two Manufacturing Approvers, one QA approver, and the option to add any other approvers.

Process Approval – should allow user to add "Days Until Effective" and "Process Category". Should require QA Approval, and the option to add any other approvers.

OBSOLETIONS

Who should approve an obsoletion? What additional property information should be gathered at the time of obsoletion?

QA Approver must approve obsoletion, with the option to add any other approver. Require a 'reason for obsoletion'.

WEB PUBLISHING

Will documents published at your site need to be accessible from Factoryworks?

Yes.

What property information should be displayed on the e-sig page of documents that are published to the website?

Name, Title, Owner, Version, Effective Date and QA Type

What property information should be displayed on each page of the published document?
Name, Title, Owner, Version, Effective Date and QA Type