Create and Maintain Document and Part Structure

Create and Maintain Document and Part Structure

1.0 PURPOSE

This procedure defines the requirements for creating and maintaining a document and part structure in Windchill.

2.0 REFERENCES

2.1 Applicable Documents

Number	Title
86324	BOM Import
87118	Guide to Create and Maintain Document and Part Structure
90005305	Design History File (CATD)
90048428	Creating and Updating SAP Routing (CATD)
90117822	Structure/Routing Creation Form (CATD)
90138671	Device Master Record (CATD)
90143293	IR Creating and Updating SAP Routing (CATD)
50-0131	Device Master Record (NMD)
56-0369	Creating and Maintaining the Design History File (NMD)
56-8102	Routing Traveler Process- Portland Only (NMD)

2.2 External References

Number	Title
N/A	N/A

3.0 RESPONSIBILITIES

Function or Title	Responsibility
Creator/Editor (C/E)	Creates and updates structure.
Manufacturing Engineering/ Process Development (ME/ PD)	Assist C/E to correctly develop product structure.
Quality Engineering/ Development Quality (QE/DQ)	Assist C/E to correctly develop product structure based upon the Design History File.
Quality Systems	Assist C/E to correctly develop quality system structure.

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4.0 DEFINITIONS

Term	Definition
Additional Relationship	An object at the same level as the associated object.
Design History File (DHF)	See One SJM Glossary 86056 for definition.
Device Master Record (DMR)	See One SJM Glossary 86056 for definition.
Document Object	An object that consists of primary content (e.g., Word document, Excel file) for a controlled document.
Groupings	An object that groups certain like objects.
Object	A document, part, ECR, CO, CA, etc., that is identified and retained in Windchill.
Obsolete	A lifecycle state where the object is identified as no longer being used.
Quality Systems Structure	The association of documents related to the Quality Management System.
Part Object	A part controlled in Windchill.
Product Structure (DMR)	The association of objects related to building the device.
Product Family Group	A grouping of parts and documents that form a structure that is specific to a Product.
Recursive Structure	When a child object is structured to a parent object and the parent object is structured to the same child object.
Routing	A user defined SAP form generated to track manufacturing operational steps.

5.0 FLOW CHART

N/A

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6.0 REQUIREMENTS

6.1 Structure Types

Step	Action
1	The following are types of structure that are maintained:

Structures Types	
Quality Systems Structure	Applicable for quality systems related documents.
Product Structure (DMR)	Applicable to the creation and/or update to manufacturing related documents and product/part specifications.
Device Master Record (DMR)	Applicable for the organization of quality records and documents that are part of Device Master Record.
Design History File (DHF)	Applicable for the organization of quality records and documents that are part of Design History Files.

6.2 General Structure

Step	Action

1	Any new structure or changes to existing structure are defined and communicated on a Change Order.
	• Item structures shown in the remainder of this document are part of the above types of structure. Created as an object, updated and maintained within the respective libraries.
	• These instructions are for objects that are at a Released (alpha) status. Items at Pre-Released (numeric) status may not have a complete structure so the configurations may vary.
	• Recursive structuring is not allowed. User should check for recursive structuring. If error exists, Windchill will display WARNING: Recursive found.
	• Structures may be viewed from both directions.
	  ○ From the parent object, click on the Structure tab and then expand the structure to view children.
	  ○ From the child object, click on the Related Objects tab to view parents located in the Where Used section.
	• Children objects may be released as an orphan prior to the release of the parent object. Structure should be created at the time of releasing the parent object.
	• Sibling Relationship is structuring a sibling object to another object. This structure is created from the Additional Relationships Tab of an object.

6.2 General Structure

Step	Action

	• To create new structure, choose one of the following:
	  ○ Create the structure in Windchill
	  ○ Import from a BOM Import Form
	  ▪ Assign Change Activity task to Doc Services to import BOM.
	• For changes to existing structure
	  ○ Update the structure in Windchill
	• For Non-Rev Change Order, choose one of the following:
	  ○ Complete the Structure/Routing Creation Form
	  ○ Attach redlines of the currently approved structure
	  ○ Add changes to the Description field

6.3 Parent/Child Relationship

Step	Action
1	To create a parent/child relationship for any document or part object, navigate to the Details page of the parent.

2	Follow Appendix A: Structure Requirements
	• **Document Type**
	  ○ Windchill main document type that houses the Sub Type.
	• **Parent**
	  ○ Windchill Document Sub-Type. Object to create the structure from.
	• **Child/Associated Documents**
	  ○ Child or associated document that will be linked to the parent object.
	• **Structure, Reference Documents, Additional Relationships**
	  ○ Types of relationships that will be created by structuring a child or associated document to a parent object. Tab in Windchill in which the relationship can be viewed.
	• **DMR requirements**
	  ○ Item will display in DMR Report. Items checked must be structured as indicated.

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6.4 Document to Document Structure

Step	Action
1	Document to Document structure is created on the Structure tab. • Documents can be structured using either the Quality System Structure or the Product Structure (DMR) but not both.
2	Parent document can only have children structured to them with the same state or higher. • A Released document cannot have a Pre-Released document structured underneath it.
3	Parent documents can only have children structured to them with the same document hierarchy level or lower. • Work Instruction should not have a Standard Operating Procedure structured underneath it.
4	• If the Parent will be set to Inactive or Obsolete, the structure may remain in place. • If the Child will be set to Inactive or Obsolete, the inactive or obsolete child must be removed from the structure.

6.5 Part to Part Structure

Step	Action
1	Part to part structure is created on the Structure tab. • Parent part can only have children structured to it with the same state or higher • A Released part should not have a Pre-Released part structured underneath it.
2	Parent part can only have children structured to it with the same type or lower based on part hierarchy. • Part ZSMI should not have a ZFIN structured underneath
3	Substitute Part is: • Equivalent part (fully interchangeable) used to replace another part in an assembly. • Linked to the part it is substituting through the Manage Replacement menu selection of the part it is replacing. • Windchill Substitute Parts are equivalent to SAP Alternate Parts. **NOTE: Do not use the Windchill Alternate Parts section due to SAP integration.**

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6.6 Structure – Related Objects Tab

Step	Action
1	**Reference Documents** Reference Documents relationships are created by structuring a child document to a parent document or part object.
2	**Described By Documents** Described By Documents relationships are created by structuring a material specification to the part object. **NOTE: This approach is not recommended as it creates a one to one relationship that has to be re-created every time the part object is revised.**

6.7 Structure - Additional Relationships Tab

Step	Action
1	**Additional Relationships** Additional Relationships are created for sibling objects for a part or document object.

6.8 Quality Systems Configuration

Step	Action
1	For Quality System procedures the following structuring rules apply: • This is a document to document structure • Documents listed in the Applicable Documents section must be structured with the exception of Quality Plans/Reports. • External References and References Documents shall not be structured to the document. • For QS documents moving to Obsolete – structure must be removed. • For QS documents moving to Inactive – structure should remain in place.

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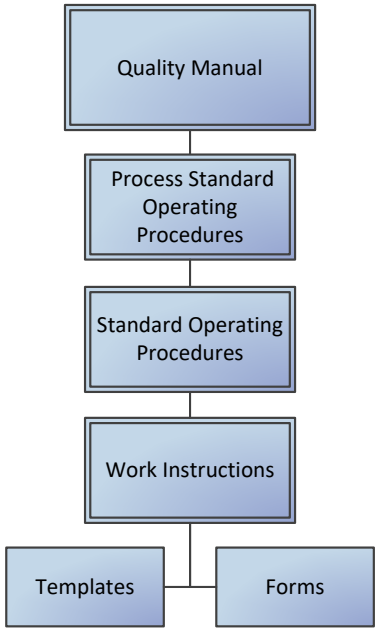
6.8 Quality Systems Configuration

Step	Action	
2	Configuration (hierarchy) of Quality System documents	

7.0 APPENDICES

Appendix A: Structure Requirements

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APPENDIX A: STRUCTURE REQUIREMENTS

Document Type	Parent	Child/Associated Document	**Structure** (Structure Tab)	**Reference Documents** (Related Objects Tab)	**Additional Relationships** (Additional Relationships Tab)	**DMR** requirements
Quality System	Process Standard Operating Procedure	Standard Operating Procedure	X			
Quality System	Quality Manual	Process Standard Operating Procedure	X			
		Standard Operating Procedure	X			
Quality System	Quality Report	Quality Plan	X			
Quality System	Quality System Work Instruction	Form	X			
		Guidance	X			
		Manufacturing Work Instruction	X			
		Quality System Work Instruction	X			
		Template	X			
		Reference	X			
Quality System	Standard Operating Procedure	Form	X			
		Guidance	X			
		Quality System Work Instruction	X			
		Template	X			
		Reference	X			
CAPA	CAPA Closure	CAPA Document Type			X	
	CAPA History File				X	
	CAPA Extension Request				X	
	CAPA File Document				X	
	CAPA Request				X	
	CAPA Risk Assessment				X	
	CAPA VoE				X	
	Risk Indicator Review				X	
Manufacturing	Inspection Procedure	Form	X			X
Manufacturing	Manufacturing Procedure	Equipment / Tooling / Fixture	X			X
		Equipment Specification	X			X
		Form	X			X
		Inspection Procedure	X			X
		Manufacturing Procedure	X			X
		Manufacturing Work Instruction	X			X

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Document Type	Parent	Child/Associated Document	**Structure** (Structure Tab)	**Reference Documents** (Related Objects Tab)	**Additional Relationships** (Additional Relationships Tab)	**DMR** requirements
		Quality Service Specification	X			X
		Visual Standard / Aid	X			X
		Process Specification	X			X
Manufacturing	Manufacturing Quality Report	Manufacturing Quality Plan	X			
Manufacturing	Manufacturing Work Instruction,	Equipment / Tooling / Fixture	X			X
		Equipment Specification	X			X
		Form	X			X
		Manufacturing Work Instruction,	X			X
		Process Specification	X			X
		Quality Service Specification	X			X
		Reference Figure	X			X
Misc Production	Risk Management Report	Risk Management Plan	X			
Misc Production	Training Document	Manufacturing Work Instruction,			X	
Misc Production	Training Script	Manufacturing Procedure			X	
Procedure	Equipment, Calibration Procedure	Form	X			
Procedure	Equipment, Maintenance Procedure	Form	X			
Procedure	Product Service Procedure	Form	X			
Procedure	Receiving Inspection Procedure	Form	X			
Qualification	Analytical Instrument Qualification Report	Analytical Instrument Qualification Protocol	X			
Qualification	Environment Qualification Report	Environment Qualification Protocol	X			
Qualification	Installation / Operation Qualification Report	Installation / Operation Qualification Protocol	X			
Qualification	Installation Qualification Report	Installation Qualification Protocol	X			
Qualification	Microbiology Equipment Qualification Report	Microbiology Equipment Qualification Protocol	X			
Qualification	Operation Qualification Report	Operation Qualification Protocol	X			
		Manufacturing Procedure			X	
Qualification	Other Qualification/Study	Manufacturing Procedure			X	
Qualification	Performance Qualification Report	Performance Qualification Protocol	X			
		Manufacturing Procedure			X	

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Document Type	Parent	Child/Associated Document	**Structure** (Structure Tab)	**Reference Documents** (Related Objects Tab)	**Additional Relationships** (Additional Relationships Tab)	**DMR** requirements
Qualification	Product Performance Qualification Report	Product Performance Qualification Protocol	X			
		Manufacturing Procedure			X	
Qualification	Production Test Method Validation Report	Production Test Method Validation Protocol	X			
		Manufacturing Procedure			X	
Qualification	Purchased Component Qualification Report	Part Object			X	
Qualification	Software Validation (Non-Device) Report	Software Validation (Non-Device) Plan	X			
Qualification	Software Verification (Non-Device)	Software Verification (Non-Device) Plan	X			
Qualification	Sterilization Validation Report	Sterilization Validation Protocol	X			
Qualification	Technical Report	Manufacturing Procedure			X	
		Part Object			X	
Records Retention	Field Action Closure Requests	Field Action Document Type	X			
Records Retention	Field Action Consignee Lists and Communications		X			
Records Retention	Field Action Government Communications		X			
Records Retention	Field Action Govt Report		X			
Records Retention	Field Action Govt Supporting Docs		X			
Records Retention	Field Action Reconciliation		X			
Records Retention	Field Action Reference Document		X			
Records Retention	Field Action Sales Packet		X			
Records Retention	Manufacturer Manual	Equipment Specification			X	
Records Retention	Measurement Template	Equipment Specification			X	
Records Retention	REACH	Part Object			X	
Records Retention	RoHS	Part Object			X	

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Document Type	Parent	Child/Associated Document	**Structure** (Structure Tab)	**Reference Documents** (Related Objects Tab)	**Additional Relationships** (Additional Relationships Tab)	**DMR** requirements
Records Retention	RoHS/ REACH	Part Object			X	
Specification	Equipment / Tooling / Fixture	Equipment Specification	X			X
		Installation Qualification Report	X			
		Installation / Operation Qualification Report	X			
		Development Installation Qualification Report		X		
Specification	Equipment Specification	Equipment, Calibration Procedure	X			X
		Equipment, Maintenance Procedure	X			X
		Installation Qualification Report	X			
		Installation / Operation Qualification Report	X			
		Development Installation Qualification Report		X		
		System Requirements Specification (Non-Device)	X			
Specification	Lab Equipment Specification	Lab Work Instruction	X			
		Test Method	X			
		Analytical Instrument Qualification Report	X			
Specification	Software Design Document (Non-Device)	Software Validation (Non-Device) Report	X			
		Non Device User Requirements Specification	X			
		Software Requirements Specification (Non-Device)	X			
		System Requirements Specification (Non-Device)	X			
Specification	Software Requirements Specification (Non-Device)	Software Validation (Non-Device) Plan	X			

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Document Type	Parent	Child/Associated Document	**Structure** (Structure Tab)	**Reference Documents** (Related Objects Tab)	**Additional Relationships** (Additional Relationships Tab)	**DMR** requirements
Testing	Test Method	Process Specification	X			
		Form	X			
		Manufacturing Procedure		X		X
		Test Method Validation Report	X			
Testing	Test Method Validation Report	Test Method Validation Protocol	X			
Testing	Test Method Transfer Report	Test Method Transfer Protocol	X			
Part Object	Part Object	Artwork Specification		X		X
		Biomed Product Service Procedure		X		X
		Controlled Environment Specification		X		X
		ERP Routing		X		X
		Firmware Executable		X		X
		General Specification		X		X
		Inspection Procedure		X		X
		Instructions for Use		X	X*	X
		Labeling Specification		X		X
		Manufacturing Procedure		X		X
		Manufacturing Work Instruction		X		X
		Material Specification		X		X
		Packaging Specification		X		X
		Part Object	X			X
		Product Service Procedure		X		X
		Shop Floor Paperwork		X		X
		Software Executable		X		X
		Software License Entitlement		X		X
		Supplementary IFU		X	X*	X
		Supplementary IFU Artwork		X		X
		Supply Specification		X		X
Part Object	Part Object (Buy)	Receiving Inspection Procedure		X		X

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Document Type	Parent	Child/Associated Document	**Structure** (Structure Tab)	**Reference Documents** (Related Objects Tab)	**Additional Relationships** (Additional Relationships Tab)	**DMR** requirements
Design and Development Other	Additional Release Authorization Report	Additional Release Authorization Plan		X		
Design and Development Other	Development Installation Qualification Report	Development Installation Qualification Protocol	X			
Design and Development Other	Development Technical Report	Manufacturing Procedure		X		
Design Verification	Design Test Method	Manufacturing Procedure		X		
		Design Test Method Validation Report	X			
Design Verification	Design Test Method Validation Report	Design Test Method Validation Protocol	X			
Process Validation	Master Validation Report	Master Validation Plan	X			
		Manufacturing Procedure		X		
		Equipment / Tooling / Fixture		X		
		Equipment Specification		X		

*** For ZLSDManual Table integration -** Linkage created through Additional Relationship is required in addition to Reference Document structure.