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Create and Maintain Documents

1.0 PURPOSE

This procedure defines how to create and maintain a document in the SJM Quality System, legacy Quality Systems, Clinical Validation IT Marketing and Legacy Corporate, Production, and Product Development Libraries in Windchill.

2.0 REFERENCES

2.1 Applicable Documents

Number	Title
87116	Guide to Create and Maintain Documents
87117	Create and Maintain Document and Part Structure
87165	Document Format and Content

2.2 External References

Number	Title
N/A	N/A

3.0 RESPONSIBILITIES

Function or Title	Responsibility
Business Owner	Ensures the accuracy of the document content based on the requirements of the represented functional area.
Creator/Editor (C/E)	• Creates and updates document according to the requirements defined in this procedure. • Create/update structure.
Manufacturing Engineering/ Process Development (ME/ PD)	Assist C/E to ensure: • Manufacturing related document types and formats are correct. • Affected Sites are identified. • Structure is accurate.
Quality Engineering / Development Quality (QE/DQ)	Assist C/E to ensure: • Manufacturing and Development related document types and formats are correct. • Affected Sites are identified. • Structure is accurate.

Function or Title	Responsibility
Quality Systems	Assist C/E to ensure: • Quality System document types and formats are correct. • Affected Sites are identified. • Structure is accurate.

4.0 DEFINITIONS

Term	Definition
Attachment	A document, data file, zip file, etc. that supports an object.
Attribute	Fields populated on an object that define its use.
Change Order (CO)	An object that allows planning, managing, monitoring, and approval of new/revised objects of the change activities.
Document	The primary content for controlled object.
Document Object	An object that consists of primary content (e.g., Word document, Excel file) for a controlled document.
Format	The visual design of a document used within the organization.
Inactive (Phase Out)	A lifecycle state when objects are no longer intended for use, but may be used to complete work in progress.
Iteration Change	A change to an object with no effect to the lifecycle state version.
Manufacturing (Related Document Type)	A document that defines, supports, or has a direct impact on manufacturing.
Obsolete	A lifecycle state where the object is identified as no longer being used.
Pre-Released	A lifecycle state where the object is available for development activities.
Quality Systems (Related Document Type)	A document that defines, supports, or has a direct impact on the quality system.
Released	A lifecycle state where the object is available for production activities.
SAP	Enterprise Resource Planning (ERP), a business operating system used to manage finances, assets, costing, production operations materials, plants and executions of a common set of data and programs.
Specification	A detail description of the design and material used to make the product.

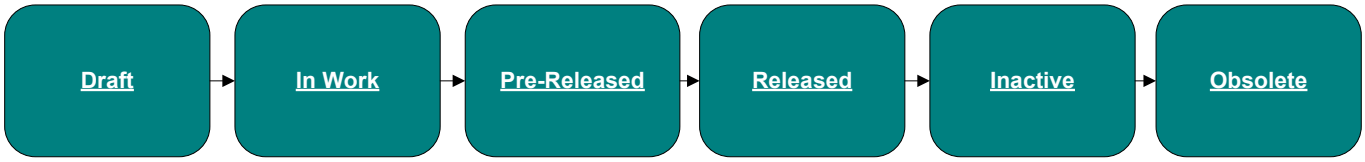
Create and Maintain Documents

Term	Definition
Version	An identifying letter or number which is used to identify the Implementation, or Pending Implementation, of a change to a particular object as part of a Change Order. ***NOTE:*** ***Alpha versions not used in Windchill are I, O, and Q.***
Windchill (WC)	Product Lifecycle Management (PLM) system used to manage objects associated with the lifecycle of a product from its conception to its obsolescence.

5.0 FLOW CHART

Lifecycle States for Documents

NOTE: A document may not go through every Lifecycle state.



Create and Maintain Documents

6.0 REQUIREMENTS

6.1 General Document Object Information

Step	Action
1	User must have Creator/Editor (CE) access to create documents.
2	Each library has a defined set of Document Types and Document Sub Types available. The document must be created in the correct library.
3	Document Type and Document Sub Type become attributes that drive the Change Control Process, related system processes, facilitate searches, and pre-determined formatting requirements such as: • Document attributes • Appropriate document template • Document Name (limited to 60 characters or less) • Approval roles (Change Implementation Board) • Training requirements

4	Legacy Documents are loaded at the discretion of Documentation Services or part of system migrations. If not part of a migration plan, contact Documentation Services for direction.
	• The Revision attribute defines the selection of the State attribute.
	  ○ For Alpha documents, the State selection is In Work.
	  ○ For Numeric documents, the State selection is Draft.
	• A Change Order (CO) is required by the Windchill Workflow to obtain the state of Released or Pre-Released.

5	Document lifecycle state is maintained in Windchill, but is not required to be listed on documentation. Documents which have been replaced with a new version are marked as Superseded. **NOTE: It may be necessary to list state on documentation shared with external parties that do not have access to Windchill. This can be done by going to Visualization tab, Representations/Annotations section, right click the native file, select Files, and click PDF.** • Refer to 87116, Guide to Create and Maintain Documents on creating documents in the Windchill. • Refer to 87123, Create and Manage Change Order WI, for managing document attributes, versions, and lifecycle states.

6.2 Lifecycle State: Draft

Step	Action
1	**Draft State** • Draft state is used for the initial creation of a document. • While at Draft state a Creator/Editor (C/E) has the ability to reassign the document type and subtype. The document must not have a prior Released or Pre-Released state and is not on a Change Order.
2	**Establishing a Draft State** a. Determine the appropriate document type and subtype based on library and definition of subtypes, see Appendices A, B, and C. b. Obtain the current Released copy of the document template, if applicable. c. Populate the document template per the associated work instruction and/or the 87165, Document Format and Content WI. **NOTE: The template number and version remain in the footer of the document for verification of template currency.**

6.3 Lifecycle State: Pre-Released

Step	Action
1	**Pre-Released State** • Pre-Released state is used during the development phase. A document at a Pre-Released state is considered released for development use. • Windchill state will be Draft during editing and Pre-Released for the latest approved numeric version. • Document objects are not required to go to Pre-Released state; instead, the state can directly go from Draft to Released or Obsolete if all of the required attributes, structure, and associated documentation requirements are met. **NOTE: Pre-Released state was previously titled Draft Approved. While all state titles have been updated in WC, some documents will reflect a state of Draft Approved as part of the watermarking until they are updated. These states are considered equivalent.**
2	**Promoting Documents to Pre-Released State** a. Populate document attributes as applicable. b. Execute a Change Order with a target state of Pre-Released to revise the document object to/within a Pre-Released state.

Create and Maintain Documents

6.4 Lifecycle State: Released

Step	Action
1	**Released State** • Released state is used to designate the documents available for use in production or the applicable quality system. Windchill state will be In Work while editing and Released for the latest approved alpha revision. • Parent/Child structure is required for Released state unless appropriate justification is provided. See 87117, Create and Maintain Document and Part Structure. • If a document object is moved to Draft and determined it is not necessary for use, it is acceptable for that document object to bypass Released state and go directly to Obsolete state.
2	**Promoting Documents to Released State** a. Structure the document objects, as applicable. b. Populate document attributes, as applicable. c. Execute a Change Order to revise the document object to/within Released state.

6.5 Lifecycle State: Inactive

Step	Action
1	**Inactive State** • The Inactive state is used when a document is being inactivated for daily use but, is necessary for continuation of activities in progress. Typically this will be designated on an implementation plan to define who is using the inactive document, what it is used for, and the duration of the usage, as applicable. • QS Documentation that is Inactive must have a watermarked statement indicating its replacement. **NOTE: Inactive state was previously titled Phase-Out. While all state titles have been updated in WC, some documents will reflect a state of Phase-Out as part of the watermarking until they are obsolesced. These states are considered equivalent.**

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6.5 Lifecycle State: Inactive

Step	Action
2	**Promoting Documents to Inactive State** a. Execute a Change Order to promote the document object to Inactive state. b. Only Released or In-Work states can be promoted to an Inactive state. Other states cannot be promoted to Inactive **NOTE: A CO with a target state of Inactive will move all materials on the CO to an Inactive state.** c. Once a document has been inactivated and it becomes necessary to reactivate the document, a Change Order must be initiated.

6.6 Lifecycle State: Obsolete

Step	Action
1	**Obsolete State** • The Obsolete state is used when a document will no longer be used. • A document can move directly to Obsolete from any other state when it is determined that obsolescence is necessary. • After a document has been promoted to Obsolete, it cannot be revised to any other state. • Promoting a document to the Obsolete state does not check attributes, structure, or required those items to change. It is intended to freeze all current attribute entries.
2	**Promoting Document to Obsolete State** Use the Change Order in WC to promote the document to Obsolete, ensuring creation and inclusion of all of the required CO attachments. Refer to 87123 for CO attachment guide. **NOTE: A CO with a target state of Obsolete will move all materials on that CO to an Obsolete state.**

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7.0 APPENDICES

Appendix A: Definition of Document Sub Type (Product Development Library)

Appendix B: Definition of Document Sub Type (Production Library)

Appendix C: Definition of Document Sub Type (Quality System Libraries)

Appendix D: Document Attributes

Create and Maintain Documents

APPENDIX A: DEFINITION OF DOCUMENT SUB TYPE

(Product Development Library)

Product Development Library		
Document Type	**Document Sub Type**	**Definition**
Design and Development Other	Additional Clinical Authorization (ACA)	The authorization of additional sites for investigational devices after Clinical Trial Authorization approval.
Design and Development Other	Additional Release Authorization (ARA)	Captures the approval to distribute product to additional geographies after the initial Market Release.
Design and Development Other	Clinical Evaluation	An evaluation of a Clinical Trial, typically written by the regulatory department. The Document defines the risk/benefit ratio of the device and deems if it is safe for human use.
Design and Development Other	Clinical Product Qualification Plan	Defines the development requirements and qualification plan for a limited release of devices for a human clinical evaluation.
Design and Development Other	Clinical Product Qualification Protocol / Report	Provides requirements (protocol) and results (report) related to clinical product batch qualification.
Design and Development Other	Clinical Trial Authorization	The authorization for releasing an investigational device.
Design and Development Other	Design History File (DHF)	Used as the foundation document (anchor) to build a Design History File (DHF) structure within Windchill. DHF is a compilation of records demonstrating that the design was developed in accordance with the IBP and with the PDP SOP.
Design and Development Other	Design Review	Formal documented reviews conducted at appropriate stages of the device's design development that assure that the PDP SOP and appropriate design control requirements are being met.
Design and Development Other	Design Transfer	Ensures that the device design is correctly translated into production specifications.
Design and Development Other	Development Equipment / Tooling / Fixture	Drawings and related information associated with hardware, software and general fixtures defining their critical components, critical dimensions, critical functions, material connections; schematics (electrical and pneumatic), warranty, service, etc. for DHF equipment used to test, verify and/or support product development. Not intended for production use.

Create and Maintain Documents

Product Development Library		
Document Type	**Document Sub Type**	**Definition**
Design and Development Other	Development Equipment Specification	Equipment specifications defining functional requirements, ranges and accuracies for DHF equipment. Not intended for production use.
Design and Development Other	Development Installation Qualification	Qualification documentation to establish by objective evidence that all key aspects of the development equipment and ancillary system installation adhere to the manufacturers approved specifications, and that the recommendations of the supplier of equipment are suitable for the applied use. Not intended for production use.
Design and Development Other	Development Technical Report	Technical evaluations and studies that are performed to support development analysis and efforts.
Design and Development Other	Device Plan	Any device software or hardware planning document (e.g., Device Software Development Plan).
Design and Development Other	Device Design Document	Any device software or hardware design document (e.g., Device Software Architecture Design, Device Software Off the Shelf (OTS) Software Design, and Device Software Detailed Design).
Design and Development Other	Inspection Validation	Plan, protocol, and report used to validate a specific method of inspection.
Design and Development Other	Integrated Business Plan	Constitutes the product development contract and project plan.
Design and Development Other	Limited Market Release (LMR)	Authorizes manufacture of a predefined limited quantity of product over a limited duration (generally less than or equal to eighteen months) where risk levels have been defined and data exists to demonstrate conformance of the product to the defined requirements at the defined risk levels. LMR is intended for release to specific accounts and/or approved countries. A documented survey to physician customers may be used in an LMR to obtain physician feedback regarding handling characteristics, preference, and/or overall product experience.
Design and Development Other	Market Release	Authorizes the specific use of approved products in the field.
Design and Development Other	Miscellaneous DHF	Constitutes part of the DHF that is not associated to another document type.

Create and Maintain Documents

Product Development Library		
Document Type	**Document Sub Type**	**Definition**
Design and Development Other	New Technology Assessment (NTA)	Allows for controlled release of an approved commercial product for the intention of generating product experience. Global Clinical Affairs is responsible for the conduct of NTAs, including communication of status and results. NTAs may include collection of patient data as long as the applicable regulatory requirements are met (i.e. patient informed consent, EC/IRB approval). An NTA is used to make a determination on full market release based on pre-defined acceptance criteria. In general, an NTA is a more robust assessment than a LMR and generally the data collection goes beyond the acute product usage phase.
Design and Development Other	Non Device Software Executable	Compiled non-product software used in product development activities. This document subtype is for use in legacy IESD sites only.
Design and Development Other	Physician Access Release (PAR)	Release based on a physician requested application; e.g. Custom Device in Europe, Special Access in Canada, Special Access Scheme in Australia, and Special Release Permission (YAKKAN) in Japan & Special Access License in Singapore, Indonesia and the Philippines. Approval must be documented on a PAR checklist.
Design and Development Other	Special Release Authorization (SRA)	The authorization for a specials product as defined in the specials product procedure. This allows for meeting specific non-inventory customer requests.
Design and Development Other	Supplier Assessment	An assessment performed by Supplier Quality or other internal resources on a supplier's process or material.
Design Validation	Clinical	Plan, protocol, report, etc. documentation that constitutes clinical activities.
Design Validation	Design Validation	Plan, protocol, report, etc., documentation that provides objective evidence that the device specifications conform to the user's needs and intended use(s).
Design Verification	Biocompatibility	Plan, protocol, report, etc., documentation that constitutes Biocompatibility activities.
Design Verification	Design Test Method	Defines a specific method of testing, not used as a standard DHR procedure.
Design Verification	Design Test Method Validation	Plan, protocol, and report used to validate a specific method of testing.

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Product Development Library		
Document Type	**Document Sub Type**	**Definition**
Design Verification	Design Verification	Plan, protocol, report, etc., documentation that provides confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.
Design Verification	Distribution Test/ Package Verification	Plan, protocol, report, etc., documentation relevant to distribution and/or package testing activities.
Design Verification	Packaging Validation	Establishes by objective evidence that packaging specifications conform to the users' needs and intended use(s).
Design Verification	Shelf Life/ Accelerated Aging	Protocol, report, etc., that constitutes output of the shelf life verification activities.
Process Validation	Master Validation	Plan, report, etc. that supports the top level process validation efforts for an entire production line or complex process.
Process Validation	Process Validation	IQ, OQ, or PQ protocols, reports, etc., documenting objective evidence that the process output is consistent with the design specifications.
Requirements Document	Applicable Standards Document	Summarizes the standards related to the design being developed.
Requirements Document	Customer Requirements	Summarizes customer (requirements) design input information for a given new product.
Requirements Documents	Design Input / Design Output Summary	Summarizes the results of the design efforts for a specific product against the design requirements.
Requirements Document	Device Requirements	Defines device software or hardware requirements.
Requirements Document	Product Requirements	Top-level design document that communicates finished device requirements in engineering terms.
Risk Management	Cybersecurity	Report cybersecurity threats, vulnerabilities, controls, residual risk, risk to benefit analysis and maintenance planning, and reporting associated with a device or accessory.
Risk Management	FMEA, Design	A systematic method of identifying, prioritizing, and mitigating potential design component and assembly failure modes. A design failure mode is defined as the reason a design component or assembly fails to perform as intended.
Risk Management	FMEA, Process	A systematic method of identifying, prioritizing, and mitigating potential process and equipment failure modes. A process failure mode is defined as the reason a process fails to output the specified product as intended.

Create and Maintain Documents

Product Development Library		
Document Type	**Document Sub Type**	**Definition**
Risk Management	FMEA, Use	A systematic method of identifying, prioritizing, and mitigating potential product use and functional failure modes. A use failure mode is defined as a mode in which the design clinically fails to perform as intended.
Risk Management	Risk / Hazard Analysis	Process to investigate the safety of a device or accessories, by identifying hazards associated with the device.
Risk Management	Risk Management Plan / Report	Plan or Report to document the safety or hazards associated with a device or accessory.

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APPENDIX B: DEFINITION OF DOCUMENT SUB TYPE

(Production Library)

Production Library		
Document Type	**Document Sub Type**	**Definition**
CAPA	CAPA Closure	A summary including section for Verification of Effectiveness (VoE) Plan.
CAPA	CAPA Extension Request	Request for extension of the target closure or Verification of Effectiveness date.
CAPA	CAPA File Document	May be used for corrective and preventive action documentation for the CAPA phases (i.e., Define, Measure, Analyze, Improve, and Control), 4-panel updates, interim actions, closure checklist, and other supporting CAPA documents.
CAPA	CAPA History File	Used as the foundation document (anchor) to build a CAPA History File structure within Windchill. A CAPA History File is a compilation of records that describe the complete history of a specific CAPA.
CAPA	CAPA Request	CAPA Initiation Request.
CAPA	CAPA Risk Assessment	Risk Assessment supporting the Health Hazard Evaluation (HHE) decision.
CAPA	CAPA VoE	Verification of Effectiveness (VoE) results.
CAPA	Risk Indicator Review	May be used for Risk Indicator Review (RIR) documentation including RIR records, minutes and presentations supporting analysis of data to determine recommendations for CAPA requests.
Distribution Book	Distribution Book	May be used to identify location of documentation residing in a specific area.
DMRE	Device Master Record Element	Object used as a building block to create a Device Master Record structure.
Format	Format	*Documentation Services Use Only* – Identifies label formats.
Manufacturing	ERP Routing	Used to control manufacturing operations, when combined with a Bill of Material allows creation and execution of a production order in SAP.
Manufacturing	Form	Generally used to collect data and is typically a required output of a process. A Manufacturing Form is used to capture data that is the output of manufacturing or production support related activities.

Create and Maintain Documents

Production Library		
Document Type	**Document Sub Type**	**Definition**
Manufacturing	Inspection Procedure	Manufacturing floor work instructions are designed to verify (inspection and test) the conformity or nonconformity of a product or component to process specifications. An inspection procedure may be used for in-process or final product acceptance activities.
Manufacturing	Manufacturing Procedure	Provides detailed work instructions to manufacture the product to meet the requirements of the design specification.
Manufacturing	Manufacturing Quality Plan	A plan that defines the activities necessary to ensure appropriate consideration of the impact, risk, and potential effect on product quality resulting from activities related to systemic improvement, change or transition.
Manufacturing	Manufacturing Quality Report	A report that demonstrates that the activities defined in the associated Manufacturing Quality Plan have been completed and to capture any deviations that may have resulted as part of execution of the plan.
Manufacturing	Shop Floor Paperwork	Identifies the materials, processes, when completed provides a record of manufacturing data and operator identity for a given production build.
Manufacturing	Visual Standard / Aid	A document (photo, sample, video clip, etc.) that identifies acceptance or defects for a particular product.
Manufacturing	Work Instruction, Manufacturing	Defines instructions for activities related to general manufacturing practices, not specific to product or product family (ex. cleaning, pest control etc.).
Misc Production	Facilities	Used for documents related to the facilities department.
Misc Production	Firmware Executable	Executable software that is embedded into hardware and is generally considered part of the hardware. Usually firmware is stored in non-volatile memory.
Misc Production	Marketing Literature - Inventoried	Advertising and promotional materials that are for marketing purposes and kept in inventory (SAP).
Misc Production	Non Production Marketing Literature	Advertising and promotional materials that are for marketing purposes.
Misc Production	Reference Figure	Identifies a graphic that is used in work instructions, etc.

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Production Library		
Document Type	**Document Sub Type**	**Definition**
Misc Production	Risk Management Plan / Report	A Risk Management Plan documents the risk management activities for a device throughout its life cycle, assigns responsibilities and authorities, defines requirements for review, defines criteria for acceptability and determines verification activities. A Risk Management Report is a review prior to commercialization that the plan was appropriately implemented, overall risk is acceptable and appropriate methods are in place to obtain relevant production and post-production information.
Misc Production	Software Executable	Compiled software for use as part of a product. The Windchill item will only contain a pointer to a controlled software repository.
Misc Production	Software License Entitlement	Provides authorization codes for installation and use of a software product.
Misc Production	Training Document	Defines the training requirements for a particular activity.
Misc Production	Training Script	Provides written dialogue of the voice audio content within a training aid.
Procedure	Biomed Product Service Procedure	Customer Support procedures for products.
Procedure	Equipment, Calibration Procedure	Defines step-by-step work instructions for setting up measurement or test equipment to a known standard.
Procedure	Equipment, Maintenance Procedure	Defines maintenance requirements of hard tooling and other equipment used to manufacture and support products.
Procedure	Lab Work Instruction	Details the necessary steps and documentation of a process in order to meet laboratory requirements.
Procedure	Lockout / Tag out Procedure	A work instruction for a piece of equipment that establishes the requirements for the control of hazardous energy utilizing the lockout or tag out of energy isolating devices whenever maintenance or servicing is performed on machines or equipment. It shall be used to ensure that the machine or equipment is stopped, isolated from all potentially hazardous energy sources and locked out or tagged out before employees or contractors perform any service or maintenance work where unexpected start-up or energize the machine or equipment or the release of stored energy could cause injury.

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Production Library		
Document Type	**Document Sub Type**	**Definition**
Procedure	Product Service Procedure	Defines required steps to update product in the field that Abbott personnel are responsible for servicing. This service is typically performed by a Field Service Technician.
Procedure	Receiving Inspection Procedure	Provides step-by-step to verify (inspection and test) the conformity or nonconformity of a component to design specifications. An inspection procedure used for incoming acceptance activities.
Qualification	Analytical Instrument Qualification	Constitutes the verification that hardware and software (non-device) are installed, configured, and operate per specification and according to the intended use of the analytical instrument.
Qualification	Environment Qualification	Establishes objective evidence that the environmental conditions meet the requirements as defined by the specification.
Qualification	Installation / Operation Qualification	Constitutes the verification that hardware and software (non-device) have been installed, configured and operates as specified.
Qualification	Installation Qualification	Establishes by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the manufacturers approved specifications, and that the recommendations of the supplier of equipment are suitable for the applied process.
Qualification	Microbiology Equipment Qualification	Constitutes the verification that the lab equipment is installed, configured, and operate per specification and according to the intended use of the microbiology lab equipment.
Qualification	Operation Qualification	Establishes by objective evidence process control limits, training and action levels which result in product that meets all predetermined requirements.
Qualification	Other Qualification / Study	Used when Qualifications and/or Studies do not fall within the requirements of other Business Qualification activities. Typically defines how a validation activity will be conducted including methodologies, equipment, the characteristics to be tested, acceptance criteria and how results will be reported.
Qualification	Performance Qualification	Constitutes the verification that hardware and software (non-device) of a process or production line performs to specified requirements.

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Production Library		
Document Type	**Document Sub Type**	**Definition**
Qualification	Product Performance Qualification	Establishes by objective evidence, that the process or collection of processes under anticipated conditions, consistently produces a product which meets all predetermined requirements.
Qualification	Production Test Method Validation	Plan, protocol, report used to validate a specific method of testing.
Qualification	Purchased Component Qualification Report	Report that contains results and material acceptance decisions for all purchased component / service qualification activities.
Qualification	Software Validation (Non-Device)	Plan, protocol, or report documenting conformance of non-device software specifications to user needs and intended uses, and that the particular requirements implemented through the non-device software can be consistently fulfilled.
Qualification	Software Verification (Non-Device)	Plan, protocol, or report that documents conformance of non-device software specifications to user needs and intended uses, and documents that the particular requirements implemented through the non-device software can be consistently fulfilled quality.
Qualification	Sterilization Validation	Plan, protocol, or report documenting assurance records for sterilization activities that they meet prescribed requirements.
Qualification	Technical Report	Technical evaluations and studies that are performed to support process and product feasibility, and analysis.
Records Retention	Lab Notebook	Used to assign a Windchill number to a specific laboratory notebook for the purposes of traceability.
Records Retention	Manufacturer Manual	May provide any of the following information: • Manufacturer's equipment specifications • Instructions of how to properly use the equipment • Instructions for recommended calibration • Instructions for recommended preventative maintenance • Precautions and warnings for equipment damage and user safety • Troubleshooting and repair (when applicable) • Spare parts list (when applicable)
Records Retention	Measurement Template	Validated Excel Spreadsheet with portions prepopulated

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Production Library		
Document Type	**Document Sub Type**	**Definition**
Records Retention	NRTL Report	Nationally Recognized Test Laboratory (NRTL); a certification or test report issued to comply with U.S. consensus-based product safety test standards.
Records Retention	REACH	Ability to demonstrate compliance to the REACH directive, typically supplier certification or test report; intent is to ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals as identified in the directive.
Records Retention	RoHS	Ability to demonstrate compliance to the RoHS directive, typically supplier certification or test report; aims to restrict dangerous substances commonly used in electronics and electronic equipment to levels specified by the directive.
Records Retention	RoHS/ REACH	Ability to demonstrate compliance to the RoHS/REACH directives, typically supplier certification or test report; aims to restrict dangerous substances commonly used in electronics and electronic equipment to levels specified by the directive.
Records Retention	Windchill Training Record	Provides evidence of Windchill classroom training.
Records Retention	Field Action Closure Requests	Documents and supporting material submitted to regulatory authorities requesting closure of field actions.
Records Retention	Field Action Consignee Lists and Communications	Consignee Lists and communications.
Records Retention	Field Action Government Communications	Communications with regulatory authorities regarding field actions.
Records Retention	Field Action Govt Report	Periodic Reports provided to regulatory authorities regarding field action status; 806 Packet.
Records Retention	Field Action Govt Supporting Docs	Supporting documentation provided to regulatory authorities.
Records Retention	Field Action Reconciliation	Reconciliation materials for field actions.

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Production Library		
Document Type	**Document Sub Type**	**Definition**
Records Retention	Field Action Reference Document	Copies of completed controlled documents necessary for completion of a field action.
Records Retention	Field Action Sales Packet	Communication packet provided to internal Sales Representative.
Specification	Artwork Specification	Specifies all features and physical requirements of a product's labeling artwork required to produce the printed product. **NOTE: Physical requirements should include items such as paper weight, IFU dimensions, folding requirements, etc.**
Specification	Controlled Environment Specification	Defines the specification requirements for Controlled Access Environment (CAE), Biological Safety Cabinet (BSC), and Laminar Flow Hood specifications.
Specification	Equipment/ Tooling/ Fixture	Hardware specifications, software configurations, equipment qualification criteria, drawings, material connections; schematics (electrical and pneumatic), warranty, service, etc., used during production to manufacture, test, verify and/or support products.
Specification	Equipment Specification	Defines equipment specifications, requirements, ranges, and accuracies.
Specification	General Specification	Defines the specification requirements for items other than materials (e.g., Clean Room Environments).
Specification	Instructions for Use	Product information or instructional artwork including handling, indications, contraindications, etc. in English, at a minimum. **NOTE: Translated Instructions for Use (without English content) that are not subject to in-box product sterilization may be approved with the Supplementary IFU document sub type.**

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Production Library		
Document Type	**Document Sub Type**	**Definition**
Specification	Lab Equipment Specification	Defines equipment specifications, requirements, ranges, and accuracies for laboratory instrumentation.
Specification	Labeling Specification	Specifies all features and physical requirements of a product's labeling.
Specification	Material Specification	Specifies all features and physical requirements (dimension, shape, position, composition, tolerance limits, etc.) of a design.
Specification	Packaging Specification	Specifies all features and physical requirements (dimension, shape, position, composition, tolerance limits, etc.) of a product's packaging.
Specification	Process Specification	Defines the controlling parameters of a manufacturing process for a specific product. This typically includes a flowchart of the entire process.
Specification	Quality Service Specification	Defines the requirements of an outsourced service that has an impact on the product or manufacturing process (e.g., sterilization, clean room maintenance, calibration).
Specification	Software Design Document (Non-Device)	Defines the design for a specific software non-device application, program, etc.
Specification	Software Requirements Specification (Non-Device)	Defines the requirements for a specific non-device software application, program, etc.
Specification	Supplementary IFU	Translated instructions including handling, indications, contra-indications, etc. for the use of the product, included in the device packaging in a specific language added after the final pack operation (typically a single-language print-on-demand IFU).
Specification	Supplementary IFU Artwork	Specifies all printing/physical requirements for supplementary IFU artwork. **NOTE: Physical requirements should include items such as IFU dimensions, folding requirements, etc**.
Specification	Supply Specification	Specifies all features and physical requirements (dimension, shape, position, composition, tolerance limits, etc.) of an item used to support the manufacture of a product.

Create and Maintain Documents

Production Library		
Document Type	**Document Sub Type**	**Definition**
Specification	System Requirements Specification (Non-Device)	Defines the essential requirements (functions, performance, design constraints, and attributes) of the non-device software and its external interfaces.
Specification	Non Device User Requirements Specification	Defines the user requirements for non-device software.
Testing	Test Method	Defines a specific method of testing.
Testing	Test Method Validation	Involves testing to confirm that the method is fit for its intended use.
Testing	Test Method Transfer	Documented process designed to verify a certain laboratory's capability of performing the analytical test methods intended use.

Create and Maintain Documents

APPENDIX C: DEFINITION OF DOCUMENT SUB TYPE

(Quality System Libraries)

Quality System Libraries		
Document Type	**Document Sub Type**	**Definition**
Quality System	ERMS Change Analysis	Documents the analysis of changes between the previous and current revisions of an external requirement (e.g. industry standard, regulatory document).
Quality System	Form	Generally used to collect data and is typically the required output of a process. A Quality System Form is used to capture data that is an output of quality system related activities.
Quality System	Guidance	Guidance documents are written to provide best practices. They can provide additional information, or a methodology that is not procedurally required, to assist individuals with fulfilling the requirements defined in procedures. Guidance documents do not define requirements.
Quality System	Process Standard Operating Procedure	Show the interrelationships that exist between several QS elements in terms of inputs, process steps, and outputs. PSOPs describe an over-arching QS process.
Quality System	Quality Manual	Defines the company's quality policy and provides an overview of the quality system requirements.
Quality System	Quality Plan	Defines the activities necessary to ensure appropriate consideration of the impact, risk, and potential effect on the quality system resulting from activities related to systemic improvement, change or transition.
Quality System	Quality Report	Demonstrates that the activities defined in the associated Quality System Quality Plan have been completed and captures any deviations that may have resulted as part of execution of the plan.
Quality System	Quality System Work Instruction	A procedure that details the necessary to execute the requirements of the Quality System.

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Quality System Libraries		
Document Type	**Document Sub Type**	**Definition**
Quality System	Reference	Reference materials provide information in support of existing quality system processes and procedures. Reference materials are not procedural, but they may provide instruction for interpreting the information. Examples include, glossaries, labeling requirements lists, charts, maps, etc.
Quality System	Standard Operating Procedure	Defines the operational requirements for the company's major activities.
Quality System	Template	A controlled document that provides preset content and formatting requirements. Its use is intended to drive consistency. Documents created from a template become unique document in Windchill.

Create and Maintain Documents

APPENDIX D: DOCUMENT ATTRIBUTES

Document Attributes		
Attribute	**Description for Use**	
Number	Creation of a new document will have a Windchill generated number. The same number assigned to the part will also be assigned to the document for the listed document sub-types: • Artwork Specification • IFU • Labeling Specification • Supplementary IFU • Supplementary IFU Artwork • Shop Floor Paperwork	
Name	Document Name should clearly identify the document. Examples: • IQ / OQ Portico Delivery System Over Mold • Process Validation SOP • Quality Plan for Documentation Change Control Procedures **NOTE: Limited to 60 characters.**	
Affected Site(s)	All available sites are available for selection.	Select the site(s) where the document is used. If the document is associated to a part, it must have the same affected site. **NOTE: This attribute is critical as it drives many documentation Change Control activities, including approvals, training, distribution, etc.**
Business Owner	All available functional roles are available for selection.	Choose the Business Owner that is responsible for owning the document and any future changes. Where there is more than one business owner, select the owner with the highest level of impact. **NOTE: This attribute is critical as it drives approval requirements, thus ensuring that updates are reviewed and approved by affected groups.**
Product Segment(s)	All available product segments are available for selection.	Choose the product segment that supports the affected product line.
Affected Products	All available product(s) are available for selection.	Select all products that use the document. If the document is Quality Systems related, select N/A. If the product line is not available choose Other Product Not Listed.

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Document Attributes		
Attribute	**Description for Use**	
Production View PDF	Select Yes to force the document to only be opened as a PDF file.	
External Approval (outside of Windchill)	All available approval or notification required is available for selection.	Select when document requires external approval and/or notification.
External Approval Comments	Free Form Text	Indicate vendor. Indicate person responsible to obtain approval and/or notification from vendor. For Angio-Seal and FemoSeal documents, indicate “Terumo_SJM Shared” when documents should remain sync’d with Terumo Windchill library or “Terumo Notification” when Terumo should be notified of document changes.
External System **NOTE: This attribute is only applicable to Document Type-Specification in the Production Library.**	N/A	Select when the document does not apply to labeling.
	Easy Label	Select when the label will be printed via the Easy Label system.
	Nice Label	Select when the label will printed via the Nice Label system.
	enLabel (Integrated)	Select when the label will be automatically interfaced with Windchill
Language - Country	All available Language-Country codes are available for selection.	Select the appropriate Language – Country codes.

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Document Attributes		
Attribute	**Description for Use**	
Manufacturing Aids	Select N/A if: • No manufacturing aids exists for the procedure Select one of the options for Manufacturing Aids: • Training Aid Training Aid refers to Video Based Training Aids Video Based Training (VBT) Aids are videos that demonstrate best practices and manual technique for an operation or task. • Production Aid Production Aid refers to Standard Work sheets Standard Work sheets are guidance documents that provide an outline of the most efficient way to perform a series of steps for an operation or task. • Training and Production Aids Aids created and utilized to improve efficiency of training delivery or product line performance. **NOTE: By selecting Training Aid and/or Production Aid, a Pre-Release Task is sent to the appropriate team or individual to assess if there is any impact to the Manufacturing Aid.**	
Description	Describe the intent of the document. **NOTE: This is similar to the purpose section of the document. Attribute is not required.**	
Legacy – X Ref Number	Free Form Text	Used when new document numbers have been assigned and there is the desire to cross reference the legacy document number.
Related to CAPA	Select Yes or No	Select Yes if related to a CAPA.
CAPA Number	Free Form Text	Optional, available on Quality System and Manufacturing document types only.
Revision CAPA Related to	Free Form Text	Optional, available on Quality System and Manufacturing document types only.
CAPA Explanation	Free Form Text	Optional, available on Quality System and Manufacturing document types only.