Document Format and Content

1.0 PURPOSE

This procedure defines the format and content requirements for controlled documents residing in the SJM Quality System, legacy Quality Systems, Production, and Product Development Libraries in the Windchill PLM System.

2.0 REFERENCES

2.1 Applicable Documents

Number	Title
86115	Quality System SOP WI Template

2.2 External References

Number	Title
N/A	N/A

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3.0 RESPONSIBILITIES

Function or Title	Responsibility
Business Owner	Ensures created and modified documents comply with the requirements. Ensure use of appropriate templates based on document type and/or activity as part of change review and approval.
Creator/Editor (C/E)	Creates and modifies documents to comply with the requirements. Ensure use of appropriate templates based on document type and/or activity as part of change review and approval.

4.0 DEFINITIONS

Term	Definition
Applicable Documents	A list of documents that are relevant to the execution of activities.
Reference Documents	External documents that support procedural content.

5.0 FLOW CHART

N/A

6.0 REQUIREMENTS

Controlled documents residing in the Windchill PLM system, SJM Quality System, legacy Quality Systems, Production, and Product Development Libraries must be created per the requirements stated in this procedure.

6.1 General Format

Step	Action
1	When creating or revising documents: • For Quality Systems procedures and Manufacturing Work Instructions, use template 86115. • For all other documents, the approved templates and forms in the business element process documentation or in Appendices A through D of this procedure take precedence over the formatting requirements below. Newly created or revised documentation (excluding records provided by another organization (e.g. RoHS certificates, manuals) must contain, at a minimum, the following elements: • The company logo must comply with the company branding requirements and must appear in the upper left header area of each document page. • The document header for all documents must contain the following information: ○ Unique document Number

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6.1 General Format

Step	Action
	○ Current document Version ○ Document sub-type (e.g., Standard Operating Procedure, QS Work Instruction, Quality Plan) ○ Document title, which should clearly and concisely describe the document • The document footer area for all documents must contain a confidentiality statement appropriate to the document usage. The typical statement is: *This confidential document is the property of Abbott and shall not be reproduced, distributed, disclosed or used without the express written consent of Abbott.* ○ Externally-facing documents (e.g., customer letter templates, regulatory documents/communications, and supplier quality forms) may have a different statement as provided by Legal. ○ The page number and total number of pages **NOTE: The main body of the document should be paginated separately from each attachment or appendix as necessary.** • A Table of Contents (TOC) may be generated for longer documents (e.g., documents exceeding 8 pages) and for complex documents containing many sections. • Controlled documents should be limited to three heading levels. • Shading in tables or spreadsheets should be light in color to ensure legibility for copying and scanning purposes. Shading should not be applied to areas in which data is entered. • Font style and size must be non-script, easily read, and legible when copied. Recommended type fonts are Times New Roman, Arial, or Calibri. It is preferred that only one font type be consistently used throughout the document. • Abbreviations or acronyms should be spelled out when first used, or, they should be listed in the Definitions section. • Roman numerals or lower case alpha characters should be used to identify actions or ordered items; bullets are used to identify non-sequential list items.

6.2 Use and Format of Notes, Cautions, and Warnings

Step	Action
1	Notes can be used to further clarify content or to describe exceptions. Note information: • Should be obvious, and positioned near the details described. • Should be created in bold face type. For example: **NOTE: Ensure that the note content appears below the information it is supporting.** Caution information: • Should be positioned near the action(s) that could result in damage to equipment, property and/or minor injury. • Should be created in bold face type: For example: **CAUTION: Not lubricating the drive shaft daily can result in damage to the motor.** Warning information: • Should be positioned immediately before the activity that could result in serious injury or death. • Should be created in bold face type. For example: **WARNING: Working near biohazardous waste without wearing the appropriate PPE will result in serious infection from contaminants.**

6.3 Form and Template

Step	Action

1	• Appropriate use of templates is the responsibility of the Business Owner, Change Manager, and Creator/Editor and Approvers utilizing Appendices A through D or governing procedure.
	• Forms and templates must have headers and footers that meet the General Format requirements section.
	• To ensure consistent formatting of documents, templates are released in the Windchill PLM system and should be used as applicable.
	• When a template is used:
	  ○ If the sections indicated in a template do not apply to the document being created, indicate that the unused section is not applicable. For example, enter N/A to indicate that the information was considered but was deemed not applicable.
	  ▪ Do not change content of the Form. Only fields on the Form should contain data.
	  ○ Sections may be added to a template as necessary.

6.3 Form and Template

Step	Action
	NOTES: ➢ **The unique Document Number, Version and Doc Type may be located in the header or the footer on Forms and Templates.** ➢ **Releasing a template under a unique document number is preferred over attaching it to a Work Instruction or Standard Operating Procedure. The templates structured or attached to this document in Windchill are default templates and do not supersede templates that are specified by other processes (See Appendices A through D for a list of templates).**

6.4 General Content

Step	Action
1	• Document content should be written to an appropriate level for the reader. • Use Microsoft Word as the default program for the creation of controlled documents. When Microsoft Word is not suitable other programs such as (e.g., Excel, Power Point) may be used. • Bookmarks and links may be used in documents. **NOTE: If bookmarks or links are used in documents, the Creator/Editor of the content should verify the accuracy of the bookmarks or links each time that the content is revised.** **CAUTION: When using links to external content be aware that those links could break which could cause the need for a document revision.**

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6.5 Document Format and Content

Step	Action
1	The following sections are required to be used in procedures (i.e., Quality System SOPs and Work Instructions, and Manufacturing Procedures and Work Instructions) and are recommended for other documents when appropriate. **NOTE: Approved templates and forms in the business element process documentation or in Appendices A through D of this procedure takes precedence over the information below.** **PURPOSE** *Define what the document intends to describe, define, clarify, establish, or accomplish.* *As necessary for clarity, define what this procedure applies to (e.g. functions, business units, value streams). Note that applicable locations are already described in the Affected Sites attribute of Windchill and should not be specifically repeated here.* **REFERENCES** **Applicable Documents** *List any controlled documents (preferably in numeric order) that are direct outputs of the procedure. See Definitions section of this procedure for the definition of Applicable Documents. For information about the configuration of applicable documents, see 87117, Create and Maintain Document and Part Structure.* **NOTES:** ➢ **Documents listed in the Applicable Documents section must be at a Released state if being added to the Applicable Documents section.** ➢ **Applicable document at a Pre-Released or Released state can be added to a Pre-Released document. For protocols/plans and reports, Released or Pre-Released documents can be listed.** ➢ **Unreleased (unapproved) documentation (Creation, Draft, or A.0 (In Work)) may not be used as an Applicable Document.** ➢ **Applicable Documents can be referenced as necessary within the procedural text of the document by document name and/or number.** **External References** *List any external references that apply to country-specific requirements within the procedure.* *Include a note, when applicable, identifying what section(s) the country-specific requirement(s) is/are not applicable to the process governed by the procedure.* *External references that are already listed in the Quality Management System (QMS) Document Matrix or Quality Manual may NOT be listed in any other QMS procedures.* *See Definitions section of this procedure for the definition of Reference Documents.*

6.5 Document Format and Content

Step	Action
	NOTES: ➢ **External References may be cited within the body text of the procedure as necessary.** ➢ **Internal Abbott Documents are NOT listed in the External References. For example: *for more information about [topic], see [doc number], [doc name].*** ➢ **Reference documents are NOT structured to the document.** **RESPONSIBILITES** *Indicate which functions, organizational levels, or other accountabilities that are involved with the accurate performance, maintenance, etc. of this procedure.* **DEFINITIONS** *List the definitions that are specifically necessary to help clarify terms or concepts used within the document. Inclusion of high-level regulatory definitions is not recommended; these terms are defined in the Quality System Glossary. Additionally, high-level process definitions already defined in a higher-level document should not be included.* **NOTE: Only terms used within the document should be included in the Definitions section.** **FLOW CHART** *Flow charts should be used to illustrate and clarify a procedure or process whenever possible.* **REQUIREMENTS, PROCEDURE, or INSTRUCTIONS (Tabular)** *This section should be used to document the requirements and/or steps needed to meet the intent of the document.* *Choose the appropriate section header based on the document type, (Procedure or Instructions for Work Instructions and Guidance, Requirements for SOPs.).* **REQUIREMENTS, PROCEDURE, or INSTRUCTIONS (Outline)** *This section should be used to document the requirements and/or steps needed to meet the intent of the document.* *Choose the appropriate section header based on the document type, (Procedure or Instructions for Work Instructions and Guidance, Requirements for SOPs.).* **APPENDICES** *This is an optional section. Include appendices as necessary for supporting information. When using appendices, follow the alpha numbering sequence (e.g., APPENDIX A: [Name], APPENDIX B: [Name]).*

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7.0 APPENDICES

Appendix A: Atlanta Template

Appendix B: EP Template/Procedure

Appendix C: NMD Template/Procedure

Appendix D: SH Template/Procedure

Document Format and Content

APPENDIX A: ATLANTA TEMPLATE

Atlanta Template	
Number	**Title**
TEMP-CERT	Certification of Conformance (CofC)
TEMP-FMEA	Risk Analysis Template
TEMP-FTA	Creating Fault Trees Template
TEMP-FTA-XLS	Template for Calculating FTA Probabilities
TEMP-IQ	IQ Protocol/Report Template
TEMP-SA-11	Mfg Software Method of Assurance Template
TEMP-SA-22	Mfg Software Specification
TEMP-SO	Template for Software Specification
TEMP-SO-55	Template for Software Characteristics Document
TEMP-SO-CODE-REVIEW	Software Code Review Template
TEMP-SO-PROTOCOL	Template for Software Requirements Test Protocol
TEMP-SO-RESULTS	Template for Software Requirements Test Results Document
TEMP-SO-SDD	Template for Software Design Document
TEMP-SO-SHA	Software Hazard Analysis Template
TEMP-SO-SRS	Template for Software Requirements Specification
TEMP-SO-UI	Template for Unit and Integration Testing
TEMP-ST	Template for Software Tool Control
TEMP-TP	Template Design Test Protocol
TEMP-TR	Template Design Test Report
TEMP-USABILITY-SPEC	Usability Specification Template
TEMP-USABILITY-VAL-PLAN	Usability Validation Plan Template
90255493	OQ Template
90255478	TMVP/TMVR Template
90255497	MVP/MVR Template
90255496	IMV Protocol/Report Template
90255495	PPQ Template
90255494	PQ Template
90330128	User Interface Specification Template

Document Format and Content

APPENDIX B: EP TEMPLATE/PROCEDURE

EP Template/Procedure		
Document Type/Sub Type	**Attached Template**	**Associated Template or Procedure**
Manufacturing		
ERP Routing	N/A	90048428 (where implemented), For Irvine 90143293
Form	K	N/A
Inspection Procedure	A	N/A
Manufacturing Procedure	N/A	90037944
Receiving Inspection Procedure	N/A	90114876
Shop Floor Paperwork	N/A	90115566, 90105718
Visual Standard Aid	N	N/A
Work Instruction	N/A	Microbiology 90182852
Qualification		
Environment Qualification	N/A	90182852
Installation Qualification	N/A	90105852
Microbiology Equipment Qualification	N/A	90183341
Operational Qualification	N/A	90105853
Other Qualification/Study	M	Microbiology 90182852
Performance Qualification	N/A	90105854
Product Performance Qualification	N/A	90106381
Test Method Validation	N/A	90115006
Purchased Component Qualification Report	N/A	90113943
Sterilization Validation	N/A	90182852
Technical Report	M	Microbiology 90182852
Quality Systems		
Form	K	N/A
Specification		
Artwork Specification	D	N/A
Controlled Environment Specification	T1 - Controlled Environment Specification (CAE) T2 - Temperature/Humidity T3 - Electrostatic Discharge/Damage (ESD)	N/A
General Specification	D	N/A
Instruction for Use	D	N/A
Labeling Specification	D1 or a label system generated PDF	N/A
Material Specification	D	N/A
Software Requirement Specification (Non-Device)	N/A	90126729
Process Specification	D	N/A

Document Format and Content

EP Template/Procedure		
Document Type/Sub Type	**Attached Template**	**Associated Template or Procedure**
Supplementary IFU	D	N/A
Supply Specification	D	N/A
Testing		
Test Method	R	Microbiology 90182852
Test Method Transfer	N/A	690180
Test Method Validation	M	Microbiology 90182852
Design and Development Other		
Design Development Plan	N/A	90001026 (DDP)
Design Review	N/A	90346442 (Reviews) 90004450 (Definition) 90000673 (Component) 90000674 (Design Freeze) 90004452 (Validation) 90004453 (Close-Out) 90004451 (Development) 90411932 (Design Review Report) 90008835 (Clinical PDP) 90027016 (OEM Checklist)
Development Installation Qualification	N/A	90105852
Development Technical Report	Q	N/A
Inspection Validation	N/A	90115006
Integrated Business Plan	N/A	90001026 (IBP) 90001024 (PDP Charter) 90001025 (Proposal) 90020806 (Contract)
Project Contract	N/A	90020806 (Contract)
Scaled Design Development Plan	N/A	90408545
Design Validation		
Design Validation	N/A	90002588
Design Verification		
Design Verification	N/A	90002587
Design Test Method	R	N/A
Design Test Method Validation	N/A	90115006
Process Validation		
Master Validation	N/A	90113249
Requirements Documents		
Applicable Standards Document	N/A	90004292
Customer Requirements	N/A	90004290
Design Description Document	N/A	90004293
Design Input/Design Output Summary	N/A	90004293
External Requirements Document	N/A	90004292

Document Format and Content

EP Template/Procedure		
Document Type/Sub Type	**Attached Template**	**Associated Template or Procedure**
Product Requirements	N/A	90004291
Risk Management		
FMEA, Design	N/A	90004295
FMEA, Process	N/A	90004296
FMEA, Use	N/A	90004294
Risk Analysis (includes Hazard Analysis)	N/A	90011223
Risk Management Plan/Report	N/A	90010993

Document Format and Content

APPENDIX C: NMD TEMPLATE/PROCEDURE

NMD Template/Procedure		
Document Type/Sub Type	**Work Instruction**	**Associated Template or Procedure**
Manufacturing		
ERP Routing	N/A	94-2434
Common Template for all Controls	N/A	94-2434
Inspection Procedure	50-0018	94-2434
Manufacturing Procedure	N/A	94-2434
Manufacturing Quality Plan/Report	56-0103	94-2210, 94-2434, 94-2800, 94-2436
Visual Standard Aid	N/A	94-2434
Work Instruction	N/A	Microbiology 90182852
SMT Recipe Management	N/A	41-0002-2000
Master Validation Plan	56-0661	94-2807
Finished Device Country Configurations Model	56-0193	94-2458
Misc Production		
Software Executable	N/A	94-2444
Qualification		
Environment Qualification	90182852	90182852
Installation Qualification	56-0622	94-2800, 94-2799
Microbiology Equipment Qualification	90183341	90183341
Operational Qualification	56-0623	94-2802, 94-2805, 94-2801
Performance Qualification	56-0660	94-2301, 94-2803, 94-2804
Product Performance Qualification	56-0660	94-2210, 94-2301, 94-2806, 94-2805, 94-2804, 94-2803
Test Method Validation	56-0393	94-2501, 94-2749, 50-0132
Software Validation	N/A	94-2210, 94-2749, 94-2541
Software Verification	N/A	94-2210, 94-2301, 94-2749
Sterilization Validation	90182852	90182852
Technical Report	N/A	94-2210, Microbiology 90182852
Quality Systems		
Form	N/A	94-2434
Process Control Plan, Form (Portland)	56-8131	94-8168
Process Control Plan, Form	56-0293	94-2322
Product Development Plan (NJ)	WI in Template	82-0005-0900
Manufacturing Plan (NJ)	WI in Template	82-0005-1000
Programs (NJ)	WI in Template	82-0005-1100
Test Specifications (NJ)	WI in Template	82-0005-1200
Software Development plan	N/A	94-2214
Design Validation Plan	50-0045	94-2237
Project Plan	50-0001, 56-0368	94-2281, 94-2722, 94-2285
Technical Marketing Update	N/A	94-2295

Document Format and Content

NMD Template/Procedure		
Document Type/Sub Type	**Work Instruction**	**Associated Template or Procedure**
Competitive Marketing Update	N/A	94-2296
Clinical Marketing Update	N/A	94-2297
Form, Policies and Procedure Marketing	N/A	94-2298
Clinical Literature Marketing Update	N/A	94-2299
Risk Management Plan	N/A	94-2439
Product Labeling Specification	WI in Template	94-2442
Non-Device System Classification	WI in Template	94-2448
Test Method	56-0393	94-2526
Non-Product System Plan/Protocol	56-0613	94-2540, 94-2749
User Requirements/Design Specification for Non-Product Systems	56-0613	94-2541
Project Initiation	56-0318	94-2441
Project Initiation- Market Expansion	56-0318	94-2325
Project Initiation- Design Change	56-0318	94-2324
Project Initiation- Product Development	56-0318	94-2060
Specification		
Artwork Specification	56-0107	94-2442
Controlled Environment Specification	N/A	Attached Template T
Equipment/Tooling/Fixture	56-0107	CAD drawing (drafting dept.) 94-2434
General Specification	N/A	94-2434 and CAD drawing Water System Specifications use 90182852
Instruction for Use	94-2442	94-2442
Labeling Specification	94-2442	94-2434, 94-2442
Material Specification	94-2443	CAD drawing (drafting dept.), 94-2434
Non-Device User Requirements Specification	N/A	94-2434, 94-2749, 94-2540, 94-2732, 94-2541
System Requirements Specification	56-0124	94-2434
Design Output Specifications	N/A	94-2434
Testing		
Test Method	50-0132	94-2526, Microbiology 90182852
Test Method Validation	50-0132	94-2501, Microbiology 90182852
Design and Development Other		
Design Review	50-0001	94-2283
Market Release	56-0193	94-2458
Design Validation		
Design Validation	56-0103	94-2210

Document Format and Content

NMD Template/Procedure		
Document Type/Sub Type	**Work Instruction**	**Associated Template or Procedure**
Design Verification		
Design Verification	56-0103	94-2210, 94-2284, 94-2283
Design Test Method	50-0132, 56-0393	94-2526
Design Test Method Validation	50-0132, 56-0393	94-2501
Requirements Documents		
Customer Requirements, Product Requirements	56-0124, 50-0001	94-2222
Risk Management		
FMECA, Process	56-0266	94-2436
FMECA, Software	56-0268	94-2440
Risk Analysis (includes Hazard Analysis)	56-0269	94-2438
Risk Management Plan/Report	50-0043	94-2439, 94-2437
FMECA Component and Application	56-0121	94-2435

Document Format and Content

APPENDIX D: SH TEMPLATE/PROCEDURE

SH Template/Procedure		
Document Type/Sub Type	**Attached Template**	**Associated Template or Procedure**
Manufacturing		
ERP Routing	N/A	90048428 (where implemented)
Form	K	N/A
Inspection Procedure	A	N/A
Manufacturing Procedure	N/A	90037944
Receiving Inspection Procedure	N/A	90114876
Shop Floor Paperwork	N/A	90115566, 90105718
Visual Standard Aid	N	N/A
Work Instruction	N/A	Microbiology 90182852
Qualification		
Environment Qualification	N/A	90182852
Installation Qualification	N/A	90105852
Microbiology Equipment Qualification	N/A	90183341
Operational Qualification	N/A	90105853
Other Qualification/Study	M	Microbiology 90182852
Performance Qualification	N/A	90105854
Product Performance Qualification	N/A	90106381
Test Method Validation	N/A	90115006
Purchased Component Qualification Report	N/A	90113943
Sterilization Validation	N/A	90182852
Technical Report	M	Microbiology 90182852
Quality Systems		
Form	K	N/A
Specification		
Artwork Specification	D	N/A
Controlled Environment Specification	T1 - Controlled Environment Specification (CAE) T2 - Temperature/Humidity T3 - Electrostatic Discharge/Damage (ESD)	N/A
General Specification	D	N/A
Instruction for Use	D	N/A
Labeling Specification	D1 or a label system generated PDF	N/A
Material Specification	D	N/A
Software Requirement Specification (Non-Device)	N/A	90126729
Process Specification	D	N/A
Supplementary IFU	D	N/A

Document Format and Content

SH Template/Procedure		
Document Type/Sub Type	**Attached Template**	**Associated Template or Procedure**
Supply Specification	D	N/A
Testing		
Test Method	R	Microbiology 90182852
Test Method Transfer	N/A	690180
Test Method Validation	M	Microbiology 90182852
Design and Development Other		
Design Development Plan	N/A	90401220 (DDP) 90401360 (PDP Charter) 90401383 (Proposal)
Design Review	N/A	90411941 (Design Review Report) 90411942 (Attendance) 90411944 (Deliverable Summary Report) 90411945 (Consolidated Deliverables Matrix) 90412561 (Technical Review Report) 90401203 (Clinical PDP) 90412019 (OEM Checklist)
Development Installation Qualification	N/A	90105852
Development Technical Report	Q	N/A
Inspection Validation	N/A	90115006
Integrated Business Plan	N/A	90401220 (DDP) 90401360 (PDP Charter) 90401383 (Proposal)
Project Contract	N/A	90401201
Scaled Design Development Plan	N/A	90408548
Design Validation		
Design Validation	N/A	90401358
Design Verification		
Design Verification	N/A	90401335
Design Test Method	R	N/A
Design Test Method Validation	N/A	90115006
Process Validation		
Master Validation	N/A	90113249
Requirements Documents		
Applicable Standards Document	N/A	90408620
Customer Requirements	N/A	90401202
Design Description Document	N/A	90401334
Design Input/Design Output Summary	N/A	90401334
External Requirements Document	N/A	90408620
Product Requirements	N/A	90401223

Document Format and Content

SH Template/Procedure		
Document Type/Sub Type	**Attached Template**	**Associated Template or Procedure**
Risk Management		
FMEA, Design	N/A	90401401
FMEA, Process	N/A	90401403
FMEA, Use	N/A	90401366
Risk Analysis (includes Hazard Analysis)	N/A	90401368
Risk Management Plan/Report	N/A	90401370