PDHonline Course K111 (4 PDH)

Creating a Pharmaceutical Installation Qualification

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ATTACHMENT C-1

1.0 INSTALLATION QUALIFICATION

Documentation Verification

Instructions: Complete a list of documents detailing the design, specification and purchase of this system. Include engineering specifications, purchase orders, manuals and documents identifying approved changes or deviations to the design specifications. Review available drawings, including pertinent mechanical, electrical, and piping and instrumentation diagrams (P&ID). Identify those drawings that are critical to maintaining change control for the system. Verify that the latest revisions of critical drawings reflect the system "as built," or red-line them to reflect current status.

Document #	Title	Document Type	Critical? Non-Critical?	Revision Number	Last Rev Date	Storage Location
1234	Specification for Autoclave	Specification	Critical	1		
5678	PO for Autoclave	Purchase Order	Critical	2		
91010	P&ID for Autoclave	P&ID	Critical	3		
900100	Piping arrangement for steam	Piping Arrangement	Non-Critical			
None	Hydrostatic Pressure Test	Test Report	Non-Critical			
None	U-1 Report on Autoclave	Certification	Critical			

COMMENTS:_____
_____
_____

CONDUCTED BY: _____DATE:_____

REVIEWED BY: _____DATE: _____

ATTACHMENT C-2

Manuals

Instructions: Document the existence of all manuals pertinent to this system. All system major components, including critical instruments, must be listed.

Component	Vendor	Manual Title	Location
Autoclave	ABC Autoclaves	Installation/Maintenance	Validation
Vacuum Pump	ABC Autoclaves	Maintenance	Validation
Steam Control Valve	Stewart	Calibration	Validation

Comments: It is generally best to keep the original manual in the Validation files and copies in Engineering and Maintenance

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT C-3

Drawing Verification

Instructions: Review available drawings including pertinent mechanical, electrical, and piping and instrumentation diagrams (P&ID). Identify those drawings that are critical to maintaining change control for the system. Verify that the latest revisions of critical drawings reflect the system "as built", or red-line them to reflect current status. When items are found that do not agree, use red pen to make corrections on the drawing. Once the drawings have been verified, sign and date them.

Drawing Number	Title	Rev. #	Rev. Date	File Location
1234	P&ID autoclave Steam and Condensate	1*	6/26/05	Validation
5678	Controls Single Line	2	6/27/05	Validation

Comments: *This is a red lined drawing

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT C-4

Spare Parts

Instructions: Document the existence and location of spare parts lists for each major system component. Attach lists to this attachment or reference the file location where they may be found. Make photocopies of this page prior to filling it out for additional space. Write the appropriate page numbers in.

Major System Component	Recommended Spare Parts List Exists (Yes/No)	Location of Spare Parts List (Attached or File Location)
Autoclave	Yes	In Installation Manual in Validation
Vacuum Pump	Yes	In Operating Manual in Validation
Steam Control Valve	Yes	Stand alone list in Validation Files

Comments:_____

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT C-5

SOP List

Instructions: List all SOP,s used for the operation and maintenance of the system. Review the latest revisions of the SOP's. Review each document to assure adequacy and comment as necessary. Make photocopies of this page prior to filling it out for additional space. Write the appropriate page numbers in.

Doc. No.: AF-OP-101	Rev/Version No.: 1	Rev/Issue Date: 6/26/04
Doc. Title: Operations of Autoclave AC-10		
Comments: Refer to calibration and maintenance prior to operations. Use defined loads only.		

Doc. No.:	Rev/Version No.:	Rev/Issue Date:
Doc. Title:		
Comments:		

Doc. No.:	Rev/Version No.:	Rev/Issue Date:
Doc. Title:		
Comments:		

Doc. No.:	Rev/Version No.:	Rev/Issue Date:
Doc. Title:		
Comments:		

Comments:_____

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Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT C-6

Lubricant Verification

Instructions: List the lubricants used that have the potential for product contact. Verify that all lubricants used in, near or above product contact surfaces are food grade FDA acceptable lubricants. Make photocopies of this page prior to filling it out for additional space. Write the appropriate page numbers in.

Lubricant Description / Brand	Location Used	Product Contact (Y/N)	Food Grade (Y/N)	Initials/Date
TX-50 Grease	Agitator Bearings	Potential	Yes	

Comments:_____

_____

_____

_____

_____

_____

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT C-7

Materials in Product Contact

Instructions: Review manufacturer's literature, material certifications or actual material composition stamps and record all materials, excluding lubricants that may contact final product or in-process material. Confirm that the materials of construction for product contact areas of the equipment are consistent with design specifications.

Component	Specified Material	Actual Material	How Verified?	Initial/Date
Reactor Internals	316L Stainless Steel	316L	Label on Vessel	
Agitator	316 Stainless Steel	316	Vendor Documentation	

Comments:_____

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT C-8

Test Reports and FAT / SAT

Instructions: Collect reports documenting testing performed during the manufacture and installation of this system, as required by the engineering specifications. Review those reports to verify that they have been completed properly and that all required testing was performed. Include copies of the test reports with the attachment or reference their file location. Make photocopies of this page prior to filling it out for additional space. Write the appropriate page numbers in.

Report Name & Test Reference	Performed By	Date	Location	Initial/ Date
FAT*	MB Autoclaves	7/5/04	St. Louis	

Comments: *FAT observed by J. Smith, Engineering, copy of FAT in Validation files

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT C-9

Commissioning Reports

Instructions: Collect the Commissioning Reports documenting the functional tests performed during the commissioning of this system. Review those reports to verify that they have been completed properly and that all required testing was performed. Include copies of the test reports with the attachment or reference their file location. Make photocopies of this page prior to filling it out for additional space. Write the appropriate page numbers in.

Report Name & Test Reference	Performed By	Date	Location	Initial/ Date
Commissioning of Autoclave Steam Piping	J. Smith, Engineering and J. Jones Construction Co.	10/20/04	XYZ Pharmaceuticals	

Comments: *Commissioning Report approved and on file

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT D

Test Equipment

Instructions: List all test equipment used in the performance of the OQ tests and verify current calibration.

Equipment Description	Identification Number	Last Calibration Date	Next Calibration Due Date
Machinist's Level	143-L	6/26/05	6/26/06

Comments: _____

_____

_____

_____

_____

_____

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT E

Visual Inspection

Instructions: Verify that the actual installation matches the design documents and that all systems are in place.

Equipment Name: _____ Equipment Number: _____

Describe overall installation noting any items appearing out of position relative to design documents:

_____

_____

_____

Verify components are properly anchored to floor: Anchoring is adequate? YES _____ NO _____

Verify installed components are level: Equipment verified to be level? YES _____ NO _____

Verify that all piping is complete per P&ID: Piping appears complete? YES _____ NO _____

Verify that components are properly secured to preceding and following equipment: Secure? YES ____ NO ____

Verify that all machine guards are in place: Guards in place? YES _____ NO _____

Comments: _____

_____

_____

_____

_____

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Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT F-1

Major Components Verification

Vessels

Instructions: Verify that the actual or as-built condition matches the design or purchase specifications as indicated, and that components are properly labeled.

Item Number: _____ Item Name: **Equipment Name Vessel**

1. Verify the following vessel information on the nameplate and equipment Certification Documents to be in accordance with the appropriate documents in section 8.1.

ITEM	SPECIFIED	ACTUAL	INITIALS / DATE
Manufacturer Name			
Model Number			
P.O. Number			
Date of P.O.			
Capacity			
ASME Rated			
National Board Number			
Material of Construction			
Rated Press/Temp			
Rated Press/Temp			
Location			

Comments: _____

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT F-2

Pumps and Motors

Instructions: Verify that the actual or as-built condition matches the design or purchase specifications as indicated, and that components are properly labeled.

Item Number:_____ Item Name:_____

ITEM	SPECIFIED	ACTUAL	INITIALS / DATE
Manufacturer Name			
Model Number			
P.O. Number			
Date of P.O.			
Capacity, gpm / head			
Nominal size (in/out-imp)			
Impeller Diameter, inches			
Material of Construction			
Motor HP & RPM			
Electrical Classification			
Rotation direction			
Location			

1. Verify that the items below are completed (if applicable):

   Confirm pump is connected to ground wire. Yes ___ N/A No ___

   Confirm power supply is +/-10% of the nameplate-related voltage. Yes ___ N/A No ___

   Pump Enclosure/Coupling Guards Installed Yes ___ No ___

   Safety Switch/Breaker: _____N/A_____ Location:____N/A____

   Initial Lubrication:_____

   Oil Type:_____ Oil Level:_____

_____
Initials/Date

Comments:_____

_____

_____

_____

Conducted By: _____ Date: _____

Reviewed By: _____ Date:_____

Safety Devices ATTACHMENT F-3 Page _1_ of _7_

Instructions: Test and verify the following information on the safety devices associated with the system.

Item Number: _____ Item Name: Equipment Name Rupture Disc

1. Verify the following safety device information on the nameplate to be accordance with the reference: Drawing #: _____

ITEM	SPECIFIED	ACTUAL	INITIALS / DATE
Rupture Disc			
Manufacturer Name			
Model Number			
Serial Number			
Capacity, lb/hr			
Size, inches			
Set Pressure, psig			
Temperature Rating, deg F			
Material of Construction			
Location\Line			
Discharges to			
Vacuum Support			

2. Verify that installation is completed _____
Initials/Date

Comments: _____

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT F-4

Agitator

Instructions: Test and verify the following information on the agitators associated with the system.

Item Number: _____ Item Name: Equipment Name Agitator

1. Verify the following agitator drive information on the nameplate and equipment Certification Documents to be in accordance with the reference Drawing #: _____

ITEM	SPECIFIED	ACTUAL	INITIALS / DATE
Manufacturer Name			
Model Number			
P.O. Number			
Date of P.O.			
Impeller Diameter, inches			
Material of Construction			
Motor HP & RPM			
Speed, rpm			
Electrical Classification			
Rotation direction			
Location			

2. Verify that the items below are completed (if applicable):

Confirm agitator is connected to ground wire. Yes _____ No ___

Confirm power supply is +/-10% of the nameplate-related voltage. Yes _____ No ___

Agitator Enclosure/Coupling Guards Installed Yes _____ No ___

Safety Switch/Breaker: _____ Location:_____

Initial Lubrication:_____

Oil Type:_____ Oil Level:_____

_____
Initials/Date

Comments:_____

_____

_____

_____

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT F-5

Hand Valve Verification

Instructions: Prepare a list of new hand valves associated with the system. Verify that all valves can be opened/closed and that they are labeled properly. Record the results in the table below. Use additional copies if necessary**.**

Valve Number	Line Number	P&ID Number	Verified	Valve Number	Line Number	P&ID Number	Verified
HV-143	123	1009					

Comments:_____

_____

_____

_____

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT G

Instrument List

Instructions: Complete a list of all instruments associated with the Equipment Name System and Temperature Control Unit. Classify the instruments as 'critical', 'non-critical', or 'reference'. Ensure that the critical instruments associated with the equipment have been calibrated using standards that are NIST traceable and document the SOP that is utilized to perform the calibration. Verify that a copy of the completed calibration documentation is in Maintenance files. Verify that the re-calibration interval for the instruments is indicated.

Tag No.	Description	Manufacturer / Model Number	Type (Critical / Non-Critical / Reference)	P&ID #	Cal. Date and Interval	SOP #
PI-123	Pressure indicator for steam to autoclave	W-S / 143	Critical	1009	6/26/05 6 months	CA-1003

Comments:_____

_____

_____

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

ATTACHMENT H-1

Utility Support System Verification

Electrical Power Supply

Instructions: Verify that the utilities necessary for operation have been installed in conformance with design and/or manufacturing specifications.

Verify items below are installed for all major equipment in accordance with the reference Drawing #:_____

Service Provided To:	Voltage	Power Source	Source Location	Phases
Autoclave	480 / 60 / 3Ø	Circuit Breaker CB-14	2nd Floor Electrical Room	

Note: For equipment/installation with multiple power supplies (i.e., 460V and 120V), complete for each power source. Power supplies to instruments need not be recorded here.

COMMENTS:_____

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CONDUCTED BY: _____ DATE: _____

REVIEWED BY: _____ DATE: _____

ATTACHMENT H-2

Non-Electrical Utilities

Instructions: Verify that the utilities necessary for operation have been installed in conformance with design and/or manufacturing specifications. Verify proper connectivity and labeling between equipment and utilities. Record reading off of specified instrumentation.

Utility	**Pressure (kPag)**		**Temperature (°C)**		**P&ID #**	**Initials/ Date**
	Instrument	Reading	Instrument	Reading		
Nitrogen bleed to autoclave	xx-123	15 psig	N/A		1008	

Comments:_____

_____

_____

_____

Conducted By: _____ Date: _____

Reviewed By: _____ Date: _____

PROTOCOL EXCEPTION REPORT ATTACHMENT I-1

Number: _____ Date: _____

Protocol Section/Attachment #: _____

Exception: _____

Initiator: _____ Date: _____

Investigation _____

_____

_____

_____

_____

Completed By: _____ Date: _____

Corrective Action: _____

_____

_____

_____

_____

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_____

_____

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Resolved By: _____ Date: _____

Reviewed By: _____ Date: _____

PROTOCOL EXCEPTION LOG ATTACHMENT I-2

Protocol Exception Number	Brief Description of Exception	Date Exception Resolved	Initial/Date

Comments:_____

Reviewed By: _____ Date: _____