

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 1 of 37

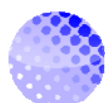
VALIDATION PROTOCOL

Prepared By: _____
East Coast Validation Services, LLC. _____ Date _____

Reviewed By: _____
Acme Biotech Manufacturing _____ Date _____

Reviewed By: _____
Acme Biotech Facilities _____ Date _____

Approved By: _____
Acme Biotech Quality Assurance _____ Date _____



Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 2 of 37

TABLE OF CONTENTS

1.0 OBJECTIVE.....3

2.0 SCOPE3

3.0 ASSOCIATED DOCUMENTATION.....3

4.0 SYSTEM DESCRIPTION.....3

5.0 DOCUMENTATION.....4

6.0 RESPONSIBILITIES4

7.0 INSTALLATION VERIFICATION5

8.0 OPERATION VERIFICATION10

9.0 EXCEPTION RESOLUTION AND EXECUTION SUMMARY.....12

ATTACHMENT 1: SIGNATURE LOG14

ATTACHMENT 2: CRITICAL COMPONENT INFORMATION VERIFICATION15

ATTACHMENT 3: SUPPORT DOCUMENTATION VERIFICATION16

ATTACHMENT 4: MATERIALS OF CONSTRUCTION VERIFICATION17

ATTACHMENT 5: PIPING MODIFICATIONS DOCUMENTATION VERIFICATION.....18

ATTACHMENT 6: UTILITY CONNECTION VERIFICATION19

ATTACHMENT 7: TEST INSTRUMENT CALIBRATION VERIFICATION20

ATTACHMENT 8: GENERAL INSTALLATION REVIEW21

ATTACHMENT 9: STANDARD OPERATING PROCEDURE REVIEW22

ATTACHMENT 10: PUMP FUNCTIONAL VERIFICATION23

ATTACHMENT 11: DISCREPANCY RESOLUTION25

ATTACHMENT 12: DEVIATION RESOLUTION.....26

ATTACHMENT 13: EXECUTION SUMMARY27

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 3 of 37

1.0 OBJECTIVE

The objective of this protocol is to define the Installation and Operation Qualification (IOQ) requirements, as well as the associated Acceptance Criteria for the Alfa Laval Model LKH25 Sanitary Pump P-101, located in the Mechanical Services Area of the Acme Biotech facility located in Thule, Greenland. This IOQ will provide documented evidence that Pump P-101 has been installed and operates per the manufacturer's specifications and in accordance with Acme Biotech requirements.

2.0 SCOPE

This IOQ protocol will address the replacement of an existing TriClover model 218 pump with an Alfa Laval model LKH25 pump. (Refer to Change Control Summary VC-xxxx.)

Pump P-101 is a component of Clean In Place (CIP) system CIP-012. As this IOQ will document that the Alfa Laval model LKH25 pump is equivalent to the TriClover model 218 pump in terms of critical attributes required for effective cleaning, the functionality of CIP-012 is beyond the scope of this protocol.

3.0 ASSOCIATED DOCUMENTATION

Document Number	Document Title
VC-xxxx	Change Control Summary, <i>Replacement of a TriClover/Alfa Laval Model 218 Pump with an Alfa Laval Model LKH25</i>

4.0 SYSTEM DESCRIPTION

Pump P-101 was previously a TriClover model 218 centrifugal pump used to deliver cleaning solutions and rinsewater for CIP-012. It has been replaced with an Alfa Laval model LKH25 centrifugal pump. Specifications for both pumps are summarized in the following table:

Specification	Current State	Proposed State
Manufacturer/Model	TriClover 218	Alfa Laval LKH25
Impeller diameter	7"	7.48"
Motor HP/speed	5 HP / 1800 RPM	3 HP / 1800 RPM
Flowrate	80 GPM	80 GPM
Pressure head	50 FT	50 FT

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 4 of 37

5.0 DOCUMENTATION

The Final Validation Package for this unit will include the results, observations, and conclusions from the execution of this protocol. All Discrepancies and Deviations observed during the execution of this protocol will be documented and their resolutions approved by Acme Biotech Quality Assurance. A copy of the executed protocol with all completed attachments, all associated exhibits and all approved Discrepancies and Deviations will be included in the Final Validation Package.

When signed by authorized representatives from Acme Biotech Manufacturing, Facilities and Quality Assurance departments, **Attachment 9: Execution Summary** will indicate that the Installation and Operation Qualification of Pump P-101 is complete and provides documented evidence that it has been installed and operates per the manufacturer's specifications and in accordance with Acme Biotech requirements.

6.0 RESPONSIBILITIES

6.1. East Coast Validation Services, LLC.

- 6.1.1. Developing, writing, and reviewing this protocol.
- 6.1.2. Executing the tests and verifications set forth in this protocol.
- 6.1.3. Providing a Summary Report that documents and summarizes the execution of this qualification protocol per Section 5.0.
- 6.1.4. Preparing the Validation Package for review and approval.

6.2. Acme Biotech – Manufacturing and Facilities Departments

- 6.2.1. Managing the validation project, assisting with scheduling, coordination of materials and information, and providing access to the equipment.
- 6.2.2. Reviewing, verifying and approving this protocol and the Summary Report. This shall include resolution, if necessary, of any Discrepancies and/or Deviations observed during the execution of the IOQ protocol.
- 6.2.3. Ensuring that all measuring, recording, and controlling instruments that impact the system operation and/or are required to provide measurements for this qualification are in current calibration to NIST traceable standards before being used to support this qualification.
- 6.2.4. Maintaining applicable Standard Operating Procedures (SOP's), including but not limited to system Operation and Preventive Maintenance.

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 5 of 37

6.3. Acme Biotech – Quality Assurance

- 6.3.1. Reviewing and approving this protocol for compliance with regulatory expectations and Acme Biotech policies prior to execution.
- 6.3.2. Reviewing the executed protocol for compliance with the Acceptance Criteria and, if necessary, approving any Discrepancies and/or Deviations occurring during the execution of the protocol.
- 6.3.3. Reviewing and approving the Summary Report.

7.0 INSTALLATION VERIFICATION

Complete Sections 7.1 thru 7.8 of this IOQ and document all required information on the indicated Attachments for each section. In cases where Expected Results are stated in Attachment entries, the term "As Expected" can be entered if the Observed Results are consistent with the Expected Results. If any results do not meet Acceptance Criteria, document these results as described in **Section 9.1: Discrepancy Resolution**. If any deviations from the protocol procedures are made, indicate them as described in **Section 9.2: Deviation Resolution**.

7.1. Signature Log

7.1.1. Objective

The objective of the Signature Log is to provide traceability of signatures and initials of those completing attachments or reviewing and signing required documents within the IOQ protocol. Signature also indicates that each participant has read and understood the protocol prior to review or execution.

7.1.2. Procedure

All personnel recording data on attachments, reviewing and signing attachments or reviewing and signing required documents within the protocol must record the required information on **Attachment 1: Signature Log**.

7.1.3. Acceptance Criteria

Signatures and initials of all personnel recording data for this protocol or reviewing the executed protocol are recorded on **Attachment 1**.

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 6 of 37

7.2. Critical Component Information Verification

7.2.1. Objective

The objective of this verification is to document that the pump critical components As Installed are consistent with specifications.

7.2.2. Procedure

Record nameplate information for the pump, motor and rotor and confirm that this information is consistent with specifications using **Attachment 2: Critical Component Information Verification**.

7.2.3. Acceptance Criteria

The pump, motor and rotor nameplate information is consistent with the documented specifications.

7.3. Support Documentation Verification

7.3.1. Objective

The objective of this verification is to confirm that documentation required to support the installation, operation and maintenance of the model LKH25 pump is available.

7.3.2. Procedure

Verify that the following information is available:

- 7.3.2.1. Pump cut sheet/specifications
- 7.3.2.2. Pump installation instructions
- 7.3.2.3. Pump Operation and Maintenance (O&M) manual
- 7.3.2.4. Manufacturer's Pump Curve data

Also verify that the CIP-012 Piping and Instrumentation Diagram (P&ID) has been revised to document that P-101 is now an Alfa Laval Model LKH25.

Document these verifications using **Attachment 3: Support Documentation Verification**, and attach copies of the above documents as Exhibits to the executed protocol.

7.3.3. Acceptance Criteria

The above documentation is confirmed to be on hand to support the installation, operation and maintenance of pump P-101.

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 7 of 37

7.4. Materials of Construction Verification

7.4.1. Objective

The objective of this section is to document that the Product Contact MOC of the Alfa Laval model LKH25 pump are consistent with the corresponding TriClover model 218 Product Contact MOC.

7.4.2. Procedure

Review the manufacturer's documentation for the Alfa Laval model LKH25 pump and confirm that the Product Contact MOC are consistent with the corresponding TriClover model 218 Product Contact MOC. Document this confirmation using **Attachment 4: Materials of Construction Verification**, and attach copies of the above documents as Exhibits to the executed protocol.

7.4.3. Acceptance Criteria

The Product Contact MOC of the Alfa Laval model LKH25 pump are documented to be consistent with the corresponding TriClover model 218 Product Contact MOC.

7.5. Piping Modifications Documentation Verification

7.5.1. Objective

The objective of this section is to confirm that any piping modifications implemented during the installation of the Alfa Laval model LKH25 pump are properly documented.

7.5.2. Procedure

Obtain copies of the following documentation associated with the piping modifications required to install the Alfa Laval model LKH25 pump with the CIP-012 system:

- 7.5.2.1. Isometric drawings
- 7.5.2.2. Weld logs and weld inspection reports
- 7.5.2.3. Pressure/leak test reports
- 7.5.2.4. Passivation reports

Attach copies of these documents as Exhibits to the executed protocol. Document this using **Attachment 5: Piping Modifications Documentation Verification**.

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 8 of 37

7.5.3. Acceptance Criteria

The above documents available, are included as Exhibits to the executed protocol, and confirm that the Alfa Laval model LKH25 pump is properly installed within the CIP-012 system.

7.6. Utility Connection Verification

7.6.1. Objective

The objective of this section is to document that the electrical service provided to P-101 meets specifications.

7.6.2. Procedure

7.6.2.1. Using a calibrated voltmeter, verify that 208 VAC 3 Φ power is supplied to P-101. Document this verification using **Attachment 6: Utility Connection Verification**.

7.6.2.2. Also document the circuit breaker that serves P-101 on **Attachment 6** and confirm that it is properly sized.

7.6.3. Acceptance Criteria

7.6.3.1. The voltage provided to P-101 is 208 VAC 3 Φ \pm 20 VAC.

7.6.3.2. The circuit breaker serving P-101 is documented on Attachment 6.

7.6.3.3. The circuit breaker serving P-101 has a capacity of at least 20A.

7.7. Test Instrument Calibration Verification

7.7.1. Objective

The objective of this section is to document that any Test Instruments used during the execution of this protocol have been properly calibrated.

7.7.2. Procedure

For each Test Instrument used during protocol execution, record the instrument type, serial number, Calibration Date and Calibration Due Date on **Attachment 7: Test Instrument Calibration Verification**. Attach copies of each instrument's Calibration documentation as Exhibits to the executed protocol.

7.7.3. Acceptance Criteria

All Test Instruments used during the execution of this protocol are documented to be in a calibrated state during execution.

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 9 of 37

7.8. General Installation Review

7.8.1. Objective

The objective of this section is to document that P-101 has been installed properly according to general GMP expectations and Acme Biotech requirements.

7.8.2. Procedure

7.8.2.1. Visually verify that P-101 is securely connected to CIP-012 piping with no visible leaks.

7.8.2.2. Verify that P-101 has been has been firmly secured to the floor with adequate accessibility for service.

7.8.2.3. Visually verify that P-101 is correctly tagged.

Document these verifications using **Attachment 8: General Installation Review**.

7.8.3. Acceptance Criteria

7.8.3.1. P-101 is securely connected to CIP-012 piping with no visible leaks.

7.8.3.2. P-101 is firmly secured to the floor with adequate accessibility for service.

7.8.3.3. P-101 is correctly tagged.

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 10 of 37

8.0 OPERATION VERIFICATION

8.1 Standard Operating Procedure Review

8.1.1 Objective

The objective of this section is to document that Acme Biotech Standard Operating Procedures (SOPs) have been revised to reflect the pump change from TriClover model 218 to Alfa Laval model LKH25.

8.1.2 Procedure

Review Acme Biotech SOPs for the following subjects and verify that any references to a TriClover model 218 pump have been revised to refer to an Alfa Laval model LKH25 pump:

8.1.2.1. Operation

8.1.2.2. Maintenance (including logbooks)

8.1.2.3. Spare parts inventory

Document this review using **Attachment 9: Standard Operating Procedure Review**.

8.1.3 Acceptance Criteria

The above identified SOPs have been revised as required to account for the pump change from TriClover model 218 to Alfa Laval model LKH25.

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 11 of 37

8.2. Pump Functional Verification

8.2.1. Objective

The objective of this section is to document that P-101, as installed per Section 7 of this protocol, functions per Acme Biotech requirements.

8.2.2. Procedure

8.2.2.1. Briefly actuate P-101 and verify that the rotor rotates in the correct direction.

8.2.2.2. Operate CIP-012 per Acme Biotech SOP under normal operating conditions, and verify that P-101 can maintain a flowrate of at least 80 gallons per minute (GPM).

8.2.2.3. Operate CIP-012 per Acme Biotech SOP, and adjust a manual valve or pressure control valve to obtain a backpressure to the pump of 50 feet Water Column (21.5 psi). Verify that P-101 maintains a flowrate of at least 80 GPM.

Note: Flowrate can be verified either by using a calibrated flow element inline with P-101 or by delivering the water flow to a container and measuring the time required to fill to a known volume using a calibrated timer.

8.2.2.4. Document these verifications using **Attachment 10: Pump Functional Verification**.

8.2.3. Acceptance Criteria

8.2.3.1. The P-101 rotor is confirmed to rotate in the correct direction.

8.2.3.2. P-101 can deliver 80 GPM under normal operating conditions.

8.2.3.3. P-101 can deliver 80 GPM with a backpressure of 50 feet Water Column (21.5 psi).

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 12 of 37

9.0 EXCEPTION RESOLUTION AND EXECUTION SUMMARY

9.1. Discrepancy Resolution

9.1.1. Objective

The purpose of the **Discrepancy Resolution** form is to document any data that did not meet the Acceptance Criteria, provide actions required to resolve the discrepancy, and/or to provide a justification for why the discrepancy is acceptable.

9.1.2. Procedure

Document all discrepancies noted during the execution of the IOQ protocol on **Attachment 11: Discrepancy Resolution**, along with resolutions or justifications. Circulate the completed **Attachment 11** for appropriate approval.

9.1.3. Acceptance Criteria

All discrepancies must be fully documented and resolved prior to approval of the Summary Report in one of three ways:

- 9.1.3.1. Justify why the change from the Acceptance Criteria is acceptable.
- 9.1.3.2. Physically change the item in question to conform to specification.
- 9.1.3.3. Replace a failing component and run the study again.

9.2. Deviation Resolution

9.2.1. Objective

The purpose of the **Deviation Resolution** form is to document any deviations from the approved protocol, and to provide a justification or resolution for why the deviation is acceptable.

9.2.2. Procedure

Document all deviations noted during the execution of the IOQ protocol on **Attachment 12: Deviation Resolution**, along with justifications or resolutions. Circulate the completed **Attachment 12** for appropriate approval.

9.2.3. Acceptance Criteria

All deviations must be fully documented, justified and approved prior to approval of the Summary Report.

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 13 of 37

9.3. Execution Summary

9.3.1. Objective

The purpose of the Execution Summary section of this protocol is to document that all Attachments have been executed, that all associated Attachment Exhibits are identified and attached to the executed protocol, and that all Discrepancies and Deviations observed during the execution of this protocol have been properly documented and acceptably resolved. The Execution Summary will document that all Acceptance Criteria have been met, or that a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.

9.3.2. Procedure

Review each protocol Attachment and confirm that it has been properly executed and documented and that all Attachment Exhibits are included with the executed protocol. Review test data and confirm that all Acceptance Criteria have been met, or that a Discrepancy or Deviation Report, documenting why the specific test results not meeting Acceptance Criteria are acceptable, has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance. Document this review using **Attachment 13: Execution Summary**.

Circulate the completed **Attachment 13** for approval by Acme Biotech Manufacturing, Facilities and Quality Assurance.

9.3.3. Acceptance Criteria

9.3.3.1. All protocol tests are confirmed to have been properly executed and documented on appropriate Attachments.

9.3.3.2. All Exhibits associated with each Attachment are identified and attached to the executed protocol.

9.3.3.3. All Acceptance Criteria have been met, or all Discrepancies and Deviations observed during the execution of this protocol have been properly documented and acceptably resolved.

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 14 of 37

ATTACHMENT 1: SIGNATURE LOG

The signatures below indicate that each signatory has read and understood this protocol prior to executing or reviewing it.

Printed Name	Signature	Initials	Company / Department	Date

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 15 of 37

ATTACHMENT 2: CRITICAL COMPONENT INFORMATION VERIFICATION

Verify that the following information is consistent with Acme Biotech and the manufacturer's specifications:

Item	Specified	As Found	As Found consistent with Specification? Yes/No	Verified By	
				Initials	Date
Pump	Alfa Laval Model LKH25				
Motor	3 HP / 1800 RPM				
Rotor	7.48"				

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 16 of 37

ATTACHMENT 3: SUPPORT DOCUMENTATION VERIFICATION

Verify that the following documentation is available to support the installation, operation and maintenance of pump P-101:

Document	Title / Number	Exhibit Number	Verified By	
			Initials	Date
Cut Sheet/ Specifications				
Installation Instructions				
Operation and Maintenance Manual				
Manufacturer's Pump Curve Data				

Document	Number/Revision	Revision Required? Yes/No	Exhibit Number	Verified By	
				Initials	Date
Acme Biotech P&ID:					

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 17 of 37

ATTACHMENT 4: MATERIALS OF CONSTRUCTION VERIFICATION

Verify that the Product Contact MOC of the Alfa Laval model LKH25 pump are consistent with the corresponding TriClover model 218 MOC:

Product Contact Surface(s)	TriClover model 218 MOC	Alfa Laval model LKH25 MOC	Consistent? Yes/No	Exhibit	Verified By	
					Initials	Date
Pump housing						
Pump rotor						
Pump seals (elastomers)						

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 18 of 37

ATTACHMENT 5: PIPING MODIFICATIONS DOCUMENTATION VERIFICATION

Obtain copies of the following documentation associated with any piping modifications that were implemented during the installation of P-101. If any of this documentation is Not Applicable, enter N/A in the appropriate spaces.

Document	Title/Number	Exhibit	Verified By	
			Initials	Date
Isometric drawing(s)				
Weld log(s)				
Weld Inspection Report(s)				
Pressure/Leak Test Reports				
Passivation Report(s)				

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 19 of 37

ATTACHMENT 6: UTILITY CONNECTION VERIFICATION

Verify that P-101 is properly connected to electrical power per the below table:

Item	Specified	As Found	As Found Consistent with Specification? Yes/No	Verified By	
				Initials	Date
Voltage	208 VAC 3 Φ \pm 20 VAC				
Breaker ID	Not Specified				
Breaker Capacity	\geq 20 A				

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 20 of 37

ATTACHMENT 7: TEST INSTRUMENT CALIBRATION VERIFICATION

Document the calibration status of all Test Instruments used during the execution of this protocol in the table below:

Instrument Description	Instrument Use	Instrument Serial Number	Calibration Date/ Calibration Due Date	Exhibit	Verified By	
					Initials	Date
Digital multimeter	Voltage verification					

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 21 of 37

ATTACHMENT 8: GENERAL INSTALLATION REVIEW

Specification	As Found	Acceptable? Yes/No	Verified By	
			Initials	Date
P-101 is securely connected to CIP-012 with no visible leaks				
P-101 is firmly secured to the floor with adequate service access				
P-101 is correctly tagged				

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 22 of 37

ATTACHMENT 9: STANDARD OPERATING PROCEDURE REVIEW

Review Acme Biotech SOPs for the following subject s and confirm that they have been revised to reflect that P-101 is now an Alfa Laval model LKH25 pump. If no revisions were required, enter "NR" in the space.

Category	SOP Title / Rev	Revised? Yes/NR	Verified By	
			Initials	Date
Operation				
Maintenance				
Equipment logbook(s)				
Spare parts inventory				

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 23 of 37

ATTACHMENT 10: PUMP FUNCTIONAL VERIFICATION

Instructions	Expected Result	Observed Result	Observed Result As Expected? Yes/No	Verified By	
				Initials	Date
Briefly actuate P-101. Verify that the rotor rotates in the correct direction	Rotor rotates to pump water out of the outlet				
Operate CIP-012 per SOP. under normal operating conditions	P-101 maintains a flow of at least 80 GPM under normal conditions.	Flowrate:			
		Method used to measure flowrate:	N/A		
		Backpressure under normal conditions:	N/A		

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 24 of 37

Instructions	Expected Result	Observed Result	Observed Result As Expected? Yes/No	Verified By	
				Initials	Date
Operate CIP-012 per SOP. Adjust a manual valve or pressure control valve to obtain a backpressure of at least 50 feet Water Column (21.5 psi).	P-101 maintains a flowrate of at least 80 GPM.	Flowrate:			
		Method used to measure flowrate:	N/A		
		Valve used to adjust backpressure:	N/A		
		Observed backpressure:	N/A		

Comments:

Reviewed By: _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 25 of 37

ATTACHMENT 11: DISCREPANCY RESOLUTION

Use this attachment to document discrepancies encountered during protocol execution.

(This sheet may be duplicated as necessary)

Discrepancy #		Protocol Section(s):	
Discrepancy Description:			
Investigation:			
Resolution / Justification:			
Satisfactorily Completed? (Y/N)		Performed By / Date	

Reviewed By: _____

Date: _____

Approved By: (QA) _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 26 of 37

ATTACHMENT 12: DEVIATION RESOLUTION

Use this attachment to document deviations from the approved protocol during execution.

(This sheet may be duplicated as necessary)

Deviation #		Protocol Section (s):	
Deviation Description:			
Justification / Resolution for Deviation:			
Satisfactorily Completed? (Y/N)		Performed By / Date	

Reviewed By: _____

Date: _____

Approved By: (QA) _____

Date: _____

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 27 of 37

ATTACHMENT 13: EXECUTION SUMMARY

PROTOCOL ATTACHMENT		VERIFICATION	VERIFIED BY	
#	TITLE		INITIALS	DATE
1	Signature Log	Execution is complete		
		Associated Exhibits (list below):		
		Associated Discrepancies or Deviations (list below)		
		All associated Discrepancy/Deviation Reports are approved		
		All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.		

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 28 of 37

PROTOCOL ATTACHMENT		VERIFICATION	VERIFIED BY	
#	TITLE		INITIALS	DATE
2	Critical Component Information Verification	Execution is complete		
		Associated Exhibits (list below):		
		Associated Discrepancies or Deviations (list below)		
		All associated Discrepancy/Deviation Reports are approved		
		All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.		

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 29 of 37

PROTOCOL ATTACHMENT		VERIFICATION	VERIFIED BY	
#	TITLE		INITIALS	DATE
3	Support Documentation Verification	Execution is complete		
		Associated Exhibits (list below):		
		Associated Discrepancies or Deviations (list below)		
		All associated Discrepancy/Deviation Reports are approved		
		All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.		

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 30 of 37

PROTOCOL ATTACHMENT		VERIFICATION	VERIFIED BY	
#	TITLE		INITIALS	DATE
4	Materials of Construction Verification	Execution is complete		
		Associated Exhibits (list below):		
		Associated Discrepancies or Deviations (list below)		
		All associated Discrepancy/Deviation Reports are approved		
		All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.		

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 31 of 37

PROTOCOL ATTACHMENT		VERIFICATION	VERIFIED BY	
#	TITLE		INITIALS	DATE
5	Piping Modifications Documentation Verification	Execution is complete		
		Associated Exhibits (list below):		
		Associated Discrepancies or Deviations (list below)		
		All associated Discrepancy/Deviation Reports are approved		
		All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.		

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 32 of 37

PROTOCOL ATTACHMENT		VERIFICATION	VERIFIED BY	
#	TITLE		INITIALS	DATE
6	Utility Connection Verification	Execution is complete		
		Associated Exhibits (list below):		
		Associated Discrepancies or Deviations (list below)		
		All associated Discrepancy/Deviation Reports are approved		
		All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.		

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 33 of 37

PROTOCOL ATTACHMENT		VERIFICATION	VERIFIED BY	
#	TITLE		INITIALS	DATE
7	Test Instrument Calibration Verification	Execution is complete		
		Associated Exhibits (list below):		
		Associated Discrepancies or Deviations (list below)		
		All associated Discrepancy/Deviation Reports are approved		
		All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.		

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 34 of 37

PROTOCOL ATTACHMENT		VERIFICATION	VERIFIED BY	
#	TITLE		INITIALS	DATE
8	General Installation Review	Execution is complete		
		Associated Exhibits (list below):		
		Associated Discrepancies or Deviations (list below)		
		All associated Discrepancy/Deviation Reports are approved		
		All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.		

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 35 of 37

PROTOCOL ATTACHMENT		VERIFICATION	VERIFIED BY	
#	TITLE		INITIALS	DATE
9	Standard Operating Procedure Review	Execution is complete		
		Associated Exhibits (list below):		
		Associated Discrepancies or Deviations (list below)		
		All associated Discrepancy/Deviation Reports are approved		
		All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.		

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 36 of 37

PROTOCOL ATTACHMENT		VERIFICATION	VERIFIED BY	
#	TITLE		INITIALS	DATE
10	Pump Functional Verification	Execution is complete		
		Associated Exhibits (list below):		
		Associated Discrepancies or Deviations (list below)		
		All associated Discrepancy/Deviation Reports are approved		
		All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.		

Document Number: VP-IOQ-09-XXXX	ACME BIOTECH	Effective Date:
Version: 000	Installation and Operation Qualification (IOQ) Protocol for the Alfa Laval Model LKH25 Pump Pump P-101	Page: 37 of 37

EXECUTION SUMMARY APPROVAL

The signatures below signify that the executed Installation and Operation Qualification protocol for the Alfa Laval Model LKH25 Sanitary Pump, Pump P-101, has been reviewed. All protocol tests are confirmed to have been properly executed and documented on appropriate Attachments, all Exhibits associated with each Attachment are identified and attached to the executed protocol, and all Acceptance Criteria have been met, or a Discrepancy or Deviation Report, documenting why the specific test results not meeting Acceptance Criteria are acceptable, has been approved by Acme Biotech. All Acceptance Criteria have been met, or a Discrepancy or Deviation Report documenting why the specific test results not meeting Acceptance Criteria are acceptable has been approved by Acme Biotech Manufacturing, Facilities and Quality Assurance.

Reviewed By: _____
Acme Biotech Manufacturing Date

Reviewed By: _____
Acme Biotech Facilities Date

Approved By: _____
Acme Biotech Quality Assurance Date