Installation and Operational Qualification Protocol

(Reference: SOP _____)

Project Name		**Project Number**	
Equipment		**Serial Number**	
Manufacturer		**Model Number**	
Process Line/Location		**Protocol number**	

	WRITTEN BY:	REVIEWED BY:
Name:		
Position		
Signature:		
Date:		

	APPROVAL TO EXECUTE:		
Name:			
Position:			
Signature:			
Date:			

	PROTOCOL COMPLETION APPROVAL:		
Name:			
Position:			
Signature:			
Date:			

1 OBJECTIVE

The objective of this protocol is to define the Installation Qualification (IQ) and Operational Qualification (OQ) requirements and acceptance criteria for the [insert system name and plant number] which will be located in the [insert area, packaging or manufacturing] at site [insert site name]. IQ/OQ is required as [insert brief description as to why required, e.g. as it is new equipment.

Successful completion of this protocol will provide a high degree of assurance that the equipment has been installed and operates in accordance with the site requirements, specifications and manufacturers recommendations and is in compliance with cGMP and site policies.

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(Reference: SOP _____)

Appendix [Insert Appendix No]
Test 001: Verification of Installed Equipment

1. Objective
The objective of this test is: 1. To verify that equipment is uniquely identified and installed in accordance with site and manufacturers' recommendations 2. To verify that equipment is scheduled for preventative maintenance 3. To ensure that the equipment installed is documented for change control / revalidation purposes
2. Procedure
Inspect the installed equipment and record details of all major process equipment as required below. Verification of installed components may be achieved by visual inspection or approved documentation / drawings. If a document or drawing is used it must be referenced.
3. Acceptance Criteria
All equipment must be uniquely identified and installed in accordance with site and manufacturers' recommendations. All major equipment items should be included for preventative maintenance

Equipment Description		**Installed**	**Initial & Date**
[Insert Equipment Name. If sub-systems include one row for each sub system]	Manufacturer		
	Model		
	Serial number		
	Plant No		
	Maintenance log No		
[Insert Equipment Name. If sub-systems include one row for each sub system]	Manufacturer		
	Model		
	Serial number		
	Plant No		
	Maintenance log No		

Comments:

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(Reference: SOP _____)

Appendix [Insert Appendix No]

Test 005: Verification of Computer System Software

1. Objective
The objective of this test is: 1. To verify that all computer system Operating Software and Application Software integrated with the system is uniquely identified and installed in accordance with site and manufacturers' recommendations. 2. To ensure that the software components of the installation are documented for change control/re-validation purposes.
2. Procedure
Inspect the installed software and record details. Verification of installed components may be achieved by visual inspection or approved documentation / drawings. If a document or drawing is used it must be referenced.
3. Acceptance Criteria
1. All software must be uniquely identified and installed in accordance with site and manufacturers' recommendations. 2. A backup copy of the software must be available.

Software Description		**Installed**	**Initial & Date**
[Insert system name]	Operating Software name		
	Operating Software version		
	Application Software name		
	Application Software version		
	Application Software Developer		
	Location of backup		

Comments:

Installation and Operational Qualification Protocol

(Reference: SOP _____)

Appendix [Insert Appendix No]

Test Ref: 010: Verification of Safety

1. Objective
The objective of this test is to verify that EHS are notified that qualification of the system is being undertaken and a safety audit if required can be performed.
2. Procedure
Contact the EHS representative and determine if a safety audit is required prior to performing any OQ testing If required enter the estimated completion date for the audit. It is the responsibility of EHS to complete this test and to ensure that the equipment is safe for operational qualification and for use.
3. Acceptance Criteria
The need for a safety audit has been established prior to OQ and if required a safety audit has been conducted by EHS and the equipment is deemed suitable for routine use.

Test #	Test Procedure	Actual	Initial & Date
1	Determine if a safety audit is required	Audit required? _____	
2	Enter the estimated completion date for the safety audit if required		
3	Document if the system is considered safe for operational qualification		

Comments:

Installation and Operational Qualification Protocol

(Reference: SOP _____)

APPENDIX [Insert Appendix No] – DEVIATION LOG AND REPORT

DEVIATION REPORT NO.:							
TEST SCRIPT / TEST PROCEDURE #:							
1. DEVIATION DESCRIPTION: **Initial / Date_____**							
Circle Classification	**Critical Deviation**	**Non-Critical Deviation**	***Circle Change Required***	**Yes Change #** _____	**No**	**Deviation #** _____	**COMMITMENT #** _____
2. RESOLUTION (attach any re-test results to this sheet): **Resolution Completed & Deviation Resolved: (yes/no) ___ Initial / Date_____**							
3. JUSTIFICATION FOR ACCEPTANCE OF DEVIATION: **Justification Completed & Deviation Accepted: (yes/no) ___ Initial / Date_____**							

	Print/Type Name	**Signature**	**Date**
Approved By: (System Owner)			
Approved By: (Validation)			
Approved By: (Quality Assurance)			