Document ID - Installation Qualification (IQ) – [Equipment/System Name]

Amend document number in footer to reflect validation document number, e.g. IQ001.

Pre-Approval

Approved by	Signature	Position	Date
Author – Confirming the technical content of this document			
Document Owner – Confirming the technical content of this document			
Quality– Confirming compliance of this document with the Quality System			

Final-Approval

Approved by	Signature	Position	Date
Author – Confirming the technical content of this document			
Document Owner – Confirming the technical content of this document			
Quality– Confirming compliance of this document with the Quality System			

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1 Introduction

The introduction should be a brief statement of the intent of the protocol. It may also include the reasons that the qualification is required if appropriate, especially if the reason is a change to existing conditions.

This Installation Qualification (IQ) details the activities required to execute the IQ phase of the qualification of the [equipment/service title] at CompanyName (ShortName). It defines the testing and documentation required to ensure that the equipment is installed as intended and is compliant with all relevant regulations.

Define what the document is to demonstrate. Detail the system to be qualified and where the requirements have come from. Add an introduction or background of the project/the system

Provide an introduction/background to what the IQ is attempting to accomplish, how it interfaces with other systems and what will be undertaken. Provide reference to overarching governance documents (e.g. VMP/VP, change controls etc.) and system impact assessments / risk assessments.

Things to consider:

- *What equipment is being qualified (name, tag numbers, location etc.)?*
- *What components of the qualification are critical (as per associated risk assessments)?*
- *Include any relevant limits for the operation of the equipment.*
- *What is the qualification trying to achieve (i.e. what outputs do you expect from a successful qualification)?*
- *What other systems interface with the equipment to be qualified? How will that interface be managed?*

2 Scope

The scope should be summary of the IQ and its intentions. Clearly identify boundaries of the scope of the protocol. If applicable, include a scope diagram to clearly describe what is out of scope and what is in scope. Consider if there are any requirements to decommission an existing system.

This protocol applies to the IQ of the [equipment/service]. It considers finishes, materials of construction, suitability for purpose, as-built status, availability of services, supply of documentation and integration into quality systems.

The scope includes:

- [item 1]
- [item 2].

The following is out of scope:

Declare areas/interfaces which are out of scope and a reference to any procedures which provide more information.

- [List exclusions]
- [List exclusions].

3 Roles and Responsibilities

The responsibilities defined below refer to the signatories on the front page. The text within should be consistent with the responsibilities defined within the VMP and any relevant VP. Edit as necessary to maintain consistency.

Personnel executing and/or assisting with the execution of the IQ are recorded in ***Test 1 Signature Register***.

Persons signing the front page of this protocol are confirming compliance with the information below:

Role	Responsibility
Preparer	The preparer should be the primary author of the document, or a delegate with an appropriate level of understanding of the technical content of the document. The preparer signs to confirm that, to their knowledge, the document is complete, complies with the IQ plan and is free from errors.
Reviewer	The reviewer should be the system owner or a delegate with an appropriate level of understanding of the functionality of the equipment/system. The reviewer signs to confirm that, to their knowledge, the document fulfils all relevant testing requirements, is logical and executable and is free from errors.
Quality	The quality approver should be the Quality Representative (or delegate) with an appropriate level of understanding of the quality systems relevant to this protocol. The quality approver signs to confirm that the document complies with relevant quality systems (including the VMP), can be adequately resourced in the time frame anticipated for execution and is free from errors.

4 Qualification Description

4.1 Equipment/System Description

Provide a brief overview of the equipment/system

4.2 Qualification Method

Provide the 'how' of the IQ execution. It is not intended to detail formal test procedures, which are documented elsewhere, but rather provide an overview of the method. Examples below:

- *Room conditions, commissioned, cleaned, in routine operation, etc.*
- *Type of testing – simulated, 'live' testing, placebo, etc.*
- *Number of people involved and whether they active or passive*
- *Estimated duration of testing if known*
- *Information on multiple or single trials*
- *Any other general information that may be useful to the reader to understand what will occur during the testing phase*

4.3 Justifications

Acceptance criteria for most qualification tests have been established in accordance with regulatory requirements, internal policy standards and established industry standards.

In some cases, it is necessary to define criteria without these established references. Any instances of these criteria in this protocol are explained below:

Test Reference	Criteria	Explanation

4.4 Test Section Details

The testable sections of this protocol are listed below. All sections marked as mandatory or applicable must be completed prior to final approval of the qualification.

Some sections will not be applicable for some qualifications. Wherever a section is not required, a brief statement as to why must be included. The test section itself should be left in, but the relevant table should be deleted, and a statement of justification inserted in its place.

Test Section	Applicable?	Reason if Omitted
1: Signature Register	Mandatory	N/A
2: Drawings	Yes	
3: Documentation	Yes	
4: Architectural and Functional Components	Yes	
5: Mechanical Components	Yes	
6: Electrical and Instrumentation Components	Yes	
7: Computer Hardware Components	Yes	
8: Computer Software Components	Yes	
9: Plant Services	Yes	
10: Product Contact Chemicals	Yes	
11: Instrument Calibration	Yes	
12: Preventive Maintenance	Yes	
13: Validation Exception Reports	Mandatory	N/A
14: Handover/Progression Approvals	Mandatory	N/A
15: Final Approvals	Mandatory	N/A
16: Attachments	Mandatory	N/A

5 Qualification Instructions

5.1 Data Collection

The qualification will comprise: