How To Ensure Successful Installation Qualification (IQ) For Medical Devices

By Alec Alpert

As part of process validation, IQ establishes the foundation for all other qualification activities. Its purpose is to ensure that manufacturing equipment has been correctly installed to meet the manufacturer's specifications and that it will operate within the expected ranges.

Depending on the product and manufacturing process, IQs will be different. An IQ for injection molding, pharmaceuticals, and the manual assembly of electronic systems will differ greatly in methodology, equipment, sophistication, and scope. Accordingly, manufacturers establish their process validation procedures and policies, reflecting the types of products and processes at hand. However, IQs typically must comply with these key regulations and standards for medical devices:

- 21 CFR 820, Quality System Regulation
- ISO 13485, Medical Devices - Quality Management Systems Requirements
- ISO 14971, Application of Risk Management to Medical Devices
- ISO 9001, Quality Management Systems Requirements
- EU MDR 2017/745, Regulation of the European Parliament and of the Council

This article addresses IQs for the manual assembly of electronic medical devices.

IQ Prerequisites

Before starting IQ activities, certain initial steps must be completed and include as a minimum:

- Equipment drawings and specifications approved and released
- Equipment maintenance and calibration procedures approved and released
- An IQ protocol approved and released
- Installation conditions and utility requirements established
- Identification of critical equipment inputs and operating ranges established
- Equipment calibration completed and up-to-date
- Personnel trained to perform IQ
- Environmental impact evaluation performed for potential safety and/or environmental impact
- An IQ acceptance criterion established

IQ Protocol

IQ activities begin with preparation of the IQ protocol. Although companies have their own guidelines for IQ protocols, resulting in IQ protocol structures unique to specific companies, the typical sections to include in the IQ protocol usually are:

Purpose

The purpose of the IQ protocol should be a summary of the intended purpose for the document.

Scope

Describe in this section the equipment being qualified, including equipment identification information. Should the protocol be intended for repeat usage without modification or update for duplicate pieces of equipment, you have to ensure that the scope states that the protocol applies to any identical model of equipment, irrespective of the usage site.

Background

In this section, describe the need for the IQ. Confirm and complete at protocol release the following information:

- Equipment description
- Intended use of equipment
- Equipment model number
- If an existing protocol is being leveraged for the qualification of new equipment that has the same model number listed in the protocol, the protocol does not need to be updated to include the new

serial number; instead, the model number and new serial number would be documented in the IQ report
- Equipment software/firmware information

Reference Documents

List in this section the procedures and other documents that define the requirements or provide guidance for the content and approach described in the protocol, such as:

- Equipment specification documents
- Tooling or equipment prints
- Preventative maintenance procedures
- Calibration procedures and work instructions
- Software validation documentation
- Equipment troubleshooting guides, etc.

Equipment Description

In this section, describe the equipment and/or tooling being qualified and the equipment being used to perform the qualification, including:

- What test process is executed by the equipment/tooling
- Materials associated with the equipment/tooling
- How the equipment/tooling functions
- Key requirements or controls involved

Most likely, there will also be auxiliary equipment, interchangeable/alternate equipment, and fixtures and tooling that should be identified with model number and serial number in the protocol.

Qualification Strategy

Identify in this section the items that need to be documented and executed to satisfy the IQ conditions and test methods. For convenience, a table with checkboxes for deliverables can be provided within the template of the IQ protocol for the following items where applicable:

IQ Reason and Purpose

- New equipment installation
- Redesign or upgrade of equipment
- Equipment requalification
- Repair of existing equipment
- Relocation of existing equipment
- Other (explain)

Equipment Information

- Equipment description
- Intended use of equipment
- Equipment model number
- Equipment serial number
- Custom equipment
- Off-the-shelf equipment
- Equipment location
- Facility layout
- Software requirements
- Safety requirements
- Calibration
- Equipment installation/utilities
- Utility verification
- Environmental conditions
- Environmental impact assessment
- Fixture first article assessment
- Preventive maintenance requirements
- Mobility assessment
- Alarms

Depending on your specific installation equipment, products manufactured, and procedures and policies, the checklist above may be longer or shorter and include different items. Again, it is presented here as an example of how a basic IQ protocol may be structured.

All equipment must be locked out/tagged out during execution of IQ activities to prevent production use.

Acceptance Criteria

Typical acceptance criteria for IQs are defined as all the applicable checklist items in the IQ protocol listed above are completed with acceptable results. The acceptance criteria should be documented as acceptable or unacceptable in the IQ report. Any unacceptable results must be investigated and corrected, with subsequent demonstration of acceptable results.

IQ Protocol Execution

Once the IQ protocol is approved and formally released, the next step is its execution by trained and qualified personnel. In a nutshell, the IQ protocol execution boils down to:

- Physically installing the equipment, fixtures, and tooling
- Thoroughly documenting completion of all checklist items in the IQ protocol
- Ensuring the correct installation of equipment

- Ensuring that the installed equipment works to specifications and meets all safety, utilities, and environmental requirements, as well as applicable laws and regulations
- Assessing whether the acceptance criteria have been met
- Concluding whether the installed equipment/tooling can be released for use

IQ Report

For the IQ report, document the results of the IQ. The results could be compiled into the tables containing the checklist items from the IQ protocol, demonstrating compliance with the requirements. Also, a narrative description of the activities may be provided, with reference to attached records. A statement whether the acceptance criteria have been met must be provided, and any deviations and issues encountered during the IQ protocol execution should be addressed.

IQ Report's Conclusion

In the Conclusion section, provide a brief summary of the conclusion drawn from the observed results. Two key questions to answer when developing the conclusion are:

- Were all acceptance criteria met?
- Are the equipment and tooling considered released for use?

If the answer is no to either of these questions, outline what actions are being taken.

About the Author

Alec Alpert is a Quality Engineer and Consultant with an extensive background in quality and compliance for medical devices from new product development, to operations, to post-market activities. He has helped to improve product quality and compliance at the leading medical device companies in applications ranging from linear accelerators, anesthesia systems, and implantable orthopedic devices to electronic imaging systems, infectious disease diagnostic systems, and electrosurgical generators. Alec is the owner of Alpert Engineering, LLC, an engineering consulting company that provides services to medical device companies. Alec is also the owner of www.alecalpert.com, where he publishes articles and white papers with practical advice on medical device technology, quality assurance, and compliance.