

IQ OQ PQ

A Quick Quality Assurance Guide

Qualification*: Activities undertaken to demonstrate that utilities and equipment are suitable for their intended use and perform properly. These activities necessarily precede manufacturing products at the commercial scale.

In heavily regulated industries, qualification breaks down to three phases:

- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)

Together, they are referred to as IQ OQ PQ.

*Source: FDA



INSTALLATION QUALIFICATION

GOALS:

Verify equipment specifications match those set by the process design

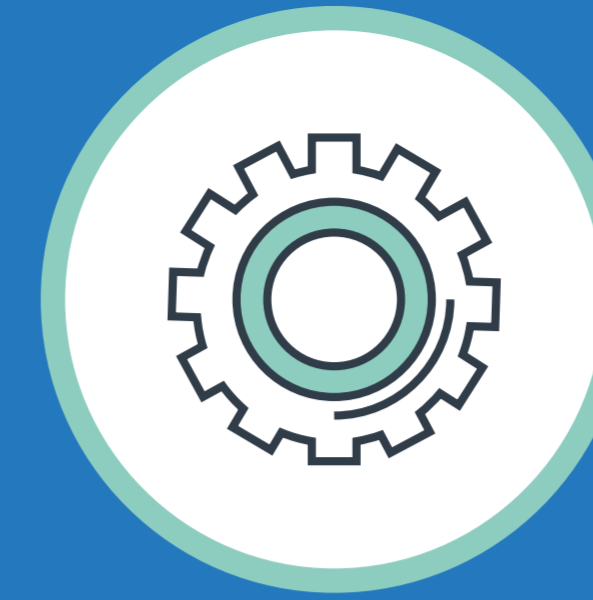
Verify that equipment has been properly handled, delivered, and installed

EXAMPLES OF ISSUES TO CHECK:

Correct equipment was delivered

Damaged or missing parts

Intended hardware meets any software requirements



OPERATIONAL QUALIFICATION

GOALS:

Confirm equipment operates according to specifications

Determine how operational parameters (temperature, etc.) will affect materials

EXAMPLES OF ISSUES TO CHECK:

Proper connection to utilities

Safety systems functioning properly

Specified operating conditions lead to desired outcome



PERFORMANCE QUALIFICATION

GOAL:

Test system under actual process conditions

EXAMPLES OF ISSUES TO CHECK:

Process limits established in OQ lead to stable, repeatable production

Check for variability in process and results under different conditions