# Tool Install & Validation Workflow Guide

## 1. Overview

This guide outlines a standardized process for qualifying new tool installations in a production manufacturing environment. It supports engineering teams working across semiconductor fabs or biotech production facilities by structuring IQ, OQ, and PQ validation stages. While the origin of this process is grounded in semiconductor cleanroom factory practices, the methodology has been adapted to emphasize broader cross-industry applicability.

## 2. Supporting Tools & References

The following assets within this starter kit complement this workflow and can be used to track progress, manage risk, and document tool readiness:

* `gantt\_timeline\_tracker.xlsx` – useful for managing install task sequencing and ownership across IQ/OQ/PQ stages.
* `seq\_validation\_tracker\_template.xlsx` – tracks sequential test results, flags instability in tool health metrics.
* `process\_change\_whitepaper\_template.docx` – formally documents IQ/OQ/PQ data to support processing on new tool
* `process\_readiness\_tracker.xlsx` – ensures readiness across functions before moving into pilot production.
* `handoff\_criteria\_template.md` – captures the requirements for transitioning tool ownership to production teams.

## 3. Notes on Cross-Industry Adaptability

This guide reflects semiconductor-rooted practices but abstracts key principles applicable to biotech and life sciences:

* IQ → OQ → PQ is a broadly recognized validation framework.
* Facility environment and equipment configuration must meet quality standards before use.
* Production Pilot on new Tool serves as a confidence-building bridge from install to routine manufacturing.
* Fingerprinting is analogous to GMP validation protocols or system baseline checks.
* SEQ testing logic can support bioreactor, fill/finish, or dosing validation over time.

## 4. Tool Install & Validation Phase-by-Phase Breakdown

### Tool Docking (Delivery)

* Vendor delivers tool to factory and docks it into allocated space.
* Factory planning or install coordination team manages logistics.
* Once physical placement is complete, Module Engineering involvement starts.

### Physical Install + Facilities Hookup – Gates Tool Fingerprinting + Equipment Settings Update

* Chemical, electrical, and network connections installed.
* Location and allocation strategies set upstream.
* Coordination with facilities and vendor teams.

### Tool Fingerprinting + Equipment Settings Update – Gates Vendor Install Qualification + Factory Environment Checks

* Module Engineer sets tool to match reference settings prioritized as:

1. Same-group reference tool
2. Department or org-wide baseline
3. Vendor defaults (only if no internal references available)

* Includes physical calibration data (e.g., robot alignments, flow controller LUTs, homing, alarm thresholds) + Equipment Settings
* Module Engineer works with Vendor install team + Operators/Technicians to record/update fingerprint and setting parameters
* *Fingerprint reference document not included here due to tool- and org-specific complexity,  
  but it should be developed and maintained separately.*

### Vendor Qualification (IQ) – Gates Handoff to Engineering Module + OQ

* Vendor executes water-only test runs to validate robot motion, sensor feedback, and basic tool health.
* Confirms facilities hookup success and baseline functionality. Vendor involvement ends unless downstream troubleshooting.

### Automation Setup – Can be done in parallel with Tool Fingerprinting/IQ

* Engineer ensures tool registration to MES and factory network.
* Process recipes cloned from reference tools and uploaded.
* Automation logic validated (e.g., recipe triggers, tool start/stop behavior).

### Factory Quality & Environment Checks – Gates Operational Qualification OQ

* Mini-environment particle tests coordinated with contamination control team.
* Equipment internal humidity and purge checks ensure factory cleanroom compatibility.
* In biotech contexts, this step may align with environmental monitoring, aseptic validation, or air handling qualification.

### Operational Qualification (OQ) – Gates SEQ Testing

* Run of production-like process using test products (lower-cost analogs).
* Evaluates basic process health: process-specific flow behavior using real chemicals, process-specific pressure profiles.
* Designed to mimic real production without risk to actual material.

### Sequential Validation (SEQ) – Gates Production Pilot PQ

* Extended tool qualification through periodic data collection across a defined sample size.
* Tool health/qual metrics (e.g., defect count, removal rate) monitored over time.
* If variation exceeds spec, testing pauses for investigation.
* Tracker and data macro logic built separately in `seq\_validation\_tracker\_template.xlsx`.

### Production Pilot (PQ)

* Run real production material under tightly monitored pilot conditions.
* Final validation to ensure tool matches production fleet baselines.
* Marks formal transition from installation to production readiness.

### Closeout Documentation

* Engineer compiles results into a Tool Install Whitepaper (`process\_change\_whitepaper\_template.docx`).
* Includes fingerprint settings, qual results, and validation summary.