



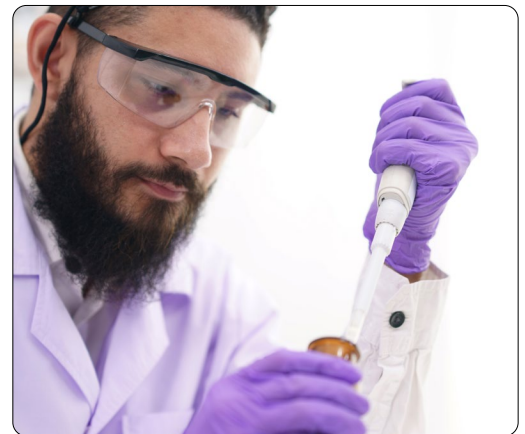
Qualification services for cell counting instruments: IQ/OQ/PQ.

Revvity's IQ/OQ/PQ program transforms instrument ownership into a partnership, so your team can focus on science, not paperwork.

In regulated bioprocessing and QC environments, instrument qualification is not optional, it is a foundational requirement for data integrity, regulatory compliance, and operational confidence. Revvity offers a qualification framework for Cellometer™ cell counters and the Cellaca™ high-throughput cell counting platforms, confirming your instrument is properly installed, operating as designed, and performing to its specifications.

Revvity's IQ/OQ/PQ program key benefits:

- **End-to-end compliance:** a single, integrated qualification program covering the full instrument lifecycle (with the option of purchasing parts of the program as needed)
- **Regulatory confidence:** pre-built protocols aligned with FDA and EMA requirements
- **Reduced risk:** systematic qualification minimizes the risk of instrument-related batch failures of cell or biological products and deviations
- **Audit readiness:** traceable documentation package for regulatory inspections
- **Expert execution:** performed by Revvity instrumentation specialists, reducing operator variability and internal resource burden
- **Faster time to compliance:** standardized protocols accelerate qualification timelines vs. building in-house programs
- **Lifecycle support:** requalification services available after maintenance, relocation, or software updates



Phase	Focus	Key output	Key materials	Recommended cadance
IQ	Installation qualification	Installation records	Protocols, checklist, plates and bead standards Optional Additional OQ protocol for 21 CFR Part 11 compliance	Instrument install Every 6-12 months (as needed, eg. after software upgrade or instrument relocation)
OQ	Operational qualification	OQ documentation and on-site Installation/ Operation Qualification certificate		
PQ	Performance qualification Counting performance across multiple concentration and viability ranges	Performance documentation and on-site Performance Qualification certificate	Protocols, checklist, plates and 7 different bead standards	Every 6-12 months (as needed)

Three phases of qualification

Phase 1: Installation qualification (IQ)

Confirming the instrument is correctly installed and configured. Typically performed at the instrument installation and can be repeated at regularly timed intervals such as every 6-12 months or as needed.

- **Verification that the instrument** was received undamaged and matches the ordered configuration
- **Confirmation** of hardware components: parts, accessories, and consumables are present and accounted for
- **Validation of software** version and system configuration against manufacturer specifications
- **Review** that power supply requirements are met
- **Documentation** of instrument serial numbers, software versions, and installation site details
- **Completion** of a site readiness checklist to confirm the lab environment meets operational requirements

Phase 2: Operational qualification (OQ)

Confirming the instrument operates as intended. Typically performed at the instrument installation and can be repeated at regularly timed intervals such as every 12 months or as needed, eg. after software upgrade or instrument relocation.

- **Verification** that all instrument functions operate within defined specifications under controlled conditions
- **Testing** of optical system performance: optics alignment, detector sensitivity, and signal-to-noise ratio
- **Confirmation** of consumable integrity: sample delivery, and flow consistency, verification of software functionality: data acquisition, analysis algorithms, and reporting outputs
- **Execution** of standardized OQ test protocols with pre-defined acceptance criteria

Output: signed OQ documentation package confirming the instrument operates as designed and is ready to perform cell counts.

Phase 3: Performance Qualification (PQ)

Confirming the instrument operates as intended across its functional range. Optionally performed at the instrument installation and can be repeated at regularly timed interval such as every 6-12 months or as needed.

- **Accuracy:** measured values compared against NIST-traceable certified reference standards (CofA included)
- **Precision:** repeatability confirmed at 10% CV or less among replicate measurements; Range: Concentration testing across the dynamic counting range (2.5×10^5 to 2×10^6 cells/mL)
- **Specificity:** discrimination between viable and non-viable cells validated at 0%, 25%, 75%, and 100% viability levels
- **Standardized bead references:** purpose-built certified bead standards allow for reproducible, traceable PQ execution

Output: signed PQ documentation package with traceability, supporting regulatory submissions and audit readiness.



	Cellaca MX/ Cellaca PLX	Cellometer Ascend	Cellometer K2	Cellometer X2	Cellometer Spectrum	Celigo
IQOQ	✓	✓	✓	✓	✓	✓
IQOQ for 21 CFR Part 11	✓	✓	✓	-	-	✓
PQ	✓	-	-	-	-	-

For more information, contact your
Revvity representative or visit revvity.com



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