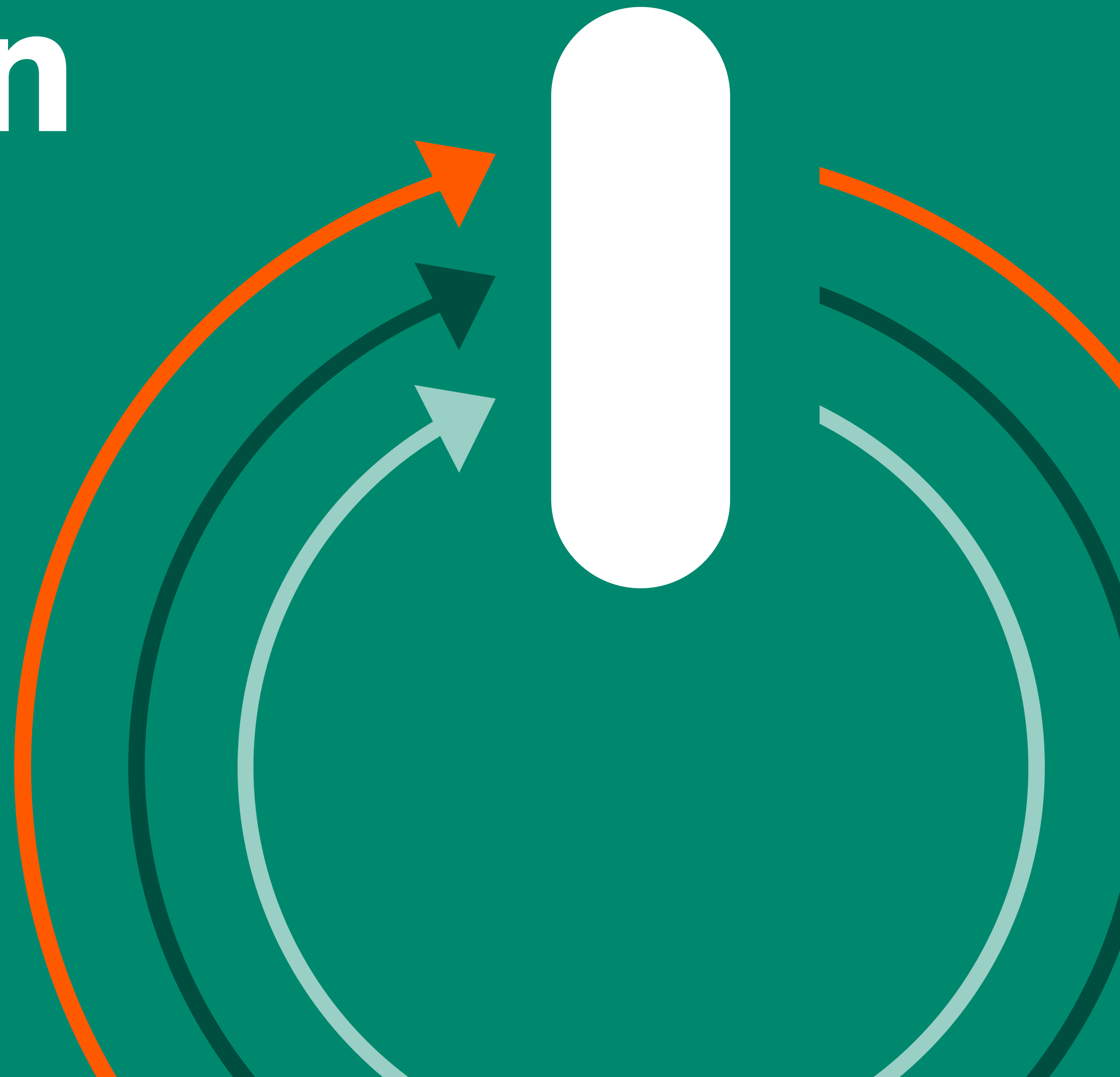


Qualification and requalification services



Qualification is more than a one-time event

If you're working in a current good manufacturing practices (cGMP) or other current GxP environment, it's critical to keep your equipment in working order. It means that your equipment must be periodically evaluated and validated. At some point in its lifetime your instrument may be repaired, relocated, upgraded, or modified in other ways. Changes can affect your instrument's performance and bring it to an unqualified state — creating risk for your operations, such as batch loss if issues are discovered too late, wasted resources if you need to backtrack, and launch investigations to discover deviation handling and failing to meet production or research deadlines.

Equipment should always be tested in the exact same conditions as it is intended to be used. To ensure the continued compliance of your system, you can add qualification to your Cytiva service contract. With this option, your RQ visit is scheduled at the same time as your preventive maintenance (PM) at the most convenient time for your operations. During RQ, our qualified engineers run necessary tests and verifications to keep your equipment to factory and user specifications. These tests were designed and optimized throughout the development of the equipment and reflect functional tests performed during assembly, as well as quality tests performed prior to delivery to your site.

The instrument requalification (IRQ) is a modified RQ centered on the testing sections related to the physical operation of the system itself. It can be performed when the software and functionality of the system has not been updated since the last qualification event. Therefore, the tests associated are removed which allows you to reduce the time needed to operationally qualify a system.



Documentation

Cytiva provides a standardized set of documentation after the RQ for your validation strategy. The document is audit ready to provide confidence in your instrument's compliance.

The documentation is also available in digitized format with eQualification.

RQ interval

Our standard recommended RQ frequency for BioProcess™ systems varies with usage and system conditions.

Our recommendations are based on industry averages. Refer to your periodic review for your exact requirements.

Five changes that might require RQ

1. Environmental conditions have changed over time. Consider the impact of changes in temperature, humidity, or atmospheric pressure.

2. Equipment has been moved/relocated. Manufacturing lines, electrical power, fixed pipe connections, and even environmental conditions, can be dramatically different from room to room, building to building, or when relocating equipment to an entirely new facility.

3. PM, repair, or upgrades have occurred. Replacing spare parts while the instrument is running could affect the specifications. Think about an event that replaces a major component on a system — affecting the wetted flow path and items in the electrical cabinet — or even pressurized air supply, if applicable. How can you confirm that replacing the part didn't disturb any other functions of the instrument?

4. Your needs have changed, which requires a modified binder. Projects and manufacturing needs change over time to meet new demands. The parameters, recording calibrations, and instructions must be updated according to the new utilization.

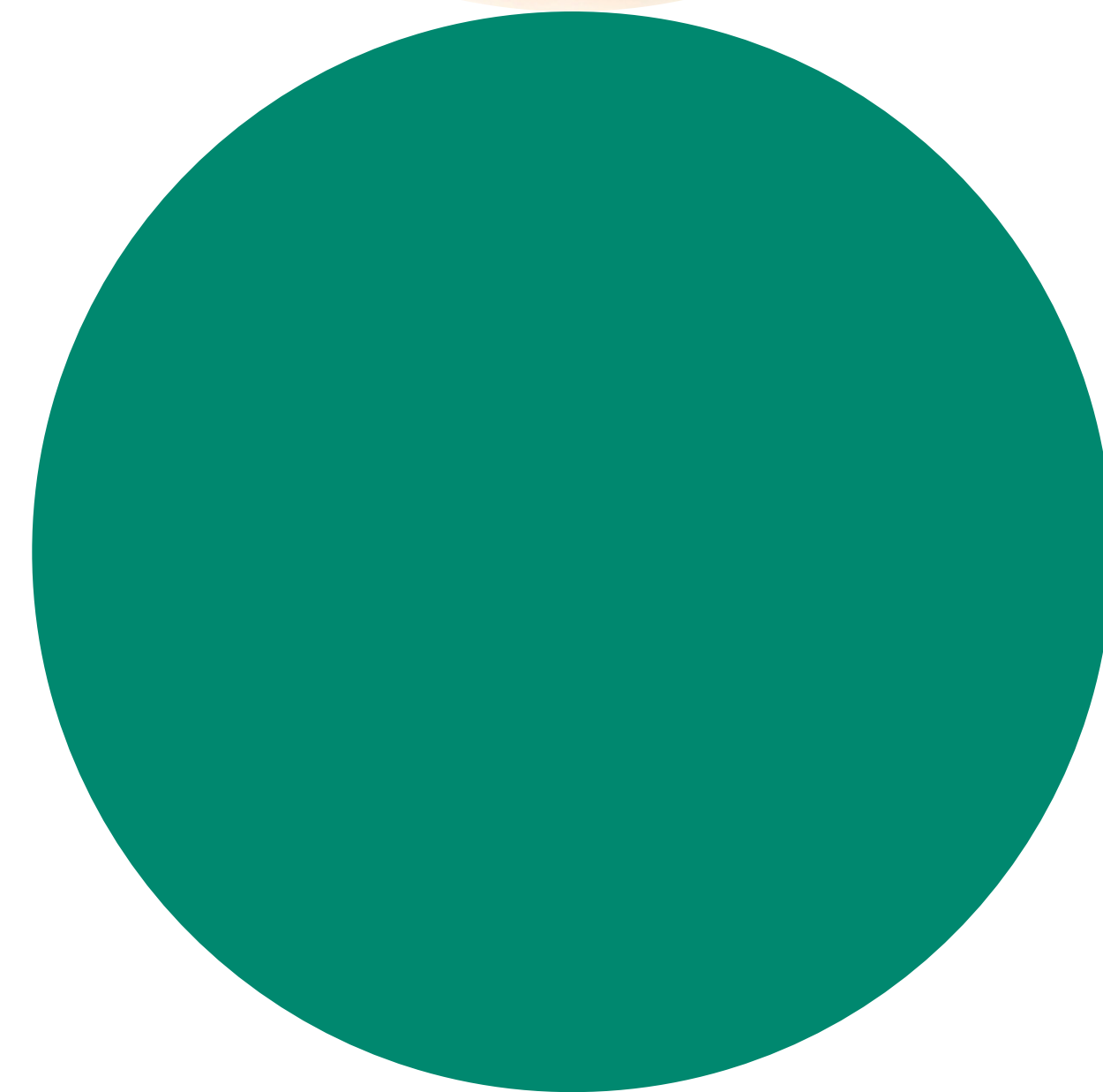
5. Regulatory guidelines have changed. Maintaining compliance with regulatory bodies is a critical endeavor in GxP environments. Changes to regulatory guidelines require updated documentation.

The importance of maintaining a qualified state

Maintaining compliance with regulatory bodies is a critical endeavor for all involved in the life sciences community.

Historically, equipment qualification was considered a one-time startup activity necessary within a regulated environment. However, the regulatory landscape has changed. Regulatory authorities now require equipment in a current good practice (cGxP) environment to be periodically evaluated and validated. Properly maintaining an instrument's qualified state is paramount to adhering to relevant regulatory organizations' criteria, including the Food and Drug Administration (FDA). A comprehensive suite of qualification services are necessary to continually provide updated, flexible, and compliant solutions for customers.

RQ is the documented verification that all critical aspects of a system remain properly installed and operating per specifications throughout the specified operating range. Designing and servicing complex bioprocess equipment requires deep understanding of both the process and the science behind it.

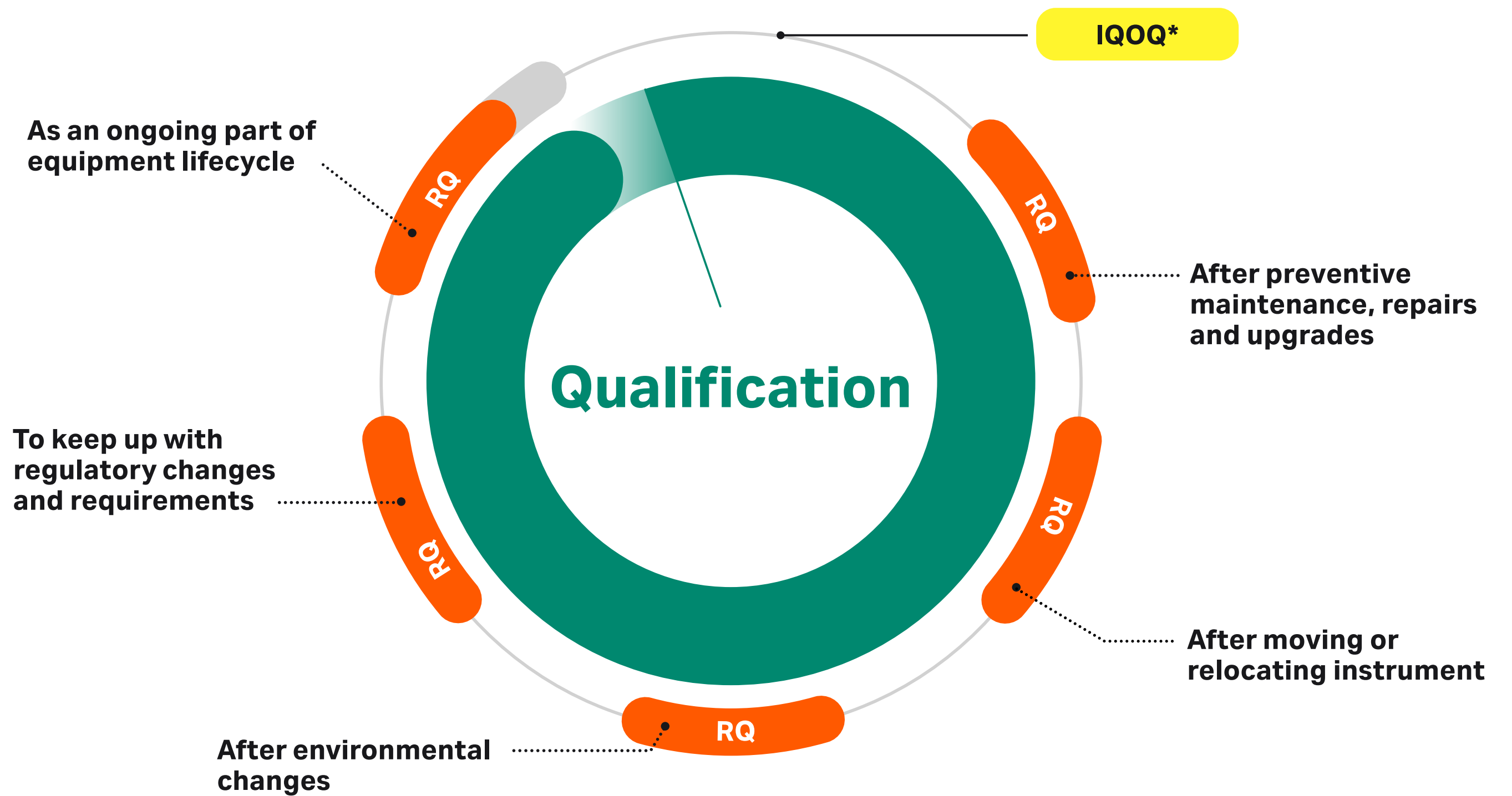


The lifecycle of qualification

Commissioning activities set the stage for a safe, functional environment that meets design requirements. These tests confirm proper specification and functionality to prepare for qualification activities.

Primary qualification activities are performed at the beginning of an instrument qualification lifecycle. Using good documentation practice (GDP), these testing protocols demonstrate that the instrument has been properly designed, installed, and tested according to pre-approved quality assurance (QA) acceptance criteria.

Secondary qualification activities occur later in the instrument qualification lifecycle. Using GDP, these activities regularly re-demonstrate that, from the critical aspects, a system is still installed and operating per specifications throughout a specified operating range.



*Installation and operational qualification (IQOQ)

Why choose Cytiva?

Our service solutions include a comprehensive library of documentation for every instrument family available, taking the guesswork out of what needs to be done for instrument qualification. To properly maintain the qualified state of Cytiva instruments, users should regularly perform preventive maintenance and requalification. When there are periodic updates to software or firmware, our change control procedures help customers accurately document and reflect user- or Cytiva-defined updates.

In addition to the available qualification documentation, Cytiva engineers trained in the performance and GDP of these protocols can visit you on-site and assist with equipment qualification or RQ.

We are here to provide you with flexible solutions and the latest in regulatory knowledge. The suite of qualification services offered combines the latest product updates, service expertise, and technology available only from Cytiva as the original equipment manufacturer.

Why select Cytiva for your qualification needs?

Our service solutions team knows the instruments Cytiva designs and manufactures. We also understand how regulations affect the installation and use of our equipment. And we keep our knowledge up to date as regulatory guidelines change.

With our qualification services you'll benefit from:

- Our access to R&D, manufacturing, and engineers — they develop, produce, and maintain our instruments.
- The tools and software we use to develop and produce our qualification products, so you get full traceability and transparency.
- Our guidance when you're considering an update to your instrument's hardware or software. We'll ensure your instrument remains in a qualified state.
- Our global network of certified Qualification Services engineers, who will ensure timely and efficient qualification.
- Our efficient order-to-deliver process. We manufactured more than 25 000 binders in four years.
- The flexibility to choose hard copy binders or eBinders.
- Updated test results as we compare performance post-qualification with original performance by our installation qualification (IQ) and operational qualification (OQ) service.

The suite of qualification services

Commissioning services – factory and site acceptance testing (FAT/SAT)

We can perform a comprehensive set of tests prior to shipping your equipment. The FAT protocol includes a selection of system functional tests and is executed in your presence. As part of the commissioning process, we conduct an additional SAT with accompanying documentation which demonstrates the installed system meets specifications, is fully functional, and ready for formal qualification.

Primary qualification – IQ and OQ

Qualification protocols provide documented evidence demonstrating that all key aspects of an installation adhere to all approved design intentions, manufacturers' recommendations, cGxP, good engineering practice, and user and process requirements. Additionally, they demonstrate that systems operated as intended throughout their anticipated operating ranges.

Requalification

RQ is the documented verification that all critical aspects of a system remain properly installed and operating per specifications throughout the specified operating range. To help ensure the qualified state of Cytiva instruments, we recommend regular preventive maintenance and RQ. Environmental and equipment conditions can change over time. A change control procedure is a systematic approach to managing all changes made to the system, software, or firmware.

Computer software verification (CSV)

CSV helps you comply with global regulation compliance guidelines for computerized systems.

Our CSV protocol formally tests, validates, and documents that your Cytiva regulated information technology system is fit-for-purpose with consistent, accurate, secure, reliable, and traceable features. CSV provides full traceability of the regulatory requirements for end user requirement, specifications, and verification steps.

Qualification maintenance

Qualification maintenance is an instrument RQ service that is performed upon the completion of routine preventive maintenance activities. The service helps you more easily maintain an instrument's qualified state by providing updated test results compared to those demonstrated originally by the IQ and OQ service. Qualification maintenance is only available for equipment that has previously been qualified by an IQ and OQ service.

Modified binders

Customizations of a standard qualification protocol are sometimes needed to meet your specific needs. We can provide modified binders through a consultative project with our qualification team. Custom projects include one review cycle.

eQualification digital qualification experience

With eQualification your digital qualification binder is made available to you as soon as your content is ready. Reviewing, approving, and sharing documents is easier and faster in this digital format compared to paper binders. Your final qualification reports include hyperlinks for improved navigation during your audits.



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