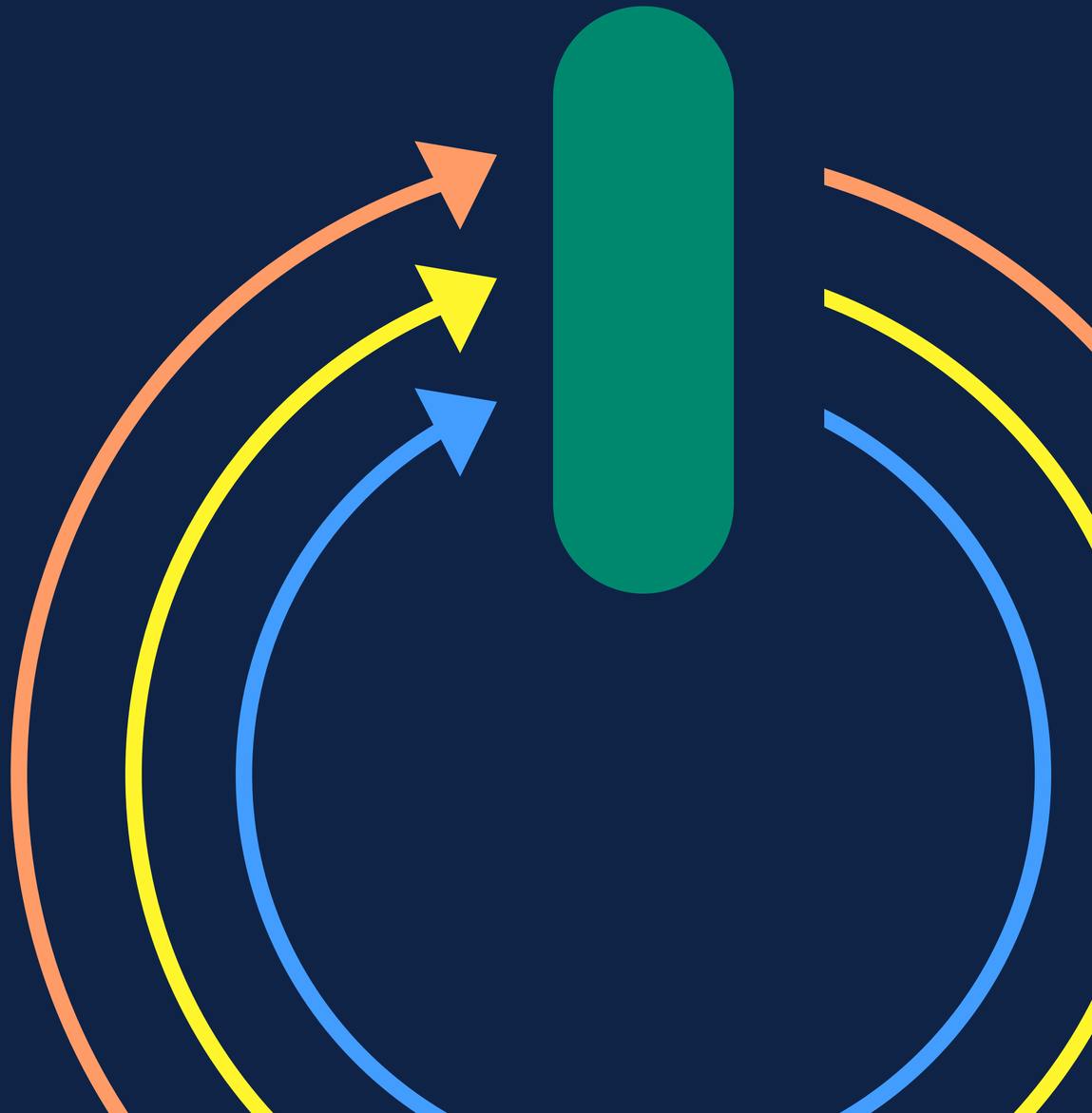
OptiRun service solutions

Qualification services



cytiva

The importance of maintaining a qualified state

Maintaining compliance with regulatory bodies is a critical endeavor for all involved in the life sciences community. Cytiva, a global service leader, is dedicated to supporting compliance through qualification services. Members of the OptiRun™ service solutions team understand how regulations affect the installation and utilization of the equipment they design and manufacture. In short, there is no better service partner to perform the suite of commissioning and qualification services that support your instruments.

Cytiva's global qualification services team provides a safe, functional environment that meets established design requirements and stakeholder expectations. These services aid our customers in meeting set criteria at every step of the qualification lifecycle.

Historically, equipment qualification was considered a one-time startup activity necessary within a regulated environment. 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.

OptiRun 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, it is recommended to regularly perform preventive maintenance and requalification. When periodic updates to software or firmware are done, change control procedures are available to customers to accurately document and reflect user-or Cytiva-defined updates.

In addition to the available qualification documentation, Cytiva engineers trained in the performance and good documentation practices (GDP) of these protocols are available to visit customers and assist with equipment qualification or requalification.

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. Through the use of 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 are performed 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.

Qualified research starts with qualification expertise

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

Contact Cytiva to discover how our commissioning and qualification expertise can help simplify the qualification of your equipment.

The suite of qualification services

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

A comprehensive set of tests are performed by the manufacturer prior to shipping equipment to a customer. The FAT protocol includes a selection of system functional tests and is executed in the presence of the customer. As part of the commissioning process, an additional SAT with accompanying documentation is performed to demonstrate the installed system meets specifications, is fully functional, and ready for formal qualification.

Primary qualification – installation and operational qualification (IQ/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, qualification protocols demonstrate that a system operated as intended throughout its anticipated operating ranges.

Secondary qualification

Requalification 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, regular preventive maintenance and requalification are recommended. 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.

Qualification maintenance

Qualification maintenance is an instrument requalification service that is performed upon the completion of routine preventive maintenance activities. The service helps customers 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 the specific needs of our customers. A modified binder can be provided through a consultative project by our qualification team. Custom projects include one review cycle.

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CY12925-24Jul20-BR