Cytiva aseptic filling

QUALIFICATION SOLUTIONS

Qualification of your aseptic filling equipment can be both time-consuming and costly. Our aseptic filling qualification solutions are specifically designed to reduce the complexity associated with qualifying your aseptic filling workcell. By engaging with our team as part of your qualification journey, you will be fully supported by our technical experts to help optimize your qualification success.

Our aseptic filling equipment allows for a standardized approach to qualification, including:

- Project management team to guide you through the journey: to ensure readiness for each step in the process and keep your project on track.
- Comprehensive documentation package.
- Execution of factory release test (FRT), factory acceptance test (FAT), site acceptance test (SAT) and installation qualification (IQ).
- On-site technical support for execution of operational qualification (OQ) protocol.
- Basic operator training and advanced user training to ensure your team is equipped with the skills and knowledge necessary to operate your workcell.
- Vapor-phase hydrogen peroxide (VPHP) cycle development training including proper handling of biological indicators (BIs) and good aseptic technique.

Fig 1. SA25 aseptic filling workcell.

Project kick-off		**System overview training**	**Factory testing**	**Ship**	**System installation at customer site**		**Performance qualification activities**	
Introduction to container closures and tooling	Facility and instrumentation readiness		Factory acceptance test (FAT)		Site acceptance test (SAT)	Installation and operational qualification	Process qualification	Airflow visualization
Introduction to environmental monitoring (EM)	VPHP decontamination		Factory release test (FRT)		Training	VPHP cycle development	VPHP validation	Cleaning qualification
Process development	Introduction to flowpaths						Environmental monitoring	Aeration validation
Qualification strategy	Network integration						Aseptic process simulation (APS)	

Fig 2. Overview of qualification journey for aseptic filling workcell.

Documentation package

A comprehensive documentation package is provided with the purchase of each aseptic filling workcell. Our standard offering provides you with documentation on as-built drawings, components, equipment functionality and setup. Our premium documentation package includes additional standard protocols for process and performance qualification (PPQ) activities.

Turnover package (TOP)

Document title	Standard offering	Premium offering
Design documentation		
General specification	✓	✓
Functional specification	✓	✓
Hardware design specification	✓	✓
Software design specification	✓	✓
Process and instrumentation design	✓	✓
Pneumatic schematic	✓	✓
Electrical schematic	✓	✓
Change tooling matrix	✓	✓
Configuration specification	✓	✓
Operational instruction	✓	✓
Site preparation guide	✓	✓
Unpacking instruction	✓	✓
Regulatory support files		
SA25 regulatory support file	✓	✓
Single-use needle and flowpath validation guide	✓	✓
Software validation file[1]	✓	✓
Quality risk management		
Failure modes and effects analysis	✓	✓
Environmental monitoring risk assessment	✓	✓
Cleaning risk assessment	✓	✓
Airflow visualization risk assessment	✓	✓
Contamination control strategy		
Hydrogen peroxide decontamination strategy	✓	✓
Horizontal airflow in the contamination control strategy	✓	✓
Material transfer strategy	✓	✓
Non-viable particulate (NVP) monitoring strategy	✓	✓
Viable environmental monitoring (EM) strategy	✓	✓
Cleaning and monitoring strategy	✓	✓

[1] Software validation file available Q2 2025.

Qualification documentation

To allow for a streamlined approach to qualification, we have developed a number of standard protocols and templates to aid you in your qualification journey.

Document title	Standard offering	Premium offering
Vendor qualification protocols		
Factory release test	✓	✓
Factory acceptance test	✓	✓
Site acceptance test	✓	✓
Installation qualification	✓	✓
Operational qualification	✓	✓
Process qualification protocols		
Airflow control and airflow visualization	×	✓
Non-viable environmental monitoring (NVEM) qualification protocol	×	✓
Viable environmental monitoring qualification	×	✓
VPHP decontamination cycle development	×	✓
VPHP aeration development	×	✓
Cleaning qualification – clean-in-place (CIP) method	×	✓
Cleaning qualification – manual method	×	✓
Performance qualification protocols		
VPHP decontamination validation	×	✓
Aeration validation	×	✓
Aseptic process simulation	×	✓
Guidance documents		
VPHP decontamination development guidelines	✓	✓
Aeration validation guidance	✓	✓
Temperature mapping	✓	✓
Handling of Apex ribbon BIs	✓	✓
SA25 aseptic process simulation guidance	✓	✓
Handling of rotary centrifugal air sampler (RCS) beta assembly	✓	✓
Additional qualification support documents		
Requirements traceability matrix	✓	✓
Process development guide for tuning pump parameters	✓	✓
Protocol customization		
OQ protocol	×	✓
VPHP validation protocol	×	✓

Integrated qualification approach

A traditional approach to installation qualification/operational qualification (IQOQ) activities can result in covering more scope than is necessary and risks duplication of testing. At Cytiva we have integrated robust testing protocols into the system qualification process and apply good documentation practices (GDP) during all testing to avoid any unnecessary duplication.

The integrated qualification approach encompassing vendor qualification testing helps prevent non-value-added redundant testing and supports an efficient use of resources while reducing risk to the overall project schedule.

Our qualification package includes protocols and execution for the following activities. A standard protocol is created for each test phase. The protocols are created from controlled templates and have been developed to verify the critical design elements at each qualification phase.

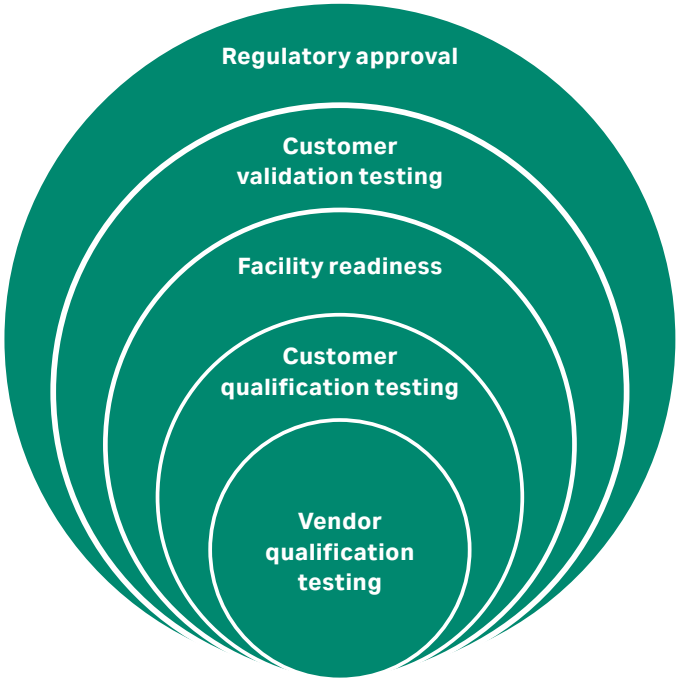

Fig 3. Our integration qualification approach model.

Factory release test (FRT)

Vendor factory release test (FRT) is performed at the manufacturing site. Various testing is performed during system build and configuration. This protocol is reviewed by the customer during the factory release test (FAT).

Factory acceptance test (FAT)

FAT takes place at a Cytiva facility in the presence of the customer. This testing is performed to gather and document evidence that verifies the system has been manufactured and operates in compliance with user requirements, design specifications, design intent and functional specifications.

Installation qualification (IQ)

Installation qualification takes place following installation of the equipment at the customer site. This protocol is executed by Cytiva personnel and verifies that the system was installed correctly.

Site acceptance test (SAT)

SAT takes place at the customer site, is performed to confirm that the system was not negatively impacted by the shipping process, and verifies that the system meets functional requirements once installed at the customer site.

Operational qualification (OQ)[2]

OQ verifies machine operation in its final location. The standard OQ protocol template is included with the purchase of each system. The method of capturing pre-approvals for OQ should be in accordance with the customer's QMS (quality management system) procedures. The customer becomes the owner of the system at this stage in the process and therefore, the owner of the document. With the integrated qualification approach, previous testing protocols, i.e., FRT, FAT, IQ, and SAT can be leveraged to avoid unnecessary repeat testing.

[2] On-site execution is not performed for operational qualification. Cytiva provides on-site technical support for this activity. The customer executes the protocol allowing them to become familiar with the technology with support and guidance from experienced Cytiva personnel.

Training

Operator training

Basic operator training equips the customer with the necessary skills to operate the system. This training consists of classroom learning and hands-on machine learning focusing on machine operation, maintenance and safety features.

Advanced user training (AUT)

Designed for users with Level 3 and Level 4 access, this training focuses on troubleshooting skills. The customer must have successfully completed the operator training prior to attending the advanced user training. This training consists of both classroom and hands-on learning sessions with trainer demonstrations and trainee execution of various operations. Upon completion of this training, the trainee will have the necessary skills and knowledge to perform more advanced operations and basic troubleshooting of the SA25.

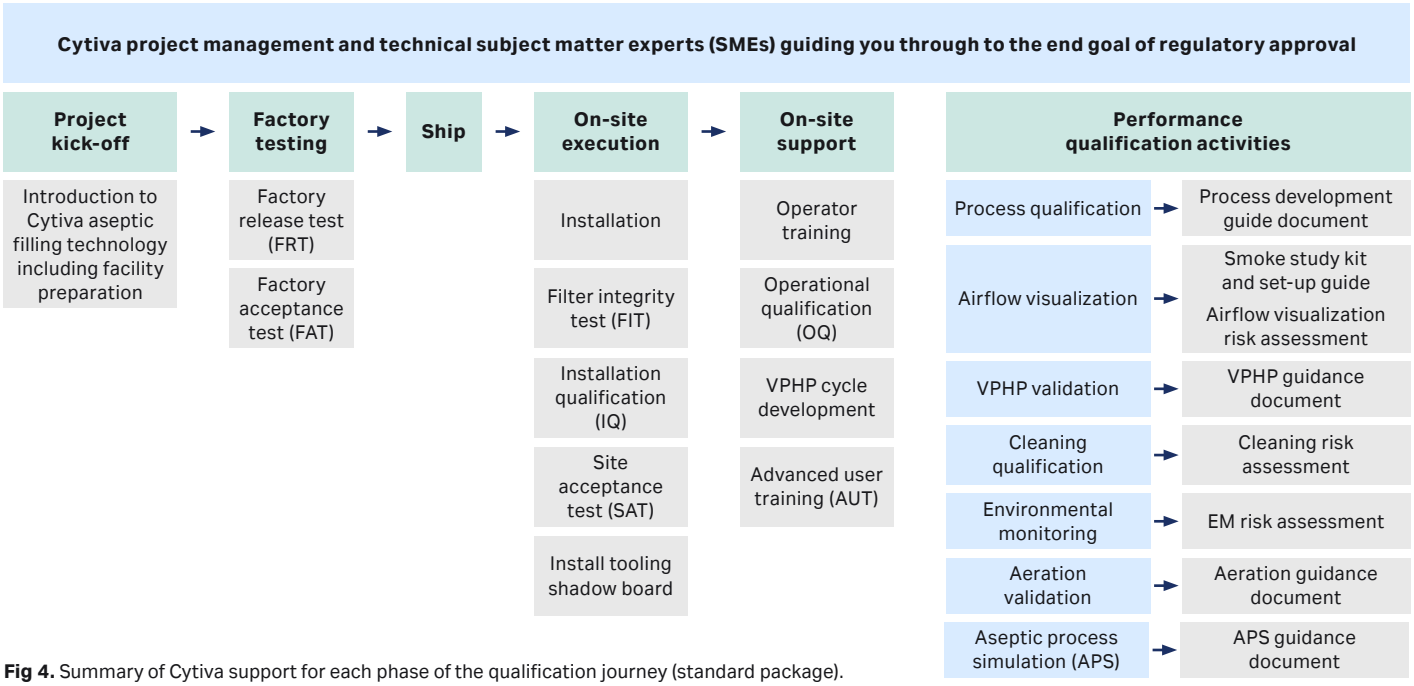

Fig 4. Summary of Cytiva support for each phase of the qualification journey (standard package).

Project management service

We're committed to helping you achieve your project milestones from onboarding through to regulatory inspection. We can guide you through each step in the process. Our project management service includes:

- Designated contact to ensure continuity of support.
- Project risk management: Reassurance that the project will be delivered on time with regular meetings to review the schedule, always looking ahead to be prepared for what is coming next, project risk register to avoid common pitfalls, clearly outlined responsibilities and documented action items.
- Project map to aid in visualizing the entire process and to make sure all steps are considered.
- Guidance and support from the equipment experts – your team gains in-depth knowledge and understanding from the project to take forward for use in future projects.

Filter integrity test (FIT)

As part of system installation and optionally as part of preventive maintenance (PM) activities, we will perform filter integrity testing on the HEPA filters. This service entails Cytiva field service engineers executing FIT on Cytiva-provided equipment.

Supporting performance qualification (PQ) documentation

Our standardized design has allowed us to create detailed process guidance that covers the appropriate steps right hrough PQ, including:

- Cleaning risk assessment
- Process development guide
- EM risk assessment
- Aeration guidance
- Aseptic process simulation guidance

Airflow visualization guide

Execution of airflow visualization or smoke studies is a regulatory expectation and an important tool in the overall contamination control strategy. Our qualification solutions include an airflow visualization risk assessment provided as part of the standard documentation package and a standard protocol for execution is available as part of the premium qualification documentation package.

To supplement these documents, an airflow visualization kit is provided that includes all the necessary parts and accessories to execute the smoke study along with a setup guide video to enable easy setup and execution.

Tooling shadow board

The SA25 aseptic filling workcell design allows for flexibility to run various formats: vials, syringes, and cartridges. To allow for safe storage of tooling and accessories when not in use, our shadow boards include the following features:

- Easy-to-clean surfaces.
- Manufactured from polycarbonate and highly resistant to most cleaning chemicals.
- Labeled sections to allow for easier identification of parts.
- Customizable design to match your chosen formats and shelving length.

VPHP decontamination cycle

Data generated during VPHP cycle development studies is used to establish the production decontamination cycles and is a reference for the overall performance qualification of the system. Cytiva factory developed VPHP cycles will provide the starting point for the development studies, drastically reducing the amount of time required to complete the studies.

Standard offering

Cytiva personnel will train the customer on how to develop their VPHP decontamination cycle for one DSI load and the FI chamber. This package consists of guideline documentation, on-site or virtual training on aseptic technique, appropriate handling of BIs (up to 5 days). Follow up support available (up to 8 hours).

Premium offering

Guideline documentation and customization of our standard protocol.

Additional on-site support for VPHP Validation execution (up to a maximum of 5 days).

Feature	Standard package	Premium package	Maintenance package
Project management service	✓	✓	×
Documentation – TOP	✓	✓	×
Documentation – qualification	×	✓	✓
Vendor qualification testing and executed protocols	✓	✓	×
Filter integrity test (install)	✓	✓	×
Filter integrity test (PM)	×	✓	✓
Operator training	✓	✓	×
Advanced user training (AUT)	✓	✓	✓
Airflow visualization kit and setup guide	✓	✓	✓
Tooling shadow board	✓	✓	✓

We offer multiple options to support you once you are in production. Contact your account manager to understand the options and select which one is suitable for your needs.

cytiva.com

For local office contact information, visit cytiva.com/contact
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