STERIS

cGMP Qualification Package

For GMP Sterilizers, Washers, VHP™ Systems and Water Systems

Reach your production phase up to 25% faster with expedited qualification from STERIS.

Smarter, Faster, Better

Introducing the cGMP Qualification Package from STERIS. This new, comprehensive offering, based on the GAMP 5 and ASTM-E2500 methodology, can reduce risk and help you reach your production phase up to 25% faster.

Your Challenges

As you look to expand your business with new equipment, there are a wide range of variables that impact your time to market. Any change that impacts your timeline from equipment development to on-site qualification can delay your return on investment.

- Qualification services are often treated as separate processes entirely - sometimes performed by various vendors or in-house teams.
- Varying test results across phases can delay production dates.
- You need 3rd party vendor services to be performed as efficiently as possible due to new safety and security visitor policies.

Expedited Qualification.
STERIS Expertise.

Expedited Qualification

The cGMP Qualification Package includes Factory Acceptance Testing (FAT), Site Acceptance Testing (SAT) and Installation Qualification/Operational Qualification (IQOQ) documentation and execution - all in one comprehensive offering.

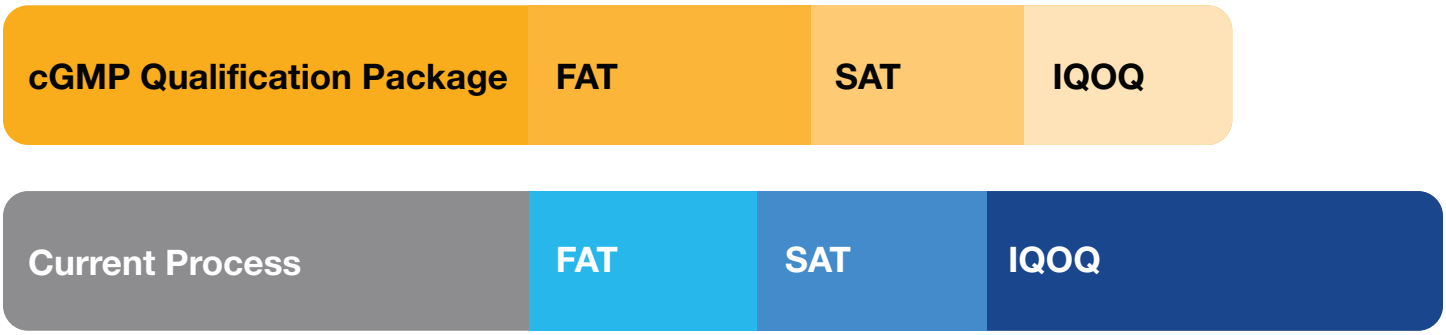
It begins at our factory during FAT with extensive installation and operational checks. Tests include electrical configurations, utility supplies and adjustments. They are designed to challenge your new unit in production-like conditions, ensuring it functions as intended.

Once your FAT protocols have been completed and approved, the unit is installed at your site and qualification continues with SAT and IQOQ testing. These tests can be completed in less time and have less variance because they leverage the extensive testing completed during the FAT.

The cGMP Qualification Package also reduces the amount of time STERIS representatives spend on site, which aligns with many new and more stringent site visitor policies.

Example Project Timeline

The STERIS cGMP Qualification Package reduces your qualification time as much as 25%, helping you reach production stage faster.



Project Timeline

FAT (Factory Acceptance Testing)

Testing at the manufacturer's facility to prove the system is designed, manufactured and functions according to Customer specification.

SAT (Site Acceptance Testing)

Once installed at the Customer site, repeat testing of FAT parameters confirms the unit meets Customer specifications.

IQOQ (Installation Qualification/Operational Qualification)

Qualification documentation of all equipment verification protocols demonstrates suitability and operability of systems and equipment.

Documentation Package

Final documentation provided in the cGMP Qualification Package service includes:

- Pre-approved executed protocols, summary of test results and signed certificates of completion for FAT, SAT and IQOQ documentation
- Corresponding print tapes for printout verification
- Calibration report and equipment specific technical data (specifications, schematics, recommended spare parts list)
- Signed certificate of completion of cGMP Qualification Package

The cGMP Qualification Package is available for the following equipment types:

Category	Qualifying STERIS Products
VHP	VHP 1000i
	VHP 100i
	VHP Flex
	VHP M100 Series
	VHP 1000ED Biodecontamination Unit
Washers	Reliance™ 280PG Washer
	Reliance 380PG Washer
	Reliance 480PG Washer
	Reliance 680PG Washer
	Reliance 980PG Washer
Sterilizers and Chambers	Finn-Aqua™ BPS Sterilizers
Water Systems	Finn-Aqua Multiple-Effect Water Stills (T and TF-Series)
	Finn-Aqua Pure Steam Generators (T and TF-Series)

For the most recent list of qualifying products for the cGMP Qualification Package, visit: sterislifesciences.com