STERIS VHP® Technology Validation & Verification\(^1\) Services

VHP® technology validation made simple

STERIS VHP (Vaporized Hydrogen Peroxide) Validation Services can help your company comply with FDA requirements by providing documentation solutions that allow for the seamless and efficient validation of your STERIS VHP Biodecontamination System. From Installation Qualification (IQ) to Performance Qualification (PQ), our validation team can help your company comply with FDA requirements with the certainty that only STERIS VHP technology experts can provide.

A STERIS VHP validation expert will work to understand your process-specific documentation requirements and then work with you to see that these requirements are met. By partnering with STERIS, you can be confident that your low-temperature sterilization needs will be taken care of by industry experts.

Fundamentally, we seek to build long-term relationships with each of our clients. Our goal is to learn how our clients work, and then adapt our procedures to fit the client. We believe in nurturing a productive, comfortable working rapport and in establishing stable project teams. Once clients work with us, they appreciate our commitment to complete each project on time and within budget, and typically ask us to bid on additional projects. When we accept a project, we accept responsibility for expediting it from start to finish. STERIS is the pioneer in VHP technology and subject matter experts to validate your VHP processes.

- Riz Khan, Lead VHP Validation Engineer, STERIS Corporation

\(^1\)Also known as IQ/OQ and PQ. New ASTM E2500 utilized the terms Installation / Operational Verification and Performance Testing.
Low Temperature Sterilization Experts that Understand FDA Requirements

As the inventor and sole proprietor of VHP technology with over 100 years experience in high- and low-temperature sterilization, STERIS is the only one capable of qualifying your STERIS VHP equipment to the consistent standards required by your organization. Our highly trained STERIS VHP Validation Specialists have on average 15 years of CGMP industry experience. This combination of technical engineering and regulatory experience means that you can be confident that your VHP sterilization process will be qualified in a proper, timely, and consistent manner.

Superior Qualification Protocols and Documentation Services

No one knows STERIS VHP technology better than STERIS, and nothing offers a higher level of compliance than STERIS documentation. Our documentation starts in the factory and supports each piece of equipment throughout its life cycle. This complete method of documentation is accurate and efficient. STERIS validation engineers will work to understand your process-specific documentation needs to provide protocols that complement your existing documentation formats.

VHP IQ/OQ

> Equipment-specific documentation originating in the factory and written according to CGMP specifications by VHP technology experts
> Document execution performed by qualified STERIS validation experts
> Includes an NIST traceable calibration
> Supports seamless and efficient qualification

VHP Cycle Development (Pre-PQ Study)

> Developed by VHP technology experts for your process-specific application
> PQ cycle parameter development
> Supports seamless and efficient qualification

VHP PQ

> Written and executed by STERIS VHP technology experts
> Consistent and defendable approach to VHP validation
> Customized to meet your organizations documentation format and process requirements
> Sterilant Intrusion and Residue Effects Testing
> Customer specific process validation
> Annual requalification programs available
> D-value testing
> Risk Assessment
> Validation support for your in-house team
> Supports seamless and efficient qualification

Final Reports

> Our VHP validation experts will provide a summary of the results obtained in IQ/OQ and PQ testing in a systematic and logical manner to make FDA or internal audits a smooth transaction

STERIS Validation & Verification Services are also available on the following products:

> VHP Biodecontamination System qualification
> VHP process validation in conjunction with isolators, RABS (Restricted Access Barrier System), filling & packaging lines, material air locks, pass thru chambers, and clean rooms
> Steam Sterilizers
> Ethylene Oxide Sterilizers
> Washers
> Pure Steam Generators
> Water Still
> And more...

For more information contact STERIS Life Sciences
Email: Validation@STERIS.com Phone: +1(800)333-8828

STERIS®

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STERIS OFFICES WORLDWIDE

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