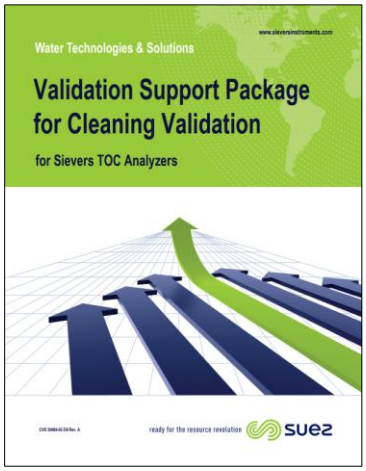
Water Technologies & Solutions
fact sheet

Sievers* Validation Support Package for Cleaning Validation (VSPCV)

description and use

The Validation Support Package for Cleaning Validation (VSPCV) is a comprehensive set of documentation providing guidance for the use of Total Organic Carbon (TOC) in laboratory, at-line, and on-line cleaning validation applications. The Sievers VSPCV includes guidance, examples, worksheets, templates, and sample protocols that will significantly reduce the time and effort required to define and execute cleaning validation requirements. The VSPCV is a powerful document package that greatly simplifies implementation of Sievers TOC Analyzers (Laboratory, Portable, and On-Line) in cleaning validation and cleaning verification applications.



key features and benefits

Application-Specific Protocols

Many pharmaceutical manufacturers seek to increase efficiency in the validation process while maintaining the highest levels of quality and regulatory compliance. In addition to laboratory-based cleaning validation support, the Sievers VSPCV guides users through the steps and documentation necessary to validate methodology and cleaning processes to achieve efficient release of production equipment.

Inspection-Ready Documentation

The Sievers VSPCV provides a science-based approach to cleaning validation and includes validation tools that can be applied to multiple aspects of pharmaceutical quality and ongoing quality control, such as:

- Cleaning process development
- Manufacturing
- Change control processes for active pharmaceutical ingredients, drug products, and biological and biotechnology products

Regulatory Document Structure

A key benefit of the Sievers VSPCV is the systematic approach to cleaning validation documentation. The VSPCV serves as a foundation document that is in compliance with other regulatory documents such as CFRs, PIC/S, ICH Guidelines, ASTM and Process Analytical Technology (PAT) guidance documents, cGMP Drug Notes, FDA guidance and USP Guidelines. In addition, the VSPCV complements existing quality practices, requirements, standards and guidelines commonly utilized within the pharmaceutical and biotechnology industries.

Time-Saving Templates

The Sievers VSPCV assists customers beyond process development and cleaning validation testing. It facilitates a science-based approach to defining key elements of a cleaning validation program, providing the user with templates for:

- Acceptance criteria calculations
- Test plans — Percent recovery studies
- Protocols and reports that encompass all aspects of process development, validation, manufacturing and process monitoring

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