Top 5 Secrets to a Successful Cleaning Validation Program

Opportunities and challenges for determining what's right for you

Pharmaceutical manufacturers are continuously challenged to demonstrate a validated cleaning program. Here are five ways to ensure a successful and compliant cleaning validation program.

1. IDENTIFY THE RIGHT TECHNOLOGY AND MOST EFFICIENT DEPLOYMENT OPTION (LABORATORY, ONLINE, AT-LINE) FOR YOUR CLEANING PROGRAM

Know your process. Choosing the right technology for a process is key to successful method implementation. There are many analytical methods commonly used for cleaning validation.

- Specific methods such as UV/VIS or HPLC test for a specific analyte in a cleaning process. While this gives confidence that the analyte of interest is in fact absent, these tests cannot detect other compounds such as degradants or detergents that could affect the quality, yield, efficacy, or safety of products. This type of analysis is limited to laboratory deployment.
- Non-specific methods such as Total Organic Carbon (TOC) analysis allow for a more comprehensive understanding of cleanliness over specific methods. Rather than searching for one analyte, TOC detects detergents, degradants, APIs, and excipients in one method. TOC also allows for a variety of deployments (lab, at-line, online) depending on what works best for your process. To learn more about choosing the right deployment with Sievers* TOC analyzers, **CLICK HERE**

2. SIMPLIFY METHOD VALIDATION AND INSTRUMENT QUALIFICATION

Method validation and instrument qualification are required to demonstrate appropriate method parameters and instrument fitness for that method. While these are crucial to a successful cleaning program, validation and qualification don't have to be complicated.

- A suitable method should be developed to show adequate compound recovery, linearity, robustness, specificity, and to set appropriate acceptance criteria. It is important to demonstrate these qualities and ensure the technology chosen can meet the needs of robust method development. Method development and validation should be practical, achievable, verifiable, and defensible.
- Instruments should undergo comprehensive qualification to qualify the installation, operation, and performance of the instrument for its intended use. SUEZ offers documentation and services to fully execute this for you.

3. CHOOSE THE BEST CONSUMABLES FOR OPTIMAL RECOVERY AND SAMPLE INTEGRITY

Consumables such as vials and standards can greatly impact the success of any analytical method. Be sure to choose traceable, compliant, and appropriate consumables for your process.

- Systems should be periodically challenged to ensure method suitability. Choose a compound, or multiple compounds, at a concentration to reflect your process and appropriately challenge instrumentation used for cleaning validation.
- SUEZ offers specialty consumables to increase successful method implementation. For example, if your process involves detecting proteins, Sievers Pre-acidified TOC vials can greatly increase recovery of sticky proteins that are often underreported. Consider solutions like these when thinking about method development.
- Online analysis is something to consider to reduce costs on vials and to increase sampling integrity. Automated analysis removes room for sampling error while saving money and time.

4. LEVERAGE DATA FOR PROCESS CONTROL, UNDERSTANDING, AND OPTIMIZATION

Choose technology that generates data that can be trusted, validated, and used for troubleshooting and important cGMP decisions. Without validated and accurate data, process understanding and process control are difficult to achieve.

- Having accurate data can give the confidence in results needed to make important quality decisions. If using TOC, show caution when choosing a particular TOC technology for cleaning validation as some are not suitable for accurate separation and detection.
- Sievers TOC analyzers offer three discrete data points that give insight into a process, ultimately allowing for control, understanding, and optimization. Inorganic carbon, total organic carbon, and conductivity are reported from one sample analysis. These data points can be used together to identify a root cause, take corrective and preventive actions, or to optimize a cleaning cycle.

5. DATA INTEGRITY

Data integrity is more important than ever in CGMP settings and must be considered when implementing analytical technology in cleaning validation programs.

- The FDA has issued numerous warning letters for failure to comply with data integrity standards when using analytical methods. Specifically, when using HPLC, findings for failure to integrate peaks or investigate ghost peaks is a common observation. Unknown peaks are unavoidable in cleaning validation and they must be thoroughly investigated and documented.
- TOC for cleaning validation not only provides a comprehensive understanding of cleanliness but Sievers TOC analyzers offer complete compliance to 21 CFR Part 11 requirements and data integrity guidelines. Data should be maintained in a secure database, readily accessible, and all activity kept in a secured audit trail. When using data to make important quality decisions, robust processes need to be in place to maintain the integrity and security of the data.
- When using online TOC for cleaning validation, there is an even higher degree of data security and integrity due to the avoidance of transcription, printing, and un-validated data transfer.

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