Material

APIs, Excipients
Cleaning Agents

Information on

Equipments

Reports

Customised

Identification of

Worst case product

Calculation of

MACO on Toxic, TD, HBEL

Residual Limis

Rinse (mg/mL)
Swab (mg / mL)

e-Cleaning Validation.

for formulations bulk drugs, vaccines and R & D.
(Human, Veterinary)

e-CV

e-CLEANING VALIDATION SOFTWARE (e-CV)

eCV determines the worst case product & calculates MACO based on Toxicity, Drug Active Dose, & ADE / PDE (HBEL)

e-CV compliance with

- GAMP
- ISPEs Risk-MaPP Baseline (Guide)
- PDA technical report 29
- 21 CFR Part 11
- Annex - II

e-CV key features

- Cloud based
- Secured data
- User friendly application
- Intuitive user interface
- Works on Google Chrome, Mozilla
- Good visualization
- Reporting friendly

e-CV efficiency

- Deployment in a short time
- Minimal user training required
- Eliminate errors
- customize or expand as you go
- Pay for what you need

e-CLEANING VALIDATION SOFTWARE

e-Cleaning Validation: This advanced software is not just a solution for today's challenges; it's a future-ready platform designed to seamlessly adapt to the dynamic landscape of your manufacturing processes to meet the GMP requirement.

Key Adaptive Features:

- **Worst Case Product Identification**: e-Cleaning Validation employs advanced algorithms to identify the worst-case product scenarios, ensuring a comprehensive approach to cleaning validation. This capability enhances your risk mitigation strategies and ensures a thorough evaluation of your cleaning processes.
- **MACO (Maximum Allowable Carryover) Calculation**: Our software automates the MACO calculation process, providing accurate and reliable results. By leveraging sophisticated algorithms, e-Cleaning Validation eliminates the complexity traditionally associated with MACO determination, allowing your team to focus on critical decision-making.
- **Rinse Solution Concentration (mg/mL)**: Achieving the optimal rinse solution concentration is critical for effective cleaning validation. e-Cleaning Validation not only calculates the ideal concentration but also provides real-time calculations and recommendations, ensuring your cleaning processes meet and exceed industry standards.
- **Swab Concentration (mg/mL)**: Precision is key in cleaning validation, and e-Cleaning Validation excels in providing detailed information of swab, surface areas and concentration. This functionality allows for accurate measurements of residue levels, facilitating a meticulous assessment of cleaning efficacy.
- **Equipment Dynamics Integration**: e-Cleaning Validation is equipped to

handle changes in your manufacturing equipment seamlessly. Whether it's the addition or deletion of equipment, our software dynamically adjusts cleaning validation parameters, ensuring continuous accuracy and compliance in the face of evolving production environments.

- **Batch Size Flexibility**: Recognizing the varying demands of your industry, e-Cleaning Validation intelligently accommodates changes in batch sizes. The software recalibrates cleaning validation criteria to align with new batch size requirements, guaranteeing that your cleaning processes remain efficient and effective, regardless of scale.
- **New Product Integration**: As your company diversifies its product portfolio, e-Cleaning Validation rises to the challenge. The software effortlessly incorporates new products into the cleaning validation framework, streamlining the validation process and minimizing downtime associated with introducing novel items to your production line.
- **Comprehensive Reporting**: Generate detailed reports effortlessly, showcasing key metrics such as worst-case product identification, MACO calculations, rinse solution concentrations, and swab concentration. These customizable reports serve as invaluable documentation for regulatory compliance and internal audits.
- **Real-time Notifications / Change Control**: Stay informed about changes impacting your cleaning validation processes. e-Cleaning Validation provides real-time notifications and alerts when adjustments are required due to equipment modifications, batch size changes, or the addition of new products, allowing your team to proactively address any potential compliance concerns.
- **Audit Trail Documentation**: Comprehensive documentation is crucial for regulatory compliance. e-Cleaning Validation maintains a detailed audit trail, capturing every change made to the cleaning validation. This feature ensures transparency and traceability, facilitating smooth audits and regulatory inspections.

- **Validation Documentation**: e-Cleaning Validation offers customized capabilities to enhance cleaning validation documentation, including protocol, data, reports and many more.

- **By choosing e-Cleaning Validation**, you are investing in a comprehensive solution that goes beyond traditional cleaning validation tools. Our commitment to innovation, compliance, and user experience sets e-Cleaning Validation Software apart as the ultimate partner in ensuring the highest standards of cleanliness and regulatory adherence within your organization.

To explore how e-Cleaning Validation can seamlessly integrate with your evolving manufacturing environment, please feel free to reach out for a personalized demonstration or further information.

To download
eCleaning Validation brochure