PharmEng Technology

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CLEANING VALIDATION (CV)

Aligning Cleaning Validation with Toxicological evaluation provides tools to implement processes to achieve results in compliance, to meet regulatory expectations, and ensure patient safety.

Modern cleaning programs focus on patient safety and should include health-based exposure limits (HBEL) considering identification of hazards and evaluation of the dose-response relationship.

DELIVERABLES INCLUDE:

- Customized solution for your CV Master Plan
  - Cleaning Process Design & Development
  - Cleaning Process Validation
  - Continued Cleaning Process Verification
- Author/revise CV SOPs
- Evaluate toxicity of biopharmaceutics, therapeutic proteins, chemicals, and active pharmaceutical ingredients
  - Determine No Observed Adverse Effect Level (NOAEL)
  - Calculate Permitted Daily Exposure (PDE)
  - Develop Acceptance Criteria that take account of limits for the carryover of product residues with consideration to toxicological evaluation.

REGULATORY & GUIDANCE DOCUMENTS:

- FDA 1993, Validation of Cleaning Processes, Guide to Inspections Validation of Cleaning Processes
- EudraLex, Vol 4 GMP Guidelines, Annex 15
- European Medicines Agency: Guideline on Setting Health Based Exposure Limits for Use in Risk Identification in the Manufacturer of Different Medicinal Products in Shared Facilities.
- ICH Q3, ICH Q2, ICH Q7, ICH Q8, and ICH Q10
- ISPE Baseline Guide Volume 7, Second Edition, Risk-based Manufacture of Pharmaceutical Products
- PDA TR 29, Points to Consider for Cleaning Validation
- PDA TR 49, Points to Consider for Biotechnology Cleaning Validation