

THE FUTURE OF CLEANING VALIDATION

Modern manufacturing demands precision, speed, and traceability. Validator delivers all three by automating complex calculations, centralizing data, and ensuring every production line is released with confidence. Designed for regulated industries, it streamlines validation activities from planning to approval reducing risk, eliminating manual errors, and accelerating batch turnaround.

Why Choose Our Software?

Automated MACO Calculations

- Automatically calculates Maximum Allowable Carryover (MACO) using industry-standard formulas, or customized to individual organizations
- Supports multiple calculation methods (dose-based, toxicity-based, ADE/PDE-based).
- Ensures consistency across products, equipment trains, and cleaning procedures.
- Reduces human error and provides full audit trails for regulatory compliance.



Dynamic Sampling Plan Generation

- Generates optimized sampling plans tailored to equipment, product risk, and cleaning procedures.
- Automatically assigns sampling locations and quantities using actual equipment schematic interface functionality
- Links each sample to its corresponding Critical Quality Attributes (CQAs) and test methods.
- Ensures sampling strategies align with regulatory expectations and internal SOPs.



Built-In Statistical Analysis & Visualization

- Performs statistical calculations automatically, including:
 - Recovery factor adjustments
 - Trending and control charting
 - Variability and capability analysis
- Generates clear, interactive graphs for rapid interpretation.
- Enables data-driven decisions with real-time analytics.



Seamless LIMS Integration

- Bi-directional data exchange with your Laboratory Information Management System.
- Automatically pulls test results, specifications, and sample metadata.
- Evaluates results and provides continued cleaning process verification (CCPV).
- Eliminates duplicate data entry and ensures a single source of truth.



Automated Line Release

- Compares cleaning test results to validated specifications in real time.
- Automatically determines whether equipment is clean and ready for the next product.
- Generates electronic release records for QA review.
- Accelerates changeover and reduces production downtime.



Real-Time Alerts & Notifications

- Notifies key stakeholders (QA, QC, Production, Validation) of failed or borderline results.
- Supports configurable escalation workflows.
- Ensures rapid response to issues that could impact product quality or timelines.



Worst-Case Scenario Analysis

- Identifies worst-case product, equipment, and cleaning combinations.
- Automatically calculates worst-case MACO and sampling requirements.
- Helps validation teams optimize cleaning strategies and reduce unnecessary testing



Compliance & Data Integrity

- Fully aligned with regulatory expectations (FDA, EMA, WHO, PIC/S).
- 21 CFR Part 11–ready electronic signatures and audit trails.
- Secure, role-based access control.
- Complete traceability from calculation to approval.



The Result

Faster validation cycles. Stronger compliance. Zero guesswork.

Your teams gain time, your processes gain consistency, and your production lines move with confidence.