IS THIS YOUR WORST CASE?

NOVA-CLEANING VALIDATION

Automated Risk-Based Contamination Control

NOVATEK
EUROPE

NOVA-CLEANING VALIDATION

THE INDUSTRY'S FIRST CHOICE FOR AUTOMATED CLEANING VALIDATION AND RISK MANAGEMENT

From both a regulatory and industry perspective, cleaning validation is recognized as being critical for patient safety and product quality because it guarantees that product contamination is effectively controlled. Manual methods for managing the cleaning process on a pharmaceutical manufacturing line are time-consuming, prone to human error, and may leave manufacturers exposed to regulatory risks.

Nova-Cleaning Validation is a **revolutionary software** module that speeds up the cleaning validation process, produces more accurate results, and reduces the risk of non-compliance.

UNIQUE AND INNOVATIVE FEATURES

Computerized risk-based worst case evaluation. Risk factors, including dosage, toxicity, cleanability, solubility and more, can be defined together or separately, allowing the user to have **complete control over the evaluation settings**. The worst case is determined and displayed for all validation groups, enabling users to focus on the biggest risk to product quality. The worst case assessment is automatically triggered when any validation group property is changed.

Fully automated MAC calculations. Carryover limits are calculated for all sample points for APIs, cleaning agents, and microbial testing. Hundreds of MAC formulas are **executed in seconds, rather than hours**. The calculations take into account all possible product A and product B combinations for the affected equipment trains and validation groups, and the lowest MAC values are highlighted, making user review of the calculated values quick and easy.

Dedicated Risk Control feature consolidates the impact of multiple changes in one snapshot of the risks and consequences of potential changes to any factor that may affect the validated state of the cleaning process. These factors include changing equipment, introducing new products, modifying batch sizes, and anything else that relates to both the product and equipment families that are part of equipment trains and validation groups.

+ ACHIEVE COMPLETE CONTAMINATION CONTROL WITH THE COMBINATION OF NOVA-CLEANING VALIDATION & NOVATEK ENVIRONMENTAL MONITORING

BENEFITS THAT SAVE YOU TIME AND MONEY

REDUCED COSTS

The ROI for implementing an automated cleaning validation system is almost immediate, with significant savings in time and resources compared to a manual process. By automating worst case determinations and thousands of MAC calculations, hours of work are accomplished in minutes.

REDUCED ERRORS

Nova-Cleaning Validation is a paperless system that reduces human error. Data errors in entries or calculations could result in the loss of millions of dollars in contaminated product.

DATA INTEGRITY

21 CFR Part 11 compliant, Nova-Cleaning Validation provides data security and compliance as well as automating system evaluations and calculations. Regulatory auditors will be able to clearly see that the process is in a state of control.

TRANSPARENCY

Electronic management and approval of master data ensures that information is shared efficiently. All data related to equipment, analytical methods, and validation groups are available to all stakeholders, providing transparency across functional groups.

STREAMLINED MANAGEMENT

Relational validation group creation for single or multiple equipment trains benefits the user by making the definition of product and equipment families easy to create and simple to manage.

SYSTEM DEFINED PROTOCOLS

Sampling plans are automatically generated for validation groups based on the defined sample points, analytical methods, and MAC limits. Users can schedule validation or monitoring events based on the approved protocols.

DATA & ANALYTICS

Holistic reporting enables users to retrieve any data in a few clicks with a variety of in-depth standard reports. Trending and statistical analysis includes capability indices, regression, scatter plot, and other graph types.
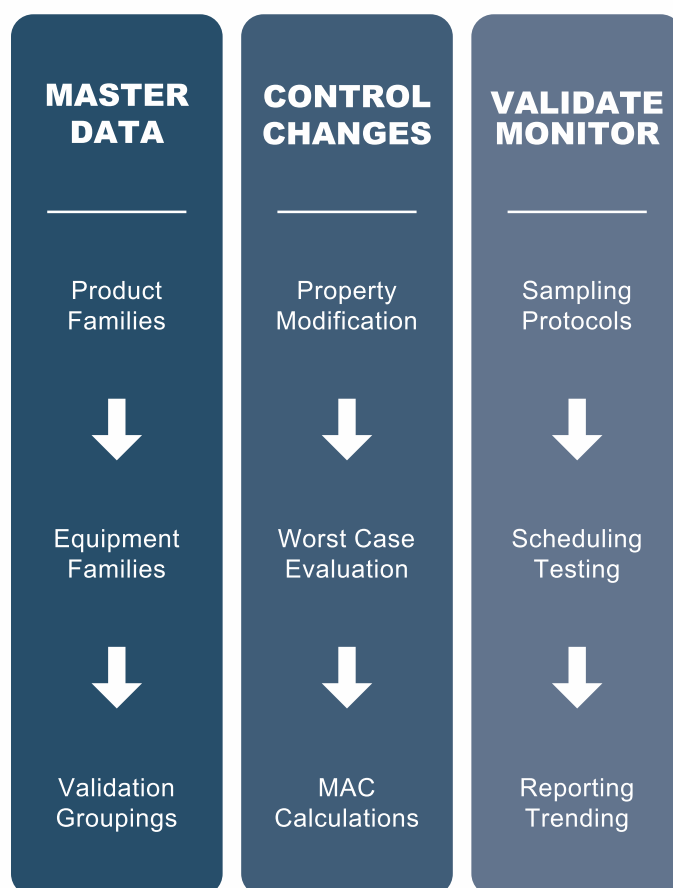
ACHIEVE COMPLIANCE AND PREVENT REGULATORY ISSUES

Nova-Cleaning Validation significantly enhances product integrity by managing changes and assessing the risks associated with cross-contamination and product impurities within a dynamic production environment.

All changes to methods, APIs, products, equipment, and family groups are automatically evaluated to ensure product integrity and regulatory compliance.

Nova-Cleaning Validation complies with 21 CFR Part 11 and EU Annex 11. The module uses a risk-based approach and is designed based on PDA Technical Reports 29 and 49, ISPE MaPP, 21 CFR Part 211.67, Validation of Cleaning Processes (7/93), and EU Annex 15.

HIGH-LEVEL PROCESS WORKFLOW

MASTER DATA	CONTROL CHANGES	VALIDATE MONITOR
Product Families	Property Modification	Sampling Protocols
⬇	⬇	⬇
Equipment Families	Worst Case Evaluation	Scheduling Testing
⬇	⬇	⬇
Validation Groupings	MAC Calculations	Reporting Trending

A HOLISTIC AND PROCESS-SPECIFIC RISK MITIGATION SYSTEM

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EUROPE

THE LEADING PROVIDER OF REGULATORY COMPLIANT SOFTWARE

The Novatek approach provides the building blocks for a complete quality management solution that can be tailored to any client's needs. Our software can be used as standalone modules or integrated with other modules to form large-scale comprehensive solutions. With 20+ years of successful installations globally, Novatek has developed an extensive base of regulatory knowledge ensuring compliance and peace of mind during audits.

SOLUTIONS

Our comprehensive business-ready portfolio of easy-to-use regulatory compliant software

CONTAMINATION CONTROL

Water & Utility Monitoring	Environmental Monitoring	Cleaning Validation	Disease Control & Hygiene Monitoring

QUALITY EXECUTION LIMS

Raw Material Analyzer	In-Process & Finished Product Analyzer	Stability Management

QUALITY PROCESS

Quality Management System

Training	Deviations	Audit	Investigations	Calibration & Preventive Maintenance
CAPA	Complaint Reporting	Document	Change Control	

ADDITIONAL SOLUTIONS

Automated Proofreader	Column Organizer	Consumable Inventory	Innovation Management	Screen Capture Tool

+ Build **your solution** with the flexibility to grow with **your needs** and implement at **your pace**

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Contact us for more information on Automated Risk-Based Cleaning Validation or any other Novatek Solution.

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