pharmakon

Cleaning Validation

Understanding the importance of cleaning validation

Cleaning validation is essential for patient safety and product quality within a GMP-compliant environment. Learn the principles, regulatory requirements, and how to document to confirm that your production cleaning processes are both effective and reproducible.

Cleaning validation is about ensuring that residues and carry-over do not affect the next batch. It is a critical GMP-requirement that comprise both product quality and patient safety.

This course provides a basic understanding of cleaning validation in the production of APIs, intermediates, and finished drug products.

You will learn how to validate the cleaning of equipment and facilities using a risk-based approach, ensuring that your cleaning processes meet EU and US GMP-requirements from regulatory authorities.

We will explore:
- Regulatory requirements
- Strategies for validating facilities and product-specific equipment
- Selection of equipment, cleaning agents, and cleaning methods
- Product dedicated vs. shared process equipment and facilities
- Analytical methods and acceptance limits
- From validation to practice – implementation in procedures
- Continuous cleaning monitoring
- Clean Equipment Hold time vs. Dirty Equipment Hold time

The instructors bring hands-on experience in cleaning validation and will share real-world industry case studies. The course format alternates between presentations and exercises, giving you the opportunity to apply theory in practice.

The course language is English.

At the course you will meet:

Carsten Germansen, VP Aptio Group CMC, MSAT & Tech Transfer, Aptio Group Denmark
Olof Rosén, PhD, Senior Consultant, Aptio Group Sweden AB

Course facts

FORMAT
2 days

PRICE THIS YEAR
17.500 DKK excl. VAT

Sign-up dates

Hillerød
12. mar. – **13. mar.**
2026

Do you have questions about this course?

Kontakt
Kursuskoordinator
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Target group

The course is aimed at support functions and others who need an introduction to cleaning validation and want to understand how it is performed and integrated within a GMP-regulated organization.

Your benefits

• you gain a fundamental understanding of cleaning validation in manufacture of API and drug product
• you learn to apply a risk-based approach to process equipment cleaning validation
• you are introduced to cleaning methods, sampling and analysis of test, enabling you to assess effectiveness and reproducibility of the cleaning process.

Your company's benefits

• your employee gains insight into when product- vs. facility-specific cleaning validation is needed
• your employee can help to ensure compliance between regulatory requirements and cleaning processes
• your employee gains a basic understanding of cleaning validation concepts and how risk management is applied.

Course agenda

The course duration is 2 days. Accommodation is included.

The course combines theory with practice-oriented cases and exercises. You will be introduced to:
• The concept of cleaning validation
• Cleaning agents and equipment
• Risk management and regulatory requirements
• Product- vs. facility-specific cleaning validation
• Acceptance criteria and analytical methods
• From validation to procedures
• Monitoring as part of quality assurance

The course language is English.

Sign up online at
www.pharmakon.dk