IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Cleaning Validation - Best Practice in Pharmaceuticals

22-23 June 27
+ 23-24 November 27

Master the principles of cleaning validation to ensure pharmaceutical manufacturing equipment meets stringent regulatory standards, preventing contamination and safeguarding public health.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

Learn how to establish and implement efficient and effective cleaning processes to ensure your equipment and facility are properly cleaned and sanitised before pharmaceutical production.

Pharmaceutical products can be contaminated by other pharmaceuticals, cleaning agents, microorganisms, or various other factors. Such contamination poses significant and serious health risks to the public. To mitigate these risks, standards and guidelines on best practices for the pharmaceutical industry have been established. Cleaning validation is a widely used practice in the industry to ensure these standards are met.

Cleaning validation is essential for the pharmaceutical manufacturing process, ensuring that equipment is adequately cleaned to prevent contamination of subsequent products. Regular monitoring and evaluation of cleaning procedures are necessary to maintain consistent and acceptable performance. A robust management system should be in place to address changes, variations, and unexpected occurrences, ensuring reliable performance throughout the equipment's usage period.

This cleaning validation training consists of two distinct modules. The first day provides an overview, covering all aspects of cleaning validation. The second day delves into advanced topics, offering an in-depth exploration of specific issues crucial to understanding the current regulatory environment.

Benefits of attending

- **Expand** your knowledge on international cleaning validation guidelines
- **Enhance** your strategies for validation protocols
- **Understand** how to prepare the cleaning validation protocol and report
- **Learn** monitoring, revalidation, and validation maintenance for validated processes
- **Master** cleaning methods, cleaning mechanisms, cleaning agents, equipment grouping and risk-based decision making
- **Clarify** the logic of audit findings
- **Get-to-grips** with utilising a life cycle approach to cleaning validation
- **Identify** how to select sampling methods and sites, as well as proper selection of blanks and control

Who should attend?

Professionals responsible for various aspects of cleaning validation, including:

- Validation scientists
- Validation service personnel
- Production engineers
- Quality assurance specialists
- Quality control technicians
- Analytical chemists
- Regulatory affairs professionals
- Pharmacologists
- Toxicologists
- Technical support scientists
- Supervisors, managers, and directors of groups supporting cleaning validation

Programme

Day 1

Cleaning validation defined

- Regulatory guidance and expectation for cleaning validation
- ICH Q7, EU GMP Annex:1, Annex:15, PI 006-3:2007
- ISPE (International Society for Pharmaceutical Engineering), PDA (Parenteral Drug Association), ASTM (American Society for Testing and Materials) Guides

Definitions and documents needed

- Cleaning validation policy
- Cleaning validity master plan
- Cleaning validation protocol report
- Understandable cleaning validation SOP
- Design/development of a cleaning process

Calculations

- Principles and calculations of residue limits for a wide variety of residue types, routes of administration, and dosage types
- Non-uniform contamination
- Surface areas in carryover calculations
- Microbial criteria of cleaning validation
- Limits for "product X to product X"
- Biofilm formation and cleaning validation concerns
- DHT (dirty hold time), CHT (clean hold time) studies challenges

Analytical methods

- Selection of analytical methods, along with appropriate levels of analytical method validation
- Establish a soil library for a cleaning validation process
- Selection of sampling methods and sampling sites, selection of blanks and controls
- Selection of cleaning agents and cleaning mechanisms
- Robust recovery data

Health-based limits

- Rationale for health-based limits
- Biopharmaceutical cleaning validation approaches
- Establish permitted daily exposure (PDE)/ allowable daily exposure (ADE)
- Health-based approach to a possible chemical contamination

Critical process parameters and critical quality attributes

- Critical process parameters
- Critical quality attributes
- How to understand recovery studies

Group exercise - how to write a bulletproof cleaning validation protocol

- Critique of format
- Critique of content

Modes of cleaning

- Water quality for the state of the art cleaning validation
- CIP (Clean-in-Place) & COP (Clean-Out-of-Place) Concerns
- Approaches for indirect-product contact surfaces
- Approaches for non-product contact surfaces
- Manual cleaning validation difficulties
- Most difficult to clean areas on a surface

Day 2

Life-cycle approach to cleaning validation

- Utilizing a life cycle approach for cleaning validation
- How to manage protein inactivation and degradation in Biotech Cleaning Validation

Risk assessment concerns

- Robust risk assesment to manage a successful cleaning program
- What is Spray covering testing?

Training

- Personnel training and qualification on cleaning validation
- Swabbing errors
- Visual cleaning and setting limits

Change control, revalidation, and continuous process verification

- Monitoring, change control, revalidation and validation maintenance for validated processes
- Using statistics in cleaning validation

Group exercise - how to perform a cleaning validation of a biopharmaceutical API (Active Pharmaceutical Ingredient)?

Cleaning validation for medical devices

- How to validate the cleaning of medical devices

Case studies

- Health authority inspection citations
- Which questions should be asked during an audit?

Bad practices

- Case studies and lessons learned from a cleaning validation bad practices
- Dangers during cleaning validation implementation

Presenter



Mustafa Edik

Mustafa Edik is a leading pharmaceutical, biotechnoloy, medical device quality and GXP expert with over 28 years of hands-on leadership in GMP, GDP, GCP, GLP, and broader GxP compliance across the pharmaceutical, biotechnology, and medical device industries.

As Turkey's first IRCA-certificated Lead Auditor for GMP and Pharmaceutical Quality Management Systems (PQMS), he brings unmatched credibility and depth to audits, compliance strategies, and regulatory readiness. Holding a BSc in Chemistry, and a BSc (Hons) in Biopharmaceutical Sciences & Engineering from Atlantic Technological University (Ireland), and an Executive MBA, Mustafa combines strong scientific foundations with strategic business acumen.

His career highlights include senior roles at Bayer Türkiye, where he progressed from Quality Control Lab Supervisor to Deputy QA Manager, and GMP Lead Auditor to Global GMP Lead Auditor, managing complex quality operations and audits in a multinational environment. He has personally led more than 4,200 hours of GxP audits across over 200 facilities worldwide.

Today, as Founder and Lead Consultant at Quality Academia Eğitim & Danışmanlık, Mustafa delivers high-impact consulting, training, and project management services to local and global clients. His expertise spans across:

- GMP/GDP audits and supplier qualification
- Validation, qualification, and quality risk management (ICH Q9)
- Root cause analysis, CAPA, OOS/OOT, change control, and data integrity
- Sterile/non-sterile manufacturing, process improvement, and cost-of-quality optimisation
- Clinical trials (GCP & ICH E6), pharmacovigilance, and third-party manufacturing
- Regulatory alignment with FDA, EMA, PIC/S, MHRA, TGA, TMMDA, WHO, and ICH standards

Mustafa has trained over 9,000 professionals in GxP topics and designed certified auditor programs for Turkish authorities including Turkish MOH and Ministry of Agriculture and Foresty. He served as Principal GMP Consultant & Auditor at the Turkish Atomic Energy Authority, supporting successful TMMDA GMP approvals for 5 radiopharmaceutical products. As the first Turkish consultant selected by the Developing Countries Vaccine Manufacturers Network (DCVMN), he has led teams of 100+ engineers, auditors, and quality specialists while managing dozens of international projects.

A prolific author, Mustafa's works include:

- “Sorularla GMP Dokümantasyonu” – a practical guide to GMP documentation
- “GMP Audits in Pharmaceutical and Biotechnology Industries” (Taylor & Francis / CRC Press, June 2024) – a comprehensive reference on effective GMP auditing practices

Recognised internationally for his practical, risk-based approach and knowledge transfer focus, Mustafa Edik is dedicated to elevating pharmaceutical quality standards, helping companies achieve compliance excellence, reduce risks, and drive operational efficiency.

Course dates

22-23 June 27	**Live online** 09:30-16:30 **UK (London)** (UTC+01) *Course code 17255*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 27 Apr**
23-24 November 27	**Live online** 09:30-16:30 **UK (London)** (UTC+00) *Course code 17532*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 28 Sep**

How to book

Online:
ipi.academy/2904

Alternatively contact us to book, or if you have any queries:

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Discounts

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- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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