IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Cleaning Validation - Best Practice in Pharmaceuticals

8-9 July 2025
+ 2-3 December 2025

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 an Independent GMP Consultant and Auditor.

After graduating as a Chemist from university, Mustafa began his 25 year plus career as a Laboratory Supervisor at Bayer, a German Pharmaceutical Company. After 15 years of working as a Quality Assurance Assistant Manager, Laboratory Supervisor, Pharmaceutical Quality Management Systems, and GMP Lead Auditor, he decided to continue his career as a Consultant. He has served the Turkish Atomic Energy Authority (TAEA) as Principal GMP Auditor and Consultant for 6 years. TAEA was audited by the Republic of Turkey Ministry of Health and granted GMP Certificate for 5 Radiopharmaceuticals. This success has won great acclaim from all health authorities and industry.

He has prepared and presented various training courses and workshops to more than 8000 individuals from 150 International and local Pharmaceutical, Medical Device, and Cosmetics companies on GMP, GDP and Pharmaceutical Quality Management Systems. He has taken part in several International Pharmaceutical Facility Establishment projects as GMP Consultant and has also set up various Quality Management Systems for Local Pharmaceutical and Medical Device Companies.

While he was the Vice President of Quality and Technical Operations at a Quality Academia Training and Consultancy firm, he acquired and converted it into a 100 % Turkish Company. As the only IRCA Certificated Pharmaceutical Quality Management Systems and GMP Lead Auditor in Turkey, he currently conducts API, Excipient, Packaging Materials Suppliers and Manufacturers, Third Party Logistics Service Providers, Sterile and Non-Sterile Manufacturing Facilities Audits according to FDA, EMA, PIC /S, TMMDA, MHRA, TGA Health Canada, and WHO regulations and guidelines.

He finished his second university degree in Biopharmaceutical Sciences BSc (Hons) at Atlantic Technological University - Ireland. He is the author of chapter 6 of the book published by PDA named “Good Distribution Practices” and his new book on ‘GMP Audits in Pharmaceutical and Biotechnology Industires’ will be published by Taylor & Francis in June 28, 2024.

Course dates

8-9 July 2025	**Live online** 09:30-16:30 **UK (London)** (UTC+01) *Course code 15322*	GBP **1,499** EUR **2,099** USD **2,399**
2-3 December 2025	**Live online** 09:30-16:30 **UK (London)** (UTC+00) *Course code 15323*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 28 Oct**

How to book

Online:
ipi.academy/2904

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

Email:
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+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **30% discount** on the second and subsequent places.
- 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.

Please note
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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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