IPI Academy

MANAGEMENT forum



Presented by
Management Forum

New EU GMP Annex 1: Compliant Sterile Medicinal Products

28-30 April 27
+ 4-6 October 27

Maintaining a sterile production environment on an ongoing basis is critical in the production of sterile pharmaceuticals, and strict adherence to guidelines and relevant standards is required to minimize contamination risks and ensure product quality and safety.

During this training, all changes in Annex 1 will be evaluated, and the minimum requirements that aseptic operations must meet will be discussed and presented to the participants through examples.

Format:
Live online

CPD:
18 hours for your records

Certificate of completion

Overview

The long-anticipated update to EU GMP Annex 1 was published in August 2022 and came into force on 25 August 2023 - marking the first revision in 14 years. This updated guidance introduces new requirements while clarifying and expanding on the 2008 version, with a focus on harmonisation with global standards.

This course provides a comprehensive overview of the changes introduced in Annex 1 and what they mean for aseptic operations. Participants will explore current expectations for sterile manufacturing environments, personnel, equipment, and robust production technologies. Core topics include contamination control, microbiology, sterility assurance, and quality risk management - all presented with real-world examples to support understanding and application.

Key areas such as environmental monitoring, cleaning and disinfection, CCS (Contamination Control Strategy), cleanroom design, RABS, isolators, and advanced technologies like BFS and FFS are all addressed. The course also outlines regulatory expectations from authorities including the FDA, MHRA, TGA, WHO, and PIC/S, with common deviations and practical recommendations discussed.

Ideal for professionals involved in sterile manufacturing, this training offers the insight and guidance needed to meet the latest regulatory standards and maintain GMP compliance with confidence.

Benefits of attending

- **Learn** about the regulatory requirements of the revised Annex 1, its impact on aseptic production, terminal sterilisation expectations, and quality challenges
- **Discover** practical tips for overcoming common difficulties still faced in Annex 1 implementation, including solution proposals for an effective Contamination Control Strategy (CCS)
- **Explore** real-world experiences and insights from colleagues and health authority inspectors applying Annex 1 in practice
- **Hear** expert recommendations on key topics such as environmental monitoring, cleaning, disinfection, and hygiene standards for personnel and facilities
- **Gain** valuable knowledge of barrier separation technologies, alternative production methods, and the regulatory requirements for processing different sterile products
- **Evaluate** the integration of automation within GMP-compliant production environments
- **Receive** suggestions for analysing trends observed in aseptic manufacturing and identifying potential areas for improvement
- **Understand** the current and future focus areas of health authority inspections, and how to align operations with regulatory expectations
- **Examine** Annex 1's requirements for personnel qualification, training, and the essential skills needed for aseptic operations

Who Should Attend

Personnel in the following roles and departments:

- Quality Assurance and Quality Control Validation
- R & D
- Audit
- Regulatory
- IT
- Warehouse and supply chain
- Engineering
- Procurement
- Health Authority Inspectors

Programme

Day 1

Aseptic Processing Guidelines and Regulations

- EU, PIC/S GMP Annex:1
- FDA sterile drug products produced by aseptic processing - current Good Manufacturing Practice (GMP)
- WHO, MHRA, TGA, PMDA Guidelines

Aseptic Facility Design Principles

- Facility types
- Equipment impact on facility design
- Process impact on facility design
- System impact on facility design

Quality Assessment and Mitigation in Aseptic Operations

- Sterility, probability, acceptability
- Risk mitigation

Risk Management Application Examples

- Failure Mode Effects Analysis (FMEA)
- Hazard Analysis and Critical Control Point (HACCP)
- Process Hazard Analysis (PHA)
- Failure Tree Analysis (FTA)
- Example: Sterile Product Filling and Finished Product

Microbiology Fundamentals

- Microbiological culture media
- Microbiology laboratory techniques
- Objectionable microorganisms
- Rapid microbiological methods
- Microbiological challenges

Environmental Monitoring

- Why is environmental monitoring (EM) performed?
- Types of environmental monitoring
- Precautions when conducting environmental monitoring
- Trending of EM data
- Example: Environmental monitoring investigation study

Bioburden Control & Sterility Assurance

- Sterility testing
- Bioburden determination

Workshop 1

- A: How do you support GMP documentation for purchased disinfectants or sporicides?
- B: What test methods do you use for efficacy testing? Do they align with regulatory expectations?
- C: What do we mean when we talk about Continuous Improvement?

Day 2

Recap of Day Two

Cleaning, Disinfection, Sanitation, Decontamination

- Example: Wiping mopping strategies
- Example: Disinfectant qualification

Can CCS be Acheived via Cleaning and Disinfection?

Sterilization

- What is the difference between sterilization and sanitization
- Types of sterilization processes
- Pre-Use Post Sterilization Integrity Testing (PUBSIT) issues
- Example: How to validate the dry heat sterilization process?

Visual Inspection

- Manual inspection
- Semi-automated inspection
- Automated inspection

Critical Utilities

- Water systems
- Pure steam
- Process gases
- HVAC

Cleanroom Design and Operation, Airlock Concept

- Design specifications
- Basic & concept design
- Modular and flexible cleanrooms
- Typical design mistakes
- Airlock concept (PAL, MAL)

BFS, FFS

- BFS equipment
- Product design
- Equipment design
- Facility design
- Qualification consideration
- Product contamination
- Example: Do you have a defect library?

High Efficiency Particulate Air (HEPA) Filters

Workshop 2

- A: What happens if a positive culture results after processing the Biological Indicators (BI) in a validated steam sterilization cycle?
- B: Data integrity considerations in Bacterial Endotoxin Test

RABS & Isolator Technology

- Isolators for Personnel and Environmental Protection
- Closed RABS
- Cytotoxic Drug Preparation Isolator
- Aseptic Transfer Systems (Liquid/Solid)
- Decontamination of Aseptically Operated Isolators
- Monitoring of the Process Environment
- Barrier System Flaws
- Validation

Programme

Day 3

Contamination Control Strategy

- CCS plan, do, check, act
- Supplementary documents
- Example: What type of documents should be included in a CCS?
- Example: Methods for contamination detection

Microbial Contamination Investigation Errors

- What is wrong thinking?
- Extraordinary Environmental Monitoring
- Case studies

How to Prevent Residue, Rouge and Fibers

- Facility appearance
- Residue, rogue, and rust remediation/prevention
- How to manage the risk of reusables in the Aseptic Processing Area

Aseptic Process Simulation (APS)

- What is an APS?
- What is the purpose?
- What are the limitations?
- APS dos and don'ts
- APS duration
- APS interventions
- APS incubation
- APS Out of Specification (OOS) Investigation

Personnel Behaviour, Qualification, Aseptic Gowning Techniques

- Why are personnel important?
- Holistic Operator Behaviour and Qualification Program
- Potential sources of particulates and gowning measures
- Considerations when defining gowning
- How to prepare a User Requirement Specification (URS) for aseptic garments
- Fabric selection and qualification

Airflow Visualization in Aseptic Manufacturing

- What is the purpose of the Airflow Visualization Process?
- What do we need for a successful AF Visualization?
- Smoke Generation Devices
- Video recording - static and dynamic conditions
- Documentation and data integrity
- How to report an AF operation?

Sterile Product Filling, Stoppering, Sealing

Quality Assurance and Control for Aseptic Operations

Workshop 3

- How to validate contamination control in Rapid Transfer Port Chambers

Regulatory Considerations for Aseptic Processing

- Audit and inspection findings

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

28-30 April 27	**Live online** 09:30-16:45 **UK (London)** (UTC+01) *Course code 17196*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 03 Mar**
4-6 October 27	**Live online** 09:30-16:45 **UK (London)** (UTC+01) *Course code 17510*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 09 Aug**

How to book

Online:
ipi.academy/2701

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

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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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