



Presented by
Management Forum

New EU GMP Annex 1: Compliant Sterile Medicinal Products

19-21 May 2026
+ 24-26 November 2026

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 Achieved 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 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 he is preparing his latest book on 'GMP Audits' which will be published by Taylor & Francis in 2023.

Course dates

19-21 May 2026

Live online

09:30-17:00 **UK (London)** (UTC+01)

Course code 16182

GBP **1,599** ~~1,899~~

EUR **2,239** ~~2,659~~

USD **2,571** ~~3,039~~

Until 14 Apr

24-26 November 2026

Live online

09:30-17:00 **UK (London)** (UTC+00)

Course code 16569

GBP **1,599** ~~1,899~~

EUR **2,239** ~~2,659~~

USD **2,571** ~~3,039~~

Until 20 Oct

How to book



Online:

ipi.academy/2701

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



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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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