IPI Academy

MANAGEMENT forum

Presented by
Management Forum

New EU GMP Annex 1: Compliant Aseptic Operations

2-4 July 2024
+ 26-28 November 2024

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

In August 2022, (14 years after its last publication), the long-awaited EU GMP guide Annex 1 was published and comes into force on 25 August 2023. Annex 1, which includes new expectations as well as detailing the existing requirements in the 2008 publication, has been aimed to be harmonized with other updated guides. The Annex 1 guide is a versatile document that outlines the various aspects of the aseptic process as well as personnel, facilities, equipment, production, and robust technologies. 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. It is very important that the production equipment, the production environment, the production process, and the criteria to be met by personnel are clearly and comprehensibly evaluated in the main GMP documents.

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.

This course will address all current aseptic process guidance and it will provide participants with the opportunity to refresh their knowledge. How to minimize the risks of quality risk management principles will be discussed and the basics of microbiology will be explained. Environmental monitoring, bioburden and sterility assurance will be evaluated through examples, and the terms of cleaning, disinfection, sanitation and decontamination will be explained.

In Annex 1, the principles of Contamination Control Strategy (CCS), which is one of the most important expectations, will be evaluated and guidance will be given on how to prepare a sample CCS. Examples of the expectations of the health authorities regarding sterilization and visual control will be presented, and the points to be considered in Heating, Ventilation and Air Conditioning (HVAC), Water, Steam, and Gas systems will be covered.

Clean room classification, Personal Air Lock (PAL), Material Air Lock (MAL) concepts, and critical aspects in Restricted Access Barrier Systems (RABS) and Isolator systems that are starting to replace clean rooms will be evaluated. In addition, robust production techniques such as Blow Fill Seal (BFS) and Form Fill Seal (FFS) will be emphasized. The inconveniences encountered due to the violation of the microbial rules that must be followed in sterile environments due to various reasons will be conveyed with sample applications.

Important aspects of critical aseptic process simulation operations, previously known as media fill, airflow visualization study, aseptic filling, and closure will be shared with the participants.

In the last part of the training, the expectations of the health authorities of quality assurance and aseptic operations will be included, and the expectations of regulatory authorities such as FDA, MHRA, TGA, WHO, PIC/S from aseptic operations and the new Annex 1 will be addressed, and the most common deviations will be evaluated with recommendations.

Benefits of Attending

- **Learn** about the regulatory requirements of the revised Annex 1, its effects on aseptic production, terminal sterilization expectations and quality challenges
- **Gain** tips on how to overcome difficulties still experienced despite the enactment of Annex 1
- **Have** the opportunity to examine examples of experiences of colleagues and health authority inspectors in using Annex 1
- **Examine** solution proposals for the CCS
- **Hear** recommendations on critical topics such as environmental monitoring, cleaning and disinfection, personnel and facility hygiene
- **Gain** knowledge of barrier separation technologies, alternative production techniques, and regulations for processing different sterile products
- **Have** the opportunity to evaluate the integration of the automation applied in the production environment in terms of GMP
- **Hear** suggestions regarding the analysis of trends encountered in aseptic production
- **Get** an insight into the focus of health authority inspections in the future

In addition, under Annex 1 the qualification of aseptic production personnel, education and training requirements, and examples of personal skills they should have will be learned.

The expectations of the regulatory authorities and the questions that may be encountered in audits/inspections will also be discussed.

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

Welcome and Introduction

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 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

2-4 July 2024	**Live online** 09:30-16:45 **UK (London)** (UTC+01) *Course code 14253*	GBP **1,649** EUR **2,359** USD **2,669**
26-28 November 2024	**Live online** 09:30-16:45 **UK (London)** (UTC+00) *Course code 14254*	GBP **1,349** ~~1,649~~ EUR **1,939** ~~2,359~~ USD **2,201** ~~2,669~~ **Until 22 Oct**

How to book

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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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