ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Sterile Production Manager

Speakers


Dr-Ing. Jürgen Blattner
CEO, BSR


Dr Rainer Gnibl
GMP Inspector, Government of Upper Bavaria


Dr Philip Hörsch
Vetter


Arjan Langen
GE Healthcare


Stephan Löw
CSL


Carsten Moschner
CMC3


Dr Daniel Müller
GMP Inspector, Government of Baden-Württemberg


Dr Bettina Rietz-Wolf
GMP Inspector, Government of Baden-Württemberg


Matthias Schaar
Novartis


Robert G. Schwarz
GXP-TrainCon


Dr Ingrid Walther
Pharma Consulting Walther, Chair ECA Annex 1 Task Force

Annex 1 Intensive Training

Requirements for Aseptic Manufacturing and Approaches for Implementation

Live Online Training on 01/02 July 2025

Highlights

- Revision Background and Relevant New Requirements
- Quality Risk Management (QRM)
- Qualification of Sterile Facilities & Utilities
- Process Simulation/Media Fill – Requirements and Challenges
- Sterile Filtration and Container Closure Integrity and PUPSIT
- Isolators and Barrier Systems
- Contamination Control Strategy – Requirements and Approaches
- Personnel – Behaviour, Garment and more
- Monitoring

Objective

This Live Online Training offers you a unique opportunity to familiarize yourself with the new regulatory requirements of the revised final Annex 1, the impact on aseptic manufacturing, terminal sterilization and the challenges related to quality aspects. Still need to implement some points and need suggestions? Or you would like to review your approach and compare it with the experience of colleagues and inspectors?

Speakers from the authorities as well as representatives from the pharmaceutical industry and experts from technical suppliers will present their views and experiences in areas such as quality risk management, process simulation, as well as the challenging topics PUPSIT and CCIT. In addition, the much-discussed topic of contamination control strategy will be addressed and solutions presented.

The classic topics of contamination control such as environmental monitoring, cleaning and disinfection and personnel hygiene will also be discussed with you.

Background

The aseptic filling of a sterile product must be performed in a controlled environment (Grade A clean room in a corresponding classified environment). The most relevant part of the EU GMP Guide for this type of production is Annex 1 of this Guide. After a long revision period of the previously valid 2008 version and two rounds of comments, the long-awaited revised Annex 1 for the manufacture of sterile medicinal products was finally published by the European Commission on August 25, 2022. The main reason for the update was to reflect changes in the regulatory environment and new developments in manufacturing technologies, which include a significant shift towards the application of quality risk management principles.

The new Annex 1 has been in force since August 25, 2023.

Target Audience

This Live Online Training is of interest to professionals from pharmaceutical and biopharmaceutical manufacturers, authorities and suppliers with responsibilities in

- Aseptic Manufacturing, Quality Assurance, Quality Control, Auditing, Inspections

who are involved in

- Contamination Control, Engineering, Monitoring, Qualification and Validation, Internal Audits, Quality Affairs, Aseptic Process Simulation/Media Fill

Moderator

Axel H. Schroeder, Concept Heidelberg

Programme

Future Sterile Manufacturing – some Thoughts about the Annex 1 Changes and related other Documents

Contamination Control Strategy – Inspector‘s View on an Overarching Strategy

- Requirements
- Expectations & interpretations

The ECA CCS Guide – a Brief Overview

- Guide scope and purpose
- Structure & content overview

Structure and Design – Practical Aspects for a CCS

- How to develop the strategy
- How to have your documents available and accessible

Aseptic Process Simulation – Annex 1 Requirements

- Requirements
- Expectations & interpretations

Sterile Filtration & Container Closure – Annex 1 Requirements

- Sterile filtration requirements
- Pre-Use-Post-Sterilization-Integrity-Testing (PUPSIT) of sterile filters
- Container Closure Integrity Testing (CCIT
- Visual inspection process

PUPSIT – Annex 1 – Application of Risk Management

- PUPSIT: Risk Assessment for PUPSIT and considerations of associated risks in established processes

CCIT – In the Light of the New Annex 1

- Changed requirements for CCIT in finishing of sterile products
- Holistic and more scientific view on CCI systems as now multiple influencing aspects are explicitly addressed

Disinfection – Efficacy Testing and Validation

- Antimicrobial agents and their efficacy
- Testing methods
- Efficacy testing against isolates
- Validation approach

QRM in Sterile Manufacturing – Industrial Experience

- Strengths and limitations of an EM programme
- Trending: detecting changes
- Use of modern technologies
- Response to level excursions

Annex1 vs. ISO 14644-1 Requirements from a Technical Point of View

- Accordance and differences
- The issue with the particle sizes
- Qualification challenges

Enhanced Requirements on Facilities and Utilities

- Utilities: water, steam and gases
- Facilities: airlocks and pass boxes; insertion of barrier technologies
- Implicit requirements

Authorities' Point of View on RABS and Isolators

- Requirements for barrier systems in the new Annex
- Major changes compared to previous version (Annex 1, 2008)
- Inspector's comments on changed requirements

Personnel – Behaviour and Access into Cleanrooms

- Requirements for personnel in new Annex 1
- Developments since version 2008 of Annex 1
- Comments of inspector on implementation

New Requirements on a Cleanroom Garment System as an Essential Element of the Contamination Control Strategy

- The "new" Annex 1
- Contamination control strategy for garments
- Risk management

Environmental Monitoring – Current Methodology and Experiences

- Strengths and limitations of an EM programme
- Trending: detecting changes
- Use of modern technologies
- Response to level excursions

Environmental & Process Monitoring – Inspector´s View

- Summary of requirements from entire Annex 1
- Essentials for inspection

Speakers

Dr-Ing. Jürgen Blattner
CEO, BSR, Germany

Jürgen studied at the technical University Karlsruhe with focus on particle measuring and filter technologies. After that he worked for Palas with responsibilities in filter testing, aerosol generation and measuring. 2003 he founded his own company BSR with activities and services in cleanroom qualification, monitoring and the necessary equipment.

Dr Rainer Gnibl
GMP Inspector for EMA and local Government of Upper Bavaria, Germany

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP inspections worldwide.

Dr Philip Hörsch
Vetter Pharma Fertigung GmbH & Co. KG, Germany

Director Quality Assurance for Process Validation and Continued Process Verification, Quality Risk Management, Process Trending, IT Systems and Data Integrity, In-Process-Control / Visual Inspection Systems, and Specification Management / Supplier Quality Management Packaging Materials.

Arjan Langen
GE Healthcare, Director Sterility Assurance, The Netherlands

Arjan Langen has over 20 years of experience within the field of pharmaceutical microbiology. He worked for several pharmaceutical and biotech companies (Nobilon, DSM, MSD) and had various local and global roles within QC, QA, manufacturing and auditing.

Stephan Löw
CSL Behring, Marburg, Germany

Stephan studied bioprocess engineering and is employed at CSL Behring in Marburg. Before this, he worked for GSK Vaccine in different positions like Aseptic Expert, Process Manager for Formulation and Filling of Vaccines and Project Management.

Carsten Moschner
CMC3, Germany

Mr Moschner studied engineering in Karlsruhe. Until 2023, he was Managing Director of Dastex with a special focus on the development and optimisation of cleanroom garments. Among other things, he was involved in the creation of the VDI 2083 chapter for cleanroom equipment. Since 2023, Carsten Moschner has been working as a freelance consultant in the field of contamination control.

Speakers

Dr Daniel Müller
GMP Inspector, Local Authority of Baden-Württemberg, Tübingen, Germany

Currently Daniel Mueller is head of GMP inspectorate (local competent authority) at Tuebingen, Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA and overseas inspections. Before joining the authority. Dr Mueller was working in pharmaceutical industry, last serving as qualified person for sterile drug products. He is member of German expert groups 'biotechnology & tissue' and 'quality assurance'.

Dr Bettina Rietz-Wolf
GMP Inspector, Local Authority of Baden-Württemberg, Tübingen, Germany

Bettina is a pharmacist and GMP Inspector for the District Government of Baden-Württemberg and the EMA and performs GMP inspections worldwide. She was head of the German expert group EFG3 "Manufacturing of sterile products" at the ZLG.

Matthias Schaar
Novartis Pharma Stein

Matthias started his career in Novartis Stein, Switzerland in the Microbiological Department. Now he is supporting the sterile production more specialized with sterilization processes such as sterile filtration with the implementation of new products.

Robert G. Schwarz
GXP-TrainCon e.U., Austria

Robert Schwarz has a degree in bioprocess engineering and biotechnological quality management. From 2001, he led the environmental monitoring team at Baxter, and from 2005 to 2018 he was a validation specialist for device qualification, sterilisation validation and cleaning validation. Since 2010, he has also been passing on his experience as a university lecturer. In 2019, he began working as a freelance trainer and founded his consulting company GXP-TrainCon in 2022.

Dr Ingrid Walther
Pharma Consulting Walther, Former Head of the Business Unit iv Drugs, Fresenius, Germany

Dr Walther was employed in various positions in R&D, Quality Control, Quality Assurance, QP, and management of strategic projects at Fresenius SE. During her employment at Pharmaplan GmbH, she headed the Business Unit Qualification, Validation and GMP Compliance. For almost 15 years, she is working as self-employed consultant.

Date of the Live Online Training

Tuesday, 01 July 2025, 09.00 - 18.00 h
Wednesday, 02 July 2025, 09.00 - 17.00 h
All times mentioned are CEST.

Technical Requirements

We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21913.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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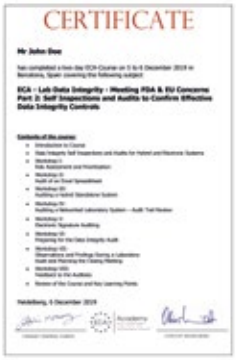
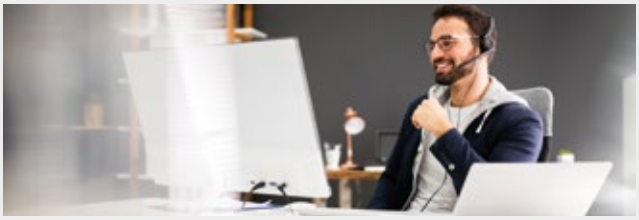

CERTIFICATE

Your Benefit: Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

You cannot attend the Live Online Event?



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Reservation Form (Please complete in full)

Annex 1 Intensive Training, Live Online Training on 01/02 July 2025

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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General terms and conditions
If you cannot attend the conference you have two options:
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2. If you have to cancel entirely we must charge the following processing fees:
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In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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