

## Speakers



**Dr.-Ing. Jürgen Blattner**  
CEO, BSR



**Dr Rainer Gnibl**  
GMP Inspector, Govern-  
ment 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 on Aseptic Manufacturing and Approaches for Implementation



Live Online Training on 03/04 July 2024



## 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 – Requirement 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, 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 is into 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 Heideleberg

## Programme

Future Sterile Manufacturing – some Thoughts about the Annex 1 Changes

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Contamination Control Strategy - Inspector's View on an Overarching Strategy

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- Requirements
- Expectations & interpretations

The ECA CCS Guide – a Brief Overview

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- Guide scope and purpose
- Structure & content overview

Structure and Design – Practical Aspects for a CCS

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

Aseptic Process Simulation – Annex 1 Requirements

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- Requirements
- Expectations & interpretations

Sterile Filtration & Container Closure - Annex 1 Requirements

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- 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

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

CCIT – In the Light of the New Annex 1

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- 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

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

## QRM in Sterile Manufacturing – Industrial Experience

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

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

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

## Enhanced Requirements on Facilities and Utilities

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

## Authorities' Point of View on RABS and Isolators

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- 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

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- 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

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

## Environmental Monitoring – Current Methodology and Experiences

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

## Environmental & Process Monitoring - Inspector's View

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

## Comparison of Annex 1 with other Relevant Documents

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- Clean room grades
- Gowning
- Monitoring
- Trending

## 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 Gnihl**  
GMP Inspector for EMA and local Government of Upper Bavaria, Germany

Dr Rainer Gnihl 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.

# Speakers



**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.



**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

Wednesday, 03 July 2024, 09.00 – 17.30 h CEST  
Thursday, 04 July 2024, 09.00 – 17.30 h 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 € 1,690

APIC Members € 1,790

Non-ECA Members € 1,890

EU GMP Inspectorates € 945

The fee is payable in advance after receipt of invoice.

## Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

## 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.

CONCEPT HEIDELBERG

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For questions regarding organisation please contact:

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## 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.

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GERMANY

### Reservation Form (Please complete in full)



## Annex 1 Intensive Training, Live Online Training on 03/04 July 2024

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

Country

Phone / Fax

E-Mail (Please fill in)

#### General terms and conditions

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1. We are happy to welcome a substitute colleague at any time.
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