ECA Academy
Your GMP/GDP Information Source

Speakers


Walid El Azab
Steris


Dr Simone Biel
Merck


Roberto Conocchia
European Medicines Agency (EMA)


Parsa Famili
Novatek International


Dr Rainer Gnibl
GMP Inspector


Dr Philip Hörsch
Vetter Pharma Fertigung


Werner Hofstetter
Octapharma


Dr Anne-Grit Klees
Merck


Roland Koch
Gasporox


Arjan Langen
GE Healthcare


Stephan Löw
CSL


Dr Jean Denis Mallet
ECA, former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS


Christina Meissner
GMP Inspector, AGES


Juliana Nassette
Ecolab


Dr Johannes Rauschnabel
Syntegon Technology


Dr Bettina Rietz-Wolf
GMP Inspector


Luigi Scaffidi
Boehringer Ingelheim


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


Jörg Zimmermann
Vetter

Annex 1 Final Version and its Impact

Current requirements on aseptic manufacturing

Live Online Conference on 14/15 December 2022

Highlights

- Revision Background and Major Changes
- Future Sterile Manufacturing – Industrial Assessment
- Expectations on Quality Risk Management (QRM)
- Qualification of Sterile Facilities & Utilities
- Process Simulation /Media Fill – Requirements and Challenges
- Sterile Filtration – Pre-Requisites, must Haves, and Exceptions
- CCIT
- From Isolators and Barrier Systems
- Contamination Control Strategies – Requirement and Approaches
- Annex 1's Specific Risks Associated with Single-Use Systems
- Environmental Monitoring
- Impact for Cleaning and Disinfection

Objective

This conference offers you a unique possibility to become acquainted with the new regulatory requirements of the revised final Annex 1, the impact on aseptic manufacturing and the challenges relating to quality aspects.

Authority speakers as well as representatives from pharmaceutical industry and experts from technical suppliers will provide you information about their thinking about the new requirements. They will discuss the statements of the new Annex 1 on topics like Quality Risk Management, Process Simulation/Media Fills well as the challenging topics of PUPSIT and the use of Single Use Materials.

The widely discussed topic of Contamination Control Strategy will also be discussed and the updated ECA Guide will be presented in support.

Subsequently, classical topics of contamination control like environmental monitoring and cleaning and disinfection are considered in the light of Annex 1.

Background

The Annex 1 "Manufacture of Sterile Medicinal Products" was published for the first time in 1971. During the following years it was updated several times, as example to align classification table of clean rooms, to include guidance on media simulations and bioburden monitoring in 2005 and 2007 or relating to capping of vials in 2010.

At the end of 2017, the first draft of a fundamental revision was published, which was intended to focus on more structured guidance, including state-of-the-art principles such as quality risk management and the consideration of new technologies and innovative processes. The draft now contained new sections, e.g. for utilities, and extended sections on topics such as production and specific technologies or on the requirements of Aseptic Process Simulation (APS).

During the subsequent public consultation, over 6000 comments were submitted to EMA, which were then processed alongside the challenge of moving to Amsterdam. This resulted in the current document, which was published on 20 February 2020 for a second, restricted consultation. After reviewing the approximately 2,000 comments submitted, the Inspector Working Group (IWG) finalised the report at the beginning of 2022 and forwarded it to the responsible bodies of the European Commission for final approval.

The long-awaited revised Annex 1 on the manufacture of sterile medicinal products was finally published by the European Commission on August 25, 2022 (1). The main reason for the update was to reflect changes in the regulatory environment and manufacturing, which includes a significant shift towards the application of quality risk management principles. The new Annex 1 will enter into force on August 25, 2023.

Target Audience

This conference 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, Monitoring, Qualification and Validation, Self Inspection, Quality Affairs, Process Simulation/Media Fill

Programme

Introduction – Revision, Consultaion and the Annex 1 Task Force of RCA/EQPA

The Drivers for Updating the Annex 1 and the Major Changes Introduced

- Introduction of Annex 1
- Overview of drafting process
- Major changes introduced

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

- Requirements
- Expectations & Interpretations

ECA CCS Guideline: Example in Documenting the CCS and Future Challenges to Evaluate CCS Performance

- Present the ECA guideline and approach
- Share example of elements to add in a CCS document using ECA template
- Key information to have in a CCS
- Future challenge: use of statistic and novel software to achieve holistic assessment approach

Structure and Design – Practical Aspects for a CCS

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

Process Simulation – Annex 1 Requirements

- Requirements
- Expectations & Interpretations

Aseptic Process Simulation (APS /Media Fill) – Industrial Point of View

- Different Designs / Simulation long filling times
- Risk-based approach for interventions

Sterile Filtration – Pre-Requisites, must Haves, and Exceptions

The revised Annex 1 describes requirements when validating and utilizing a membrane filter to sterilize a medicinal product. There are still open questions such as

- Redundant filtration – the extra piece of mind?
- PUPSIT required – but exceptions allowed?
- Filter inside or outside the isolator?

PUPSIT – Annex 1 - Application of Risk Management

- PUPSIT: Risk Assessment for PUPSIT and Considerations of Associated Risks in Established Processes
- Risks of flaw masking and filter damage
- Product and process evaluations
- Risk-Benefit analysis

CCIT – In the Light of the New Annex 1

- Requirements for CCIT in finishing of sterile products
- Overview of CCIT methods
- Applicability of the different technologies for the final containers

EudraLex Annex 1 Vol. 4 (August 2022) Impact for Cleaning and Disinfection

- Regulations relating to cleaning, disinfection
- Impact to disinfectant selection and regime design
- Challenges of disinfectant residue management

Qualification of a Disinfection System Complying Annex 1 - Industrial Experiences

- Case study for qualification of disinfectants
- Efficacy – how to control?

Annex 1's Specific Risks Associated with Single-Use Systems

- Challenges when using Single-Use Systems (SUS) in sterile manufacturing
- Annex 1's expectations, such as supplier qualification, extractables evaluation, verification of integrity throughout the process, incoming control, operator training
- SUS and closed systems

Quality Risk Management in Sterile Manufacturing – Inspector's Experiences

- QRM in the Annex 1, more than CCS
- Inspectors expectations on implementation of QRM principle
- Best and worst case examples

Quality Risk Management in Sterile Manufacturing

- Dos and don'ts
- Practical examples
- Key steps in executing a risk assessment

Enhanced Requirements on Facilities and Utilities

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

Barrier Systems – the Current Way

- What makes a real barrier?
- What are the limitations of isolators, of RABS?
- Are Isolators less "performant" than RABS?

Isolators and Annex 1 – Technical and Practical Challenges

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

Environmental & Process Monitoring - Inspector´s View

- Summary of Requirements from entire Annex 1
- Essentials for Inspection

Optimizing your EM Program as per Revised Annex 1

- Traditional vs Rapid methods
- EM risk assessment
- Recovery studies
- Data integrity

Annex 1 in The Age of Digitization: Re-imagining Contamination

- TCCS and its parts – from MSC up to monitoring
- The benefits o a risk-based system- from DI up to trending
- Takeaway Tools
  - Digitization in quality management and contamination control
  - Remote and hybrid work
  - Integrated Metrics
  - Process flow metrics and KBIs

Comparison of Annex 1 with Other Relevant Documents

- Clean Room Grades
- Gowning
- Monitoring
- Trending

Annex 1: Industry Assessment after the two Rounds of Consultation

- Short discussion of selected paragraphs
- What could be achieved in the consultation?
- What to look out for in future inspections?
- What stumbling blocks have remained?

Speakers

Walid El Azab, Technical Service Manager, STERIS Corporation, Belgium

He currently provides technical support related to cleaning chemistries, disinfectants and sterility assurance products and their application and validation. Walid has held various positions including Project Manager, Inspection Readiness Manager, Quality and Regulatory Manager, and Qualified Person (QP).

Dr Simone Biel, Merck, European Field Marketing Specialist, Germany

Simone Biel is a Senior Regulatory Consultant and provides regulatory expertise to customers and internal stakeholders with a focus on Single-Use Technology and filtration. Over the years, Simone has supported biopharmaceutical drug manufacturer's implementation of Single-Use Technology in their manufacturing process and gained a deep understanding of market needs and industry trends in this field.

Roberto Conocchia, European Medicines Agency (EMA)

Roberto Conocchia is a GMP technical Lead in the inspection office at the European Medicines Agency (EMA) since March 2018. Roberto worked in three different API manufacturing sites in Italy from 2000 to 2006. He also worked from 2007 to 2018 as GMP inspector at the Italian Agency Medicine (AIFA) performing regulatory inspections of pharmaceutical manufacturers (all dosage forms).

Parsa Famili, CEO, Novatek International, Canada

Prior to joining Novatek, he held senior management positions in quality departments of Several North American pharmaceutical companies. He has participated and successfully completed several FDA, EMEA, TGA, and Health Canada audits. He was also an instructor of Chemistry and Bio-Chemistry at Vanier College in Montreal Canada.

Dr Rainer Gnibl, GMP Inspector for EMA and local Government, 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, 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 Mater.

Werner Hofstetter, Octapharma GmbH, Austria

Since 2002 he is working at the pharmaceutical production of Octapharma Pharmazeutika GmbH, Vienna and is, among other things, responsible for validation of disinfectants and the cleanroom monitoring. Since 2006 he is head of aseptic production at Octapharma.

Dr Anne-Grit Klees, Global Product Manager, Merck KGaA, Germany

Anne-Grit is microbiologist and graduated at Philipps Universität Marburg in 1992. Since 1994 she was working as a global product manager at Biotest, heipha Dr. Müller GmbH and Merck Life Science with a strong expertise on environmental monitoring in pharmaceutical industries including ready to use culture media for air and surface and personnel monitoring.

Roland Koch, Gasporox, Sweden

Roland Koch has 25 years' experience in the development and implementation of technologies and systems for the GMP regulated industry (Differential Pressure Measurements, Tunable Laser Absorption Spectroscopy, HVLD, Force Sensor Technology and NDIR). He is at GASPOROX AB in Lund (SE) as a Senior Sales and Application Engineer.

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.

Speakers

Stephan Löw, CSL Behring, 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.

Dr Jean-Denis Mallet, ECA, former head of the French Inspection Department AFSSAPS, Pharmaplan, France

Jean-Denis Mallet is a pharmacist. He was previously Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM).

Christina Meissner, AGES, Austria

Christina studied Chemistry in Vienna and Biology in Berlin. Following, she worked for nearly 4 years at the Charité in Berlin. 2012 she joined the Austrian Agency for Health and Food Safety as quality assessor. 2013 she moved to the GMP inspectorate as inspector.

Juliana Nassette, Ecolab

Juliana Nassette BSc, is a graduate Biomedical Scientist experienced within the Pharmaceutical Industry and with biocides and disinfectants use. In her former role, Juliana worked in the Microbiology Quality Control department at a Global Vaccines manufacturer performing Environmental Monitoring (EM) of classified rooms and Utility Monitoring (UM) of highly purified water systems. Juliana joined Ecolab as a Global technical consultant in 2021.

Dr Johannes Rauschnabel, Syntegon Technology

Johannes Rauschnabel is a studied chemist with a PhD from Tuebingen University. Johannes has 20 years of experience in Pharma packaging industry with roles in product management for barrier systems, as a head of process development, as a Chief Pharma Expert and since 2017: as a Director Advanced Technology Development and Innovation at Syntegon Technology GmbH (former Bosch Packaging) in Waiblingen/Germany.

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

Luigi Scaffidi, Boehringer Ingelheim, Germany

Luigi has been working at Boehringer Ingelheim for 36 years. From 1989 to 2012, after his education, in different areas and functions in research and development. Since 2012 in quality assurance of a factory filling aseptic inhalation solutions with special focus on qualification, validation, aseptic and hygiene.

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

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..

Jörg Zimmermann, Vetter Pharma Fertigung, Vice President, Vetter Development Service, External Affairs, Germany

After several positions at Vetter, including Head of Manufacturing and Head of Process Development, Mr Zimmermann is currently Vice President External Affairs, responsible among other things for cooperation with supervisory authorities and partners.

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Annex 1 - The Final Version and its Impact
Live Online Conference on 14/15 December 2022

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Date of the Live Online Conference
Wednesday, 14 December 2022, 09.00 – 18.00 h CET
Thursday, 15 December 2022, 09.00 – 17.30 h CET

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Fees (per delegate, plus VAT)
ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
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Via the attached reservation form, by e-mail or by fax message.
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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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