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ECA QP ASSOCIATION An ECA Foundation Interest Group

Speakers


Dr (Ing) Jürgen Blattner
BSR


Walid El Azab
Steris


Dr Rainer Gnibl
GMP Inspector


Dr Friedrich Haefele
former Head Fill and Finish, Boehringer Ingelheim


Arjan Langen
GE Healthcare


Stephan Löw
CSL


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


Christina Meissner
AGES, Austria


Franziska Petershagen
Vetter Pharma Fertigung


Dr Helen Sauter
Vetter Pharma Fertigung


Matthias Schaar
Novartis Pharma Stein


Dr Franz Schönfeld
Government of Upper Franconia


Dr Alexander Stoll
Fresenius Kabi


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

Annex 1 Conference

Current requirements for sterile manufacturing

Live Online Conference on 10/11 November 2020

Highlights

- Future Sterile Manufacturing – Annex 1
- Expectations on Quality Risk Management (QRM)
- Qualification of Sterile Facilities & Utilities
- Process Simulation/Media Fill – Requirements and Challenges
- Contamination Control Strategies
- Sterility and Sterility Testing and CCI
- Environmental Monitoring

The Second Draft – Changes, Developments and Experiences

Objective

This Live Online Conference offers you a unique possibility to become acquainted with the new regulatory requirements of the revised second Draft of 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 Fill and Container Closure Integrity Testing, as well as the current expectations on premises, cleanroom qualification and the appropriate monitoring.

Additionally, the speaker will compare the requirements of the new Annex 1 with the expectations of other guidance documents like ISO 14644 or the relevant US guidelines.

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.

Target Audience

This Live Online 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 Day 1

Provisional timetable, the actual schedule may vary depending on the situation

09.00 – 09.10 h
Organisationals and Introduction

09.10 – 09.30 h
The Draft, the Consultation and Its Issues

09.30 – 10.00 h
Future Sterile Manufacturing – an Authority Perspective

- Current challenges
- Regulatory developments
- Expectations

10.00 – 10.30 h
Modernisation and Implementation of Quality Risk Management (QRM) – Inspectors' Experiences and Expectations

10.30 – 11.00 h
Industrial Experiences in QRM in Sterile Manufacturing

- Principles of risk assessment
- Dos and don'ts
- How to apply risk assessments within contamination control

11.00 – 11.15 h Break

11.15 – 12.30 h
Authorities Expectations on Contamination Control Strategy & Monitoring

- Environment
- Personnel
- Media Fill

12.30 -13.00 h
Questions and Answers

13.00 – 14.00 h Break

14.00 - 14.45 h
Industrial Experiences on PST Regarding the Annex 1 Challenges

- The second draft: regulatory changes regarding APS
- Impact on the current media fill program at Vetter
- Industrial point of view – current experiences and discussion points

14.45 -15.30 h
Environmental Monitoring

- Principles of risk assessment
- Dos and don'ts
- How to apply risk assessments within contamination control

15.30 – 15.45 h Break

15.45 – 16.30 h
Enhanced Requirements on Facilities and Utilities

- Explicit requirements
- Facilities: airlocks and pass-boxes ; insertion of barrier technologies
- Utilities: water, steam and gases
- Implicit requirements
- Lyophilisation facilities
- Media-fill rooms
- Equipment for barrier technologies?

16.30 – 17.15 h
Annex 1 vs. US Guidance "Sterile Drug Products Produced by Aseptic Processing"

- Very brief history of the two guidances
- Main accordances
- Main differences

17.15 – 18.00 h
Question and Answers

Programme Day 2

08.30 – 09.15 h
Qualification in Sterile Manufacturing: Annex 1 and ISO 14644 – a Comparison

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

09.15 – 09.45 h
Access & Transfer into Clean-Areas – Expectations on

- Personnel
- Material
- Airlocks
- Clothing

09.45 – 10.45 h
Cleaning and Disinfection Requirements as Part of CCS

- Regulatory requirements and industrial needs
- Elements of a robust cleaning and disinfection programme
- Selection and validation of disinfectants
- Ongoing control of effectiveness

10.45 – 11.00 h Break

11.00 – 11.45 h
Annex 1 – Developments for RABS and Isolators

- Most important changes for biopharmaceutical manufacturing - section "barrier systems"
- Regulatory comparison of Annex 1 version 2008 and new Draft
- Industrial Experiences

11.45 -12.15 h
Questions and Answers

12.15 – 13.15 h Break

13.15 – 14.15 h
Container Closure Integrity – State of the Art Testing in Context of Annex 1

- Current Requirements
- Draft Annex 1 vs new Draft Annex 1
- Personal conclusions and outlook

14.15 – 15.15 h
Sterilization & Sterile Filtration

- Definitions
- Requirements
- Validation PUPSIT

15.15 – 15.30 h Break

15.30 – 16.15 h
The Implication of a New Annex 1 for a Global Pharmaceutical company

16.15 – 17.00 h
Questions and Answers

Speakers

Dr.-Ing. Jürgen Blattner, BSR

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.

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 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. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Dr Friedrich Haefele, formerly Boehringer Ingelheim Pharma, Germany

In May 2006 Dr Haefele joined Boehringer Ingelheim Pharma where he was responsible for the department Biopharma Fill & Finish Germany. Today, he is a member of ECA's Annex 1 Task Force.

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. Currently he is Director Sterility Assurance at GE Healthcare, responsible for the global Sterility Assurance program.

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. He started his career at the former Hoechst AG – later Sandoz Frankfurt with responsibilities in QA/QC Microbiology and aseptic processing of sterile penicillins.

Dr Jean-Denis Mallet, ECA, former head of the French Inspection Department AFS-SAPS, Pharmaplan

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). He also used to work in or with the pharmaceutical industry during many years in various positions. Now he is member of the ECA advisory board and works for Pharmaplan SAS.

Speakers

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 to the GMP inspectorate as inspector.

Franziska Petershagen, Vetter Pharma-Fertigung, Germany

Franziska Petershagen is employed at Vetter since 2004. She is involved in microbiological quality control and in the setup of the new development site in Chicago. Since 2012 she worked in the field of sterility assurance as expert for aseptic process simulation.

Dr Helen Sauter, Vetter Pharma Fertigung, Germany

Helen Sauter received her doctorate in microbiology at the University of Stuttgart-Hohenheim. She is employed at Vetter since 2013. Since 2019 she is leading the QA Department or Sterility Assurance, Lab Operation and Training Systems.

Matthias Schaar, Novartis Pharma Stein, Switzerland

Matthias studied at the Beuth University in Berlin. 2007 he joined Novartis Pharma Stein AG as Specialist Microbiology Quality Assurance (sterile production). Since 2012 Leading Team Qualification & Infrastructure in Microbiological Department at Novartis Pharma Stein AG.

Dr. Franz Schönfeld, GMDP inspector for EMA and local authorities, Germany

Dr. Franz Schönfeld is a pharmacist. After his doctorate, he worked in a hospital as well as in a public pharmacy before he started his administrative career in 2003. He is currently a GMP and GDP inspector with the government of Upper Franconia. He is also head of the Expert Group (EFG) 7 for Active Pharmaceutical Ingredients and Excipients at the Central Authority of the Federal States for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) and member of the GMDP Inspectors Working Group at the European Medicines Agency (EMA) in Amsterdam. He also holds a teaching position at the University of Erlangen-Nuremberg.

Dr Alexander Stoll, VP Competence Center Aseptic Technique , Fresenius Kabi Deutschland GmbH

Alexander completed his PhD thesis in Microbiology in 2001. After moving to Sweden, he started working for Fresenius Kabi sterile international manufacturing plant in Uppsala. Throughout the years Alexander has been holding different management positions for the Swedish manufacturing plants within QA/QC and as QP. Starting 2012 he had responsibility as a Global Operations QA head, with regional QA and plant QA functions reporting to him. In his current position as VP Competence Center Microbiology & Aseptic Technique he has built a group of subject matter experts working with all manufacturing and compounding sites, setting global standards.

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

Dr Walther was employed in various positions and has long years of experience in the fields of research and development, quality assurance/quality control and the management of strategic projects. In 1997 she assumed a position as head of the Business Unit Validation and GMP Compliance at Pharmaplan GmbH. Later she became responsible for consulting projects and became COO. In 2007, she re-joined Fresenius, heading the business unit Drugs & Oncology. Since July 2009 she runs her own business as consultant.

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Reservation Form (Please complete in full)

Annex 1 Conference, Live Online Conference on 10/11 November 2020

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Date of the Live Online Conference

Tuesday, 10 November 2020, 09.00 – 18.00 h CET
Wednesday , 11 November 2020, 08.30 – 17.00 h CET

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department.
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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
The conference 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.

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.

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.

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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