Annex 1 Conference
Current Requirements on Aseptic Manufacturing

03/04 June 2020 | Berlin, Germany

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 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 speakers 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 6,000 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 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
- Contamination Control, Monitoring, Qualification and Validation, Self Inspection, Quality Affairs, Process Simulation/Media Fill

who are involved in

- Environmental Monitoring
- Personnel
- Media Fill

Moderators

Ingrid Walther, Chair ECA Annex 1 Task Force
Axel H. Schroeder, Concept Heidelberg

Programme

Organisational and Introduction – The Draft and its Issues

- Structure
- Wording
- Definitions

Future Sterile Manufacturing – an Authority Perspective

- Current challenges
- Regulatory developments
- Expectations

Modernisation and Implementation of Quality Risk Management (QRM) – Inspectors’ Experiences and Expectation

Industrial Experiences in QRM in Sterile Manufacturing

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

Authorities’ Expectations on Contamination Control Strategy & Monitoring

- Environment
- Personnel
- Media Fill

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

Environmental Monitoring

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

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
Annex 1 vs. US Guidance “Sterile Drug Products Produced by Aseptic Processing”

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

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

- Accordance and Differences
- The Issue with the Particle Sizes
- Qualification Challenges

Contamination Control Strategies

- Define a control strategy objective
- Understand the contamination control strategy concept
- Develop a contamination control strategy - share idea
- Assess the contamination control strategy level

Access & Transfer into Clean Areas

Expectations on
- Personnel
- Materials
- Airlocks
- Clothing

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

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

Sterilization & Sterile Filtration

- Definitions
- Requirements
- Validation
- PUPSIT

The Implication of a New Annex 1 for a Global Pharmaceutical Company

Dr.-Ing. Jürgen Blattner,
BSR, Oberhausen-Rheinhausen

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 (Nobillon, 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.
Dr Jean-Denis Mallet, ECA, former head of the French Inspection Department AFSSAPS, 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.

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.

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 Helen Stöber, Vetter Pharma Fertigung, Germany

Helen Stöber 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.

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.
Date
Wednesday, 03 June 2020, 09.00 – 18.00 h
(Registration and coffee 08.00 – 09.00 h)
Thursday, 04 June 2020, 08.30 – 17.00 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
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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 and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

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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For questions regarding content please contact:
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For questions regarding reservation, hotel, organisation etc. please contact:
Mr Niklaus Thiel (Organisation Manager) at +49(0)62 21/84 44 43, or at thiel@concept-heidelberg.de.

Social Event
In the evening of the first conference day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

GMP/GDP Certification Scheme
Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.
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2. If you have to cancel entirely we must charge the following processing fees:
   - Cancellation until 2 weeks prior to the conference 10 %
   - Cancellation until 1 week prior to the conference 50 %
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Annex 1 Conference, 03/04 June 2020, Berlin, Germany

Title, first name, surname

Department                                           Company

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