ECA Academy
Your GMP/GDP Information Source

Annex 1 Conference

Current Requirements on Aseptic Manufacturing

- Authority meets Industry -

8-9 May 2018, Berlin, Germany

Speakers


JULIA ALLGAIER
Vetter Pharma-Fertigung, Germany


JÜRGEN BLATTNER
BSR, Germany


DAVID BRÜCKNER
F. Hoffmann-La Roche, Switzerland


FRIEDRICH HAEFELE
Boehringer Ingelheim, Germany


ANDREW HOPKINS
MHRA, United Kingdom


ARJAN LANGEN
MSD, The Netherlands


STEPHAN LÖW
CSL, Germany


DR JEAN DENIS MALLET
ECA & Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS


CHRISTINA MEISSNER
AGES, Austria


DANIEL MÜLLER
GMP Inspector Federal State of Baden Württemberg, Germany


FRANZISKA PETERSHAGEN
Vetter Pharma Fertigung, Germany

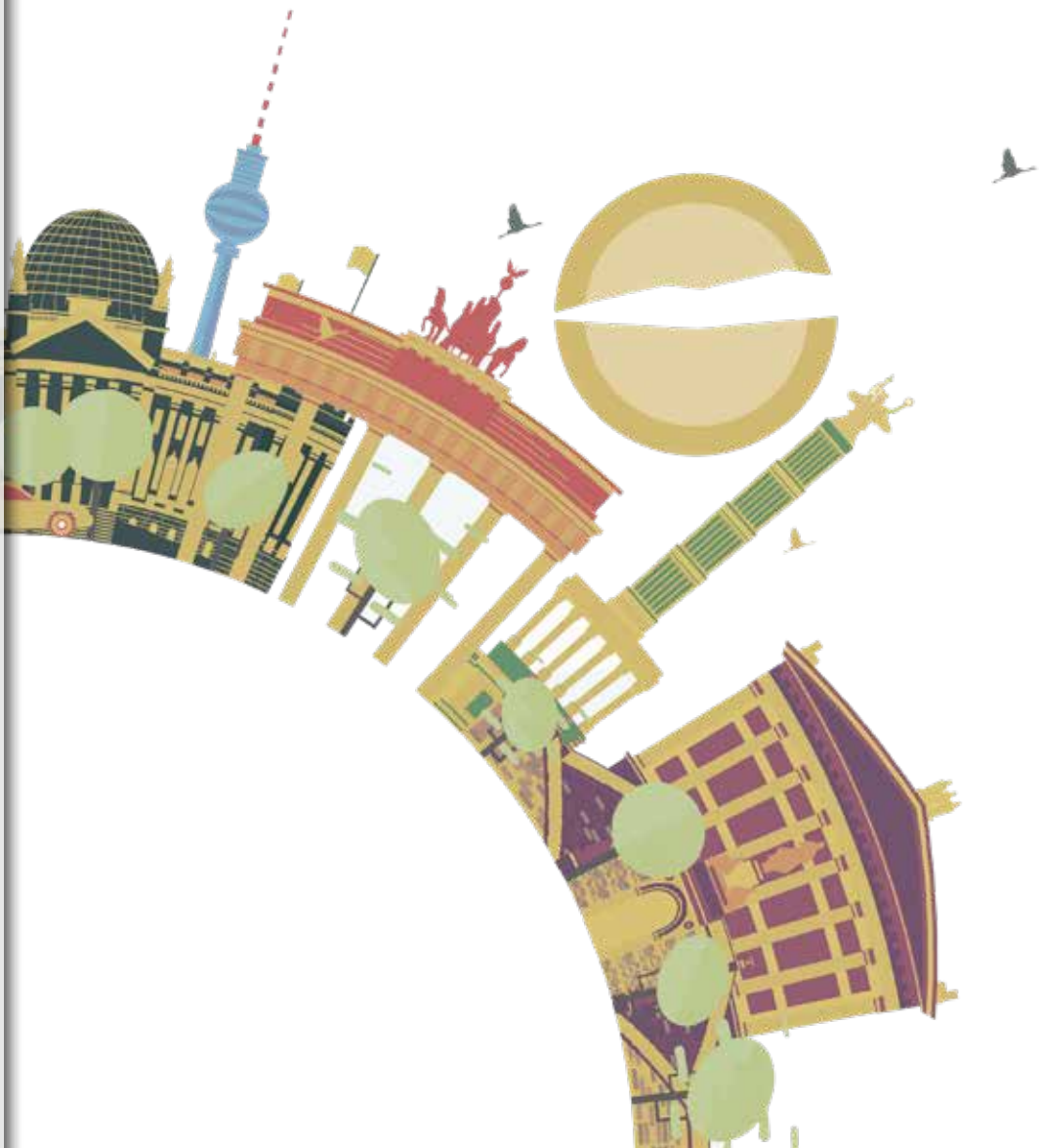

TILMANN ROCK
Roche, Germany


MATTHIAS SCHAAR
Novartis, Switzerland


BEATE REUTTER
GMP Inspectorate Federal State of Schleswig-Holstein, Germany

HIGHLIGHTS:

- Future sterile Manufacturing – Annex 1
- Modernisation and Implementation of Quality Risk Management (QRM)
- Qualification of Sterile Facilities & Utilities
- Process Simulation – Media Fill
- Container Closure Integrity – State of the Art Testing
- Contamination Control and Environmental Monitoring



Annex 1 Conference

8-9 May 2018, Berlin, Germany

Objectives

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

Authority speakers from different European Member States as well as representatives from pharmaceutical industry will provide you with information on their thinking about the new requirements. They will discuss the statements in the new Annex 1 with regard to 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. Every topic will be covered by an authority and an industry representative to compare the regulatory with the manufacturers understanding.

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, for example, to align the 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.

But for the first time, the currently published document represents a complete revision with the focus on providing a more structured guidance, including state of the art principles like Quality Risk Management and by paying attention to new technologies and innovative processes. It now includes new sections, as, for example, for utilities and enlarged topics like production and specific technologies or an increased guidance on the requirements of Aseptic Process Simulation (APS).

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

Scheduled Presentations

Future sterile Manufacturing – an Authority Perspective

- Current challenges
- Regulatory developments
- Expectations

Andrew Hopkins

Quality Risk Management (QRM)

- Inspector's expectations on implementing QRM throughout sterile manufacturing
- Premises and equipment- principles of hygienic design
- Process control strategies for personnel, hygiene, and environment

Beate Reutter

QRM in sterile Manufacturing - Annex 1 and recent Experiences

- Risk assessments and the current draft revision of Annex 1
- When and how to apply?
- Quantitative risk modelling for aseptic manufacturing

Arjan Langen

Annex 1 – Authorities Expectation on Barrier Systems and Isolators

- Most important changes for biopharmaceutical manufacturing - section "barrier systems"
- Regulatory comparison of Annex 1 version 2008 and new Draft
- GMP inspector's comments on new/intended requirements for barriers & isolators

Daniel Müller

Industrial View: Impact on sterile Manufacturing of Biopharmaceuticals relating to Barrier Systems and Isolators

- Possible impact on biopharmaceutical manufacturing
- Industrial point of view – current experiences

Friedrich Häfele

Authority Thinking on Qualification of sterile Facilities & Utilities - General Planning, Execution, Formalities

- The part "Utilities" in the Annex 1 Draft
- What is new?
- Challenges from an inspector's point of view

Christina Meissner

The New Utilities Chapter – Industrial Experiences

- Changes for water, gases, steam and cooling systems
- New "Utilities" chapter in context to Annex 15

Stephan Löw

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

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

Jürgen Blattner

Container Closure Integrity – State of the Art Testing in Context of Annex 1
Matthias Schaar

FDA Guidance "Sterile Drug Products Produced by Aseptic Processing vs. the new Annex1 – Accordances and Differences
- Very brief history of the two guidances
- The supportive tools : USP & EP
- Main accordances
- Some differences
- Comparison of glossaries
- A compared mapping of the guidances

Jean-Denis Mallet

Authorities Expectation on Contamination Control and Monitoring
- Requirements of the revised Annex 1 Draft
- Possible challenges and impacts

Christina Meissner

Consequences on Microbiological Contamination Control and Environmental Monitoring expected by industry
- General concerns within contamination control
- Contamination control strategy
- Consequences for environmental monitoring Program

Arjan Langen

Aseptic Process Simulations - Media Fill – current Challenges
- Current requirements and future expectations
- Impact from a regulatory view

Andrew Hopkins

Media Fill, just do it? – Practical Implementation
- Regulatory Changes regarding APS
- Impact of the current Mediafill Programme for a Multipurpose Manufacturing Line at Vetter

Franziska Petershagen and Julia Allgaier

Automated Media Fill Inspection – State of the Art Testing and Modern Methods in Context of Annex 1
- State of the Art
- How to innovate media fill inspection
- Validation approach
- Implementation and outlook

David Brückner

Annex 1 Revision - Sterilisation and Sterile Filtration (GMP Inspector's View)
- Most important changes in sections "sterilisation" & "sterile filtration"
- Regulatory comparison of Annex 1 version 2008 and new Draft
- GMP inspector's comments (including PUPSIT)

Daniel Müller

The Implication of a new Annex 1 for a Global Pharmaceutical Company
- Approach to assess and enforce required changes to current practice (Define action plan)
- How to integrate Annex 1 requirements into a global pharmaceutical quality system to comply with "global" standards

Tilmann Rock

Moderation

▶ 
DR INGRID WALTHER
Pharma Consulting Walther

Speakers

▶ JULIA ALLGAIER
Vetter Pharma-Fertigung GmbH, Germany


Julia Allgaier joined Vetter Pharma Fertigung in Ravensburg 2012. Since 2015 she is leading the QA Department for Sterility Assurance, Lab Operation and pharmaceutical Training Systems.

▶ 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.

▶ DR DAVID BRÜCKNER
F. Hoffmann La-Roche, Switzerland


Between 2014 and 2017 he performed his PhD at F. Hoffmann-La Roche in pharmaceutical sciences and QC microbiology. His major activities included the scientific investigation of alternative microbial systems aiming at a rapid growth detection of microorganisms. Now he is active as operational excellence manager and takes care of business process optimizations in fill finishing.

▶ DR FRIEDRICH HAEFELE
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany


In May 2006 Dr Haefele joined Boehringer-Ingelheim Pharma where he is responsible for the department Biopharma Fill & Finish Germany.

► ANDREW HOPKINS
MHRA, United Kingdom

Andrew studied microbiology and genetics at the Cardiff University and added later a post graduate diploma from Brighton University. After his studies he worked for Hoechst Marion Roussel, RP Scherer as production manager and Patheon as QA Manager. 2005 he switched to MHRA as GMDP inspector. He was a member of the inspectors Annex 1 expert group.

► DR DANIEL MÜLLER
GMP Inspector, Local Government Tübingen

Currently Daniel Müller 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 Müller 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'.

► ARJAN LANGEN
MSD, 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 roles within QC, QA and manufacturing. Currently he is a global auditor for MSD Human Health division responsible for auditing (sterile) facilities and contract labs. He is a microbiologist by training and is Green Belt certified.

► 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. 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 AFSSAPS, NNE Pharmaplan

Jean-Denis Mallet is a pharmacist. He was previously the 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 at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. He has also been auditor of the International Red Cross. Now he is member of the ECA advisory board and works for NNE Pharmaplan.

► 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 GmbH & Co. KG, Ravensburg

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.

► DR BEATE REUTTER
GMP Inspectorate Schleswig-Holstein Germany

Beate Reutter studied food technologies in Münster and Kiel. After 15 years in a Laboratory for quality control, she switched to the responsible GMP inspection authority of Schleswig-Holstein. She is head of the inspectorate and member of the inspector expert group 3 for sterile manufacturing.

► TILMAN ROCK
Head Biologics DP Quality, Roche

Tilmann studied at Northwestern University and joined Roche in 2003 as Head of Production Prefilled Syringes. After 3 years as Operational Excellence Programme Manager, he became Head Quality Systems and later Site Quality Head. Since 2013 he holds his current position as Vice President/Head Biologics Drug Product Quality.

► 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.

Social Event

On 8 May 2018, 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.

Lufthansa is Mobility Partner for all ECA Events
As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

GMP/GDP Certification Programme
This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

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- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity Manager

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

What are The ECA Foundation and the ECA Academy?
The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

How Do You Become a Member of ECA?
By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website http://www.gmp-compliance.org

What Are the Benefits of ECA?
During the membership, you enjoy

- free access to the members' area where you always find the latest update of the "GMP Guideline Manager" online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy. And as member you can also get to this detailed tree with the GMP WebApp on your smartphone or tablet PC.

- a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date

Tuesday, 08 May 2018, 09.00 – 18.00 Uhr
(Registration and coffee 08.30 – 09.00 Uhr)
Wednesday 09 May 2018 , 08.30 – 16.30 Uhr

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0) 30 21 27 0
Fax +49 (0) 30 21 27 117
Email berlin@steigenberger.de

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, social event & dinner, 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 when you have registered for the course. 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:
Mr Axel Schroeder (Operations Director) at +49-62 21/84 44 10 or per e-mail at schroeder@concept-heidelberg.de.

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

If the bill-to-address deviates from the specification to the right, please fill out here:

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Reservation Form (Please complete in full)

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8-9 May 2018, Berlin, Germany

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1. We are happy to welcome a substitute colleague at any time.
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- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
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