ECA Academy
Your GMP/GDP Information Source

# Annex 1
## Changes, Challenges and Consequences

Authority and Industry Thinking

28/29 November 2018, Berlin, Germany

### HIGHLIGHTS:

- General Issues – from Wording, Terms and Workflow
- Comparison with other Guidelines
- Facilities and Utilities – Classification and Qualification
- Contamination Controls - from Monitoring to Disinfection to Personnel
- Process Simulation
- Sterilisation, CCIT and PUPSIT

### SPEAKERS:

Maximilian Augustin
*Roche*

Walid El Azab
*Steris Corporation, Belgium*

Dr Rainer Gnibl
*Local Government of Upper Bavaria*

Arjan Langen
*MSD, The Netherlands*

Dr Daniel Müller
*Local Government of Baden Württemberg*

Robert Schwarz
*Campus Vienna, Austria*

Magnus Stering
*Sartorius Stedim Biotech*

Dr Ingrid Walther
*Pharma Consulting Walther*

This education course is recognised for the ECA GMP Certification Programme „Certified Sterile Production Manager“.
Please find details at www.gmp-certification.eu

# Annex 1 – Changes, Challenges and Consequences

28/29 November 2018, Berlin, Germany

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

## Objectives

This special course offers you a 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 as well as representatives from pharmaceutical industry 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.

## Target Group

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

## Moderators

Dr Ingrid Walther, Pharma Consulting Walther,
Axel H. Schroeder, Concept Heidelberg

## Programme

### Structure, Wording, Definitions - the current Draft

- Structure and Scope
- The Issue with Wording and Definitions
- Impact for the User

### Classification & Qualification of sterile Facilities & Utilities – Inspector´s view

- Holistic lifecycle structure (overview)
- Qualification stages
- Traceable documentation structure
- Essentials from Annex 1 - DRAFT

### Sterilisation and sterile Filtration – Inspector´s view

- New structure from Annex 1 - DRAFT
- Details from new chapter "sterilisation" & "sterile filtration"
- Filter integrity testing (incl. PUPSIT)
- Sterilisation acc. Annex 1 in line with requirements from Annex 17?

### CCIT/PUPSIT

- Overview of requirements
- Current standard
- Driving standard considering updated regulations

### Personnel - Clothing, Behaviour and more

- Most important changes of Annex 1 (draft) in section "Personnel"
- Garment and Gowning
- Qualification and training of workers
- Surveillance of health status and hygienic behaviour
- GMP inspector's comments

### Consequences on Microbiological Contamination Control and Environmental Monitoring expected by industry

- General concerns within contamination control
- Contamination control strategy
- Consequences for Environmental Monitoring Program

### Cleaning and Disinfection – in the light of Annex1

- Discussion of the different regulatory requirements
- Rotation discussion – How to be globally compliant?
- Design a robust Cleaning and disinfection program including rinse program
  - Beyond regulatory compliance – best practices for cleaning and disinfection program

### Media Fill/Aseptic Process Simulation regarding the new Annex 1

- Comparison of the main regulations regarding Media Fills
  - EU GMP Guide new Annex 1
  - FDA Aseptic Guide
  - PIC/S Guide 'Recommendations on the Validation of Aseptic Processes'
- Main changes compared to still valid Annex 1
- Implementation of new requirements into routine

### Comparison with other relevant Documents

- FDA Aseptic Guide
- ISO 14644
- Others ( e.g. PIC/S, WHO etc.)

### Barrier Systems and Isolators

- Changes from the former revision
- Comparison Cleanroom, RABS and Isolator
- "Is the classical cleanroom dead?" - Impact on aseptic processing

### QRM – Quality Risk Management in the light of Annex 1

- Quality Risk Management (QRM) in manufacturing of sterile medicinal products
- Pharmaceutical Quality System, QRM, and risk assessment(s)
- Most important changes of Annex 1 (draft) regarding QRM principles
- GMP inspector's comments

## Social Event

In the evening of the first course day you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies i n a relaxed atmosphere.

## Speakers

Maximilian Augustin | Roche

Maximilian joined Roche Diagnostics GmbH (Pharma Division) in Manufacturing Science and Technology (MSAT) as Qualification Engineer and Process Validation Manager in 2014. Today he is responsible for Media Fills/Aseptic Process Simulation in Sterile Drug Product Manufacturing Mannheim, Writing of Pharmaceutical Technical Regulatory Dossiers and Validation of Sterilisation Processes.

Walid El Azab | Steris Corporation, Belgium

Walid is a Technical Services Manager for the Life Sciences Division of STERIS Corporation. He currently provides technical support related to cleaning chemistries, disinfectants and sterility assurance products and their application and validation. His areas of expertise include both upstream and downstream biopharmaceutical operation and validation. Walid is green belt certified.

Dr Rainer Gnibl | Local Government of Upper Bavaria

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria, Munich as well as the EMA and performs GMP inspections worldwide. He is head of German expert group on "GMP-inspections". Besides he does expert and authoring activities incl. numerous publications in standard literature.

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.

Dr Daniel Müller | Local Government of Baden Württemberg

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'.

Robert Schwarz | Campus Vienna, Austria

Robert Schwarz joined Baxter, Vienna in 2001. Until 2005 he was coordinator of environmental monitoring. From 2005 until 2018 he was validation specialist for equipment qualification, sterilization/decontamination validation and cleaning validation. Additionally he is university lecturer in the field of biotech (core topics validation/qualification, aseptic processing, cleanroom technologies and QC) at the UAS (University of Applied Sciences) Campus Vienna.

Magnus Stering | Sartorius Stedim Biotech

Senior Product and Project Manager. Magnus joined Sartorius 24 years ago and has experiences in different positions in technical support, product and project management . During the last two years with an increasing number of consulting activities around PUPSIT and integrity testing in general.

Dr Ingrid Walther | Pharma Consulting Walther

She joined Fresenius AG in 1986 and was employed in various positions and has many years of experience in 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 and re-joined Fresenius in 2007, heading the business unit iv Drugs & Oncology. Since July 2009, she runs her own business as GMP compliance consultant.

## 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**


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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

**Annex 1 – Changes, Challenges and Consequences**
28/29 November 2018, Berlin, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company Department

**Important: Please indicate your company's VAT ID Number** **PO Number if applicable**

Street/P.O. Box

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

**General terms and conditions**
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
**Terms of payment:** Payable without deductions within 10 days after receipt of invoice.
**Important:** This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012) German law shall apply. Court of jurisdiction is Heidelberg.

**Privacy Policy:** By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

### Date

Wednesday, 28 November 2018, 10.00 – 18.00 h
(Registration and Coffee 09.30 - 10.00 h)
Thursday, 29 November 2018, 09.00 – 16.00 h

### Venue

TITANIC Hotels Berlin
Chausseestrasse 30
10115 Berlin, Germany
Phone +49 (0)30 311 6858-0
email Info.tbc@titanic-hotels.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, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

### Accommodation

CONCEPT has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form with all further information when you have registered for the course. 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.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

**For questions regarding content please contact:**
Mr Axel Schroeder (Operations Director)
at +49-(0)6221/84 44 10, or per e-mail at
schroeder@concept-heidelberg.de.

**For questions regarding reservation, hotel, organisation etc. please contact:**
Mr Rouwen Schopka (Organisation Manager)
at +49-(0)6221/84 44 13, or per e-mail at
schopka@concept-heidelberg.de.