ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Simon Guerrero Cruz
MSD, The Netherlands

Jörg Degen
Eurofins BioPharma Product Testing Munich GmbH, Germany

Sven M. Deutschmann
Roche Diagnostics GmbH, Germany

Radhakrishna Tirumalai, Ph.D.
USP

Nicole Klüh
Labor LS

Alexandra Stärk
Novartis Pharma Stein, Switzerland

Bioburden Workshop

Regulatory Expectations and Practical Experiences

30 June/01 July 2020 | Berlin, Germany

Highlights

- USP <1115>, USP<1229.3> and European Regulatory Requirements
- Assessment of Bioburden Excursions in Non-Sterile Products
- Bioburden for Sterile Operations
- Colony Counting and Bioburden of Combination Products
- Microbial Control Strategy for Biopharmaceutical Manufacturing
- Bioburden and ATMP

Objective

During this workshop, the following contents and questions should be addressed by presentations and panel discussions. Considering that, panel lists from the fields Non-Sterile Products, Sterile Products, Combination Products as well as biopharmaceutical APIs and HCT/Ps will on hand for the workshop.

Background

In their Pharmacopeial Forum 39(4) in 2014, the USP published the draft of chapter <1115> „Bioburden Control of Non-sterile Drug Substances and Products". The document outlines a risk-based approach to the control of potential contamination in non-sterile product manufacturing.

But "bioburden" is not only a topic of Non-Sterile Products. Annex 1 of the European GMP Guideline requires "The bioburden should be monitored before sterilisation. There should be working limits on contamination immediately before sterilisation, which are related to the efficiency of the method to be used. Bioburden assay should be performed on each batch for both aseptically filled product and terminally sterilised products."

And last but not least, bioburden testing for medical devices made or used in the USA is governed by Title 21 of the Code of Federal Regulations and worldwide by ISO 11737.

The current developments determines us to address this topic in a special workshop session to look at this from various angles and provide you with information about the regulatory background and practical examples and strategies for bioburden control. Pharmacopoeial experts, representatives of pharmaceutical quality control and from testing laboratory will show you what are the challenges of the bioburden control strategy and how they implemented an adequate control in their companies.

Target Audience

This workshop is of interest to professionals in microbiology from

- Pharmaceuticals and Biopharmaceutical Companies
- Academic Research Institutions
- Government Agencies
- Contract Service Laboratories

who are involved in

- Research and Development
- Validation
- Microbiological QA and QC

Moderator

Dr Sven M. Deutschmann,
Chair ECA Pharmaceutical Microbiology Working Group

Programme

Topic: General Information

- Bioburden control strategy dependent of the lifecycle phase of the product (so-called "Phase-appropriate control strategy")
  - Early clinical phase
  - Late clinical phase
  - Commercial phase

- Test for "specified microorganisms" and / or "objectionable microorganisms"?
  - Raw materials
  - In-process-control samples
  - Drug substance
  - Drug Product
  - Final Product

Topic: Testing

- Where is bioburden tested in processes?
- Predefinition of bioburden and / or endotoxins levels for raw materials
- Assessment of the presence / absence of "objectionable microorganisms" in your raw materials ?
- What are the method in use ?
  - TAMC
  - TYMC
  - MPN
  - Any other bioburden testing method
  - Rapid micro methods
- Is it necessary to have a limited shelf life for bioburden samples?
- How to treat so called "missing bioburden" results ?

Topic: Limits

- Predefined bioburden and / or endotoxins levels for your upstream / fermentation processes (if applicable) and downstream processes or for the whole process

- What will be preferred? A two-tiered-control system (warning and alert level) or a three-tiered control system (warning and alert level AND rejection level) ?

- Methodologies in use to define the limits, e.g.
  - how many data points are required to define the limits
  - philosophy for new processes / new manufacturing processes without having experience of process capabilities

Topic: Deviation Management

- Do you perform ID?
  - If YES, when:
    - Each colony
    - Only in case of an excursion of limits / level
  - What's the preferred ID technique
- Measures in case of an excursion of a limit

Topic: USP <1115> and USP<1229.3>

- „Bioburden Control of Non-sterile Drug Substances and Products" – USP and Industrial View
- Bioburden Monitoring , USP<1229.3> applies to Sterile Products

Presentation list:

- European Regulations
- USP<1115> Bioburden Control of Non-Sterile Drug Substances and Products
- Various types of bioburden testing
- Risk Assessment on Microbiological Control for a Low Bioburden Process
- Microbial Control Strategy for Biopharmaceutical Manufacturing
- Microbial Counts and Bioburden of Combination Products: Guidelines, Specifics and Case Studies Bioburden for Sterile Operations
- Bioburden Monitoring , USP<1229.3> applies to Sterile Products
- Bioburden Testing of Modern Medicinal Products - Practical Experience of a Contract Lab
- Technical challenges: Non-Steriles up to ATMP Assessment of Bioburden Excursions in Non-Sterile Biologics Manufacturing Processes
- Practical Examples - from classic product to HCT/P

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 in a relaxed atmosphere.

Speakers

Dr Simon Guerrero Cruz, MSD Oss, The Netherlands

Simon studied Biology and Environmental Engineering. After his Master Thesis he worked as Doctoral Researcher, Environmental Microbiology at the Radboud University. Since January 2019 he is Senior specialist at the global Center of Expertise Microbiology MSD, Environmental microbiology & research in Oss.

Dr Joerg Degen, Eurofins BioPharma Product Testing Munich GmbH, Germany

Joerg Degen studied Biology at the University of Wuerzburg. He obtained his PhD at the Fraunhofer Institute for Interfacial Engineering and Biotechnology (IGB)Stuttgart. In 2006 he joined BSL Bioservice as study director for microbiological testings for pharmaceuticals and medical devices. In his current position, he is the head of the Microbiology Laboratory at Eurofins BioPharma and Medical Device Testing.

Dr Sven M. Deutschmann, Roche Diagnostics GmbH, Germany

Sven M. Deutschmann studied biology at the University of Brunswick. In 1995 he joined Roche Diagnostics GmbH. Currently, he is responsible for the Biological Quality Control including microbiological, molecular and cell biological analytics. Beginning of 2012 he was appointed as Global Head of a Corporate Function called "Method Management and Technology" within the Biologics Operational Unit of Roche with special focus on PCR-based technologies and Rapid Microbiological Methods. Besides his local and global responsibilities he is a member of several microbiological expert groups, ,e.g. the Expert Group 1 "Biological Methods and Statistical Analysis" of the European Pharmacopeia Commissions.

Nicole Klüh, Labor LS, Bad Bocklett, Germany

Nicole holds an B.Sc. in Food Technology and an M.Sc. in in Food Processing. She is working at Labor LS as instructor in the department for non-sterile samples.

Alexandra Stärk, Novartis Pharma Stein AG, Switzerland

After studying Hygiene Technology at the Technical University of Albstadt-Sigmaringen, Alexandra Stärk has worked since 1995 at Novartis Pharma Stein AG and was heading the microbiological QA/QC department till October 2016. In October 2016 she moved into a new role within Novartis Pharma Stein AG and is now responsible for a team of microbiological experts in the department of Manufacturing, Science & Technology which defines the microbiological control strategies for sterile, non-sterile and cell & gene therapy production on a global and local level.

Dr Radhakrishna Tirumalai, USP

Dr Tirumalai has been at the USP since 2003 and is currently a Principal Scientific Liaison-General Chapters in the Science Division. He is the Liaison to the USP Expert Committee on Microbiology. He works with the industry, regulatory agencies and other external science based organizations in the development and revision of General Chapters. Dr Tirumalai represents USP on PDA expert task forces and committees related to Microbiology and Sterility Assurance.

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

_____

_____

_____

_____

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

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Bioburden Workshop, 30 June/01 July 2020, Berlin, Germany

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

City ZIP Code Country

Phone / Fax

E-Mail (Please fill in)

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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 HEIDELBERGwill 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
Tuesday, 30 June 2020, 10.00 h – 18.00 h
(Registration and coffee 09.30 -10.00 h)
Wednesday, 01 July 2020, 09.00 – 13.00 h

Venue
Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
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, 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 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.

Certificate of Participation
Shortly after the event, you will receive your certificate of participation by email.

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
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Axel H. Schroeder (Operations Director) at
+49(0)62 21/84 44 10, or at
schroeder@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Rouwen Schopka (Organisation Manager) at
+49(0)62 21/84 44 13, or at
schopka@concept-heidelberg.de.