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Bioburden Workshop

Regulatory Expectations and Practical Experiences

SPEAKERS:

Dr Marja Claassen
MSD, The Netherlands

Dr Jörg Degen
Eurofins BioPharma Product Testing Munich GmbH , Germany

Dr Sven M. Deutschmann
Roche Diagnostics GmbH, Germany

Dr Marcel Goverde
MGP

Alexandra Stärk
Novartis Pharma Stein, Switzerland

Dr Radhakrishna Tirumalai
USP

26-27 June 2018, 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

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

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Background

In their Pharmacopeial Forum 39(4) in 2014, the USP published the draft of chapter <1115> *"Bioburden Control of Nonsterile 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 determine 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 the challenges of the bioburden control strategy are and how they implemented an adequate control in their companies.

Objectives

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

Target Group

This conference 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 Marcel Goverde, *Vice-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 Nonsterile 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
- USP <1115> Industrial Implementation
- Microbial Control Strategy for Biopharmaceutical Manufacturing
- Colony Counting and Bioburden of Combination Products : Norms, Differences and Case Studies
- Bioburden for Sterile Operations
- Bioburden Monitoring , USP<1229.3> applies to Sterile Products
- Bioburden for Sterile Operations
- Bioburden control strategy of non-steriles
- Assessment of Bioburden Excursions in Non-Sterile Biologics Manufacturing Processes

Speakers

Dr Marja Claassen-Willemse, MSD Oss, The Netherlands
Maria Claassen studied Biology at the Radboud university of Nijmegen and got her PhD on Virology at the Utrecht University. After a post doc position in the field of Immunology at the Erasmus MC in Rotterdam, she joined MSD where she had varying positions in development, QC and manufacturing. Currently she is Senior Specialist of the Global Center of Expertise Microbiology, The Netherlands, involved in rapid microbiological method deployment in the QC laboratories of MSD.

Dr Joerg Degen, Eurofins BioPharma Product Testing Munich GmbH, Germany, Head of Microbiology
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.

Dr Marcel Goverde, MGP Consulting, Switzerland
Marcel Goverde has attended the University of Basel, where he majored in biology. 2002 to 2010 he was leading the quality control lab for non-sterile products as well as the lab for research & development of microbiological methods at F. Hoffmann-La Roche Ltd in Basel. From 2010-2011 he worked as microbiological expert at Novartis. In 2011 he started his own company for consulting, training and project management in microbiology. Furthermore he is a member of the working group 1 from the European Directorate for the Quality of Medicines (EDQM) which is in charge for microbiological and statistical methods.

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 and non-sterile 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.

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.

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

Bioburden Workshop
26-27 June 2018, Berlin, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

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Date

Tuesday, 26 June 2018, 10.00 h – 18.00 h
(Registration and coffee 09.30 -10.00 h)
Wednesday, 27 June 2018, 09.00 – 13.00 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
Including: Conference documentation, lunch and social event on the first day and all refreshments. The registration fee is payable in advance after receipt of invoice. 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.

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