ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Dr Marja Claassen-Willemse
MSD, The Netherlands

Dr Jörg Degen
ITM Isotopen Technologien München AG, Germany

Dr Sven M. Deutschmann
Roche Diagnostics GmbH, Germany

Nicole Klüh
Labor LS, Germany

Dr Sebastian Thölken
Novartis Pharma Stein AG, Switzerland

Radhakrishna Tirumalai, Ph.D.
United States Pharmacopoeia (USP)

Bioburden - Lessons and Panel Discussion

Regulatory Expectations and Practical Experiences

Live Online Training on 08/09 June 2021

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

Programme

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 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 Live Online Training 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

Objective

During this Live Online Training, 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 and HCT/Ps will on hand for the training.

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

- Refresher on biofilms including case studies
  - Biofilm biology
  - How to recognize biofilms in bioburden trends
  - Lessons learned from a company

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 ?

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

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

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
- Refresher on biofilms including case studies
- 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
  - Various types of bioburden testing
  - Technical challenges: Non-Steriles up to ATMP
  - Practical Examples - from classic Pharmaceutical Products to HCT/Ps
- Assessment of Bioburden Excursions in Non-Sterile Biologics Manufacturing Processes

Speakers

Dr Marja Claassen-Willemse, MSD, 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, ITM Isotopen Technologien München AG, 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. From 2006 until 2020 he worked for Eurofins/ BSL Bioservice as study director for microbiological testings of pharmaceuticals and medical devices and later as the head of the Microbiology Laboratory. In 2020 he joined ITM as Head of the Microbiology Laboratory.

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.

Dr Sebastian Thölken, Novartis Pharma Stein AG, Switzerland

Sebastian studied Pharmacy at the University of Freiburg. 2011-2015 he worked as scientist at the Albert-Ludwigs-Universität Freiburg/Breisgau. In 2015 he joined Novartis. His current position is Process Expert Microbiology, MS&T Steriles.

Radhakrishna Tirumalai, Ph.D., 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.

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

D-69007 Heidelberg
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Reservation Form (Please complete in full)

Bioburden - Regulatory Expectations and Practical Experiences, Live Online Training on 08/09 June 2021

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

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Date of the Live Online Training

Tuesday 08 June 2021, 10.00 – 18.00h CEST
Wednesday, 09 June 2021, 09.00 – 13.00 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice.

Registration

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

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Your Benefit: Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training...." This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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