ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Microbiological Laboratory Manager

Speakers

Dr Marja Claassen
MSD, The Netherlands

Dr Sven M. Deutschmann
Roche Diagnostics, Germany

Dr Christoph Höppner
Eurofins, Germany

Dr Holger Kavermann
Roche Diagnostiocs, Germany

Nicole Klüh
Labor LS, Germany

Dr Sebastian Thölken
Lonza Stein, Switzerland

Dr Radhakrishna Tirumalai
MSD, USA

Bioburden

Regulatory Expectations and Practical Experiences
- Lessons and Panel Discussion -

Live Online Training on 17/18 October 2024

Highlights

- USP <1115>, USP<1229.3>, USP <1119> 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 ATMPs
- Minimizing the Impact of Bioburden and Sterility Testing on Gene Therapy Batch Yield

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 determine us to address this topic in a special workshop session to look at this from various angles, 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

Moderators

Dr Sven M. Deutschmann, Roche, Chair ECA Pharmaceutical Microbiology Working Group
Axel H. Schroeder, Concept Heidelberg

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 be 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 methods 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>, USP<1229.3> and USP <1119>

- Bioburden control of non-sterile drug substances and products – USP and industrial view
- Bioburden monitoring, USP<1229.3> applies to sterile products
- USP <1119>

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, USP <1119>
- 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
- Minimizing the impact of bioburden and sterility testing on gene therapy batch yield
- 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 associate director, leading a team of microbiological specialists who operate globally and own the micro methods at the MSD's manufacturing division.

Dr Sven M. Deutschmann, Roche Diagnostics GmbH, Germany

Sven Deutschmann studied biology at the University of Brunswick where he obtained his PhD in cell culture technology. In his current role in Roche's "Analytical Science"-Chapter he evaluates and validates Alternative Adventitious Agents Tests and Alternative Microbiological Methods. Besides his internal responsibilities Sven is member of the German Pharmacopeia Commission and its Microbiology Committee as well as Expert in the Working Parties "Bacterial Endotoxins" and "HTS" or Chairperson of the Working Party "Mycoplasma" and Expert Group 1 "Microbiology" of the European Pharmacopeia Commission in Strasbourg, France. In 2009 he was appointed as commissioner of the Central Commission for Biological Safety, a brains trust of the Federal Office of Consumer Protection and Food Safety. In addition, Sven is chairperson of the Advisory Board of the ECA "Pharmaceutical Microbiology" Interest Group and co-author of various PDA Technical Reports.

Dr Christoph Höppner, Head of Testing Facility at Eurofins, Germany

Christoph holds a PhD in Microbiology and a degree in economics. He started his carreer at the Universtity Munich before he joined BSL Bioservice in 2005 as Head of Microbiology Department in 2005. Today he ist Head of Testing Facility and Sustainability Manager and since 2023 he is as Senior Director Microbiology Operations BPT Europe and responsible for the microbiological activities.

Dr Holger Kavermann, Roche Diagnostics

Holger Kavermann studied microbiology at the University of Göttingen and obtained his PhD in medical microbiology at the University of Munich. In 2003, he joined Roche Diagnostics GmbH as Manager QC responsible for the microbiological and cell biological analytics of QC and In-Process-Control-samples in the production of biotechnological derived active pharmaceutical ingredients. In 2013, he became head of the QC Department for Environmental Monitoring and Cleaning Validation. Since 2017, he has been the department head for Microbiology, EM and Cleaning Analytics.

Nicole Klüh, Labor LS SE & Co. KG, Germany

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

Dr Sebastian Thölken, Lonza Stein, Switzerland

Sebastian holds a PhD in Pharmaceutical Chemistry from the University of Freiburg. In 2015 he joined Novartis Steriles in Stein where he had several positions in Microbiology and production. In 2023 he came to Lonza as Principal Scientist Microbiology and is – among other things - responsible for building a new microbiology laboratory.

Dr Radhakrishna Tirumalai, MSD, formerly at USP, USA

Dr Tirumalai has been at the USP from 2003 until 2022 as Principal Scientific Liaison-General Chapters in the Science Division. He was the Liaison to the USP Expert Committee on Microbiology. He worked with the industry, regulatory agencies and other external science-based organizations in the development and revision of General Chapters. Dr Tirumalai has represented USP on PDA expert task forces and committees related to Microbiology and Sterility Assurance. Currently, he is working at MSD (US Merck) in a global position.

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Reservation Form (Please complete in full)

Bioburden - Regulatory Expectations and Practical Experiences, Live Online Training on 17/18 October 2024

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
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training

Thursday, 17 October 2024, 09.00 – 17.30 h CEST
Friday, 18 October 2024, 09.00 – 13.00 h CEST

Technical Requirements

We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
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.

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