Speakers

Dr Katja Aschermann
Tetec

Melanie Braun
Labor LS

Stefan Gärtner
Labor LS

Dr Armin Hauk
Sartorius Stedim Biotech

Dr Ana Kuschel
West Pharmaceuticals Deutschland

Anna Liznar
PathoQuest

Raphael Parusel
Tetec

Handling Biological Raw Materials & APIs

Live Online Training on 18/19 March 2025

Highlights

- Regulatory and Quality Requirements
- E&L and Biologics Containment
- Microbiological Safety and Control
- Effective Storage Solutions

Objective

This live online training is designed to address challenges such as mitigating risks of contamination, degradation and supply chain disruption. It provides industry professionals with the knowledge and skills needed to ensure compliance and optimise their processes for handling biological raw materials and active pharmaceutical ingredients.

Background

Raw materials, excipients and other products used in the manufacture of biologics must be well understood in terms of their role in the manufacturing process. Particularly in a GMP regulated environment, these raw materials, components and excipients require thorough control for consistent quality. Therefore, all critical quality attributes should be known and appropriate risk mitigation and control strategies should be established. Since there is currently less written guidance on risk-based management of biological raw materials, European Pharmaceutical Enterprises, EBE, has prepared a concept paper entitled "Management and Control of Raw Materials Used in the Manufacture of Biological Medicinal Products." But other approaches can also be helpful - a look at Annex 1 for products that need to be sterile or have a low bioburden claim. Or the QbD approaches for consistent quality of products.

Target Audience

This training will be highly valuable for:

- Laboratory managers
- Quality control managers
- Analytical scientists
- Senior laboratory personnel
- QA Units
- Qualified Persons (QPs)

It is designed for professionals from biopharmaceutical companies, ATMP developers, and manufacturers. Additionally, the training is relevant for employees of contract laboratories involved in method development, control testing, and quality assurance.

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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.

Programme

Classification and Regulatory Aspects of Biological Raw Materials
(Katja Aschermann)

- Starting Materials
- Biological Raw Materials
- Novel Excipients

QbD Approach to Registration of Raw Materials
(Katja Aschermann)

- Introduction to the QbD Approach
- Target Material Profiles and Critical Quality Attributes
- Development of a QbD Approach for Raw Materials
- Examples

Process-related Leachables
(Armin Hauck)

- What are Process Equipment Related Leachables (PERLs)
- Bioprocessing using Single Use Systems (SUS)
  - Regulatory requirements
  - The dedicated concerns
- Extractables Studies for SUS
- The extrapolation of extractables data to PERL exposure data
- PERL in safety and risk assessment
- PERL mitigation concepts

The Search for Ideal Biologics Containment
(Ana Kuschel)

- Materials types and requirements
- Selection criteria considerations
- Regulatory landspace overview
- Current solutions for biologics

Raw Material Qualification for Cell Therapies
(Katja Aschermann)

- From Risk Profile to Material Qualification
- Examples
- Quality Control of Raw Materials

Microbiological Safety: Protection Strategies for Product Quality and Health
(Melanie Braun)

- Basic principles of industrial hygiene
- Risk factors for microbiological contamination
- Case studies
- Prevention strategies, monitoring and controls

Viral Contamination Risk Control Strategy
(Anna Liznar)

- Regulatory aspects in viral safety of biological raw materials
- Viral risk identification with NGS
- Considerations for viral safety of biological raw materials used in ATMP production

Rapid Microbiological Control of Raw Materials
(Stefan Gärtner)

- General requirements for (rapid) bioburden, sterility and endotoxin tests
- Handling of small and/or complex sample volumes
- Design of validation studies
- Overview of different rapid methods for different matrices

Combined Products: Ensuring Compliance and Quality
(Raphael Parusel)

- Combined products (medical devices and medicinal products)
- CE labelling
- Legal manufacturer and distributor
- Requirements of the MDR
- Requirements of ISO13485

Effective Storage Solutions
(Raphael Parusel)

- GMP warehouse structure
- Documentation
- Storage of medicinal products and medical devices
- Hygiene and monitoring
- Implementation of ERP systems
- GDP

Moderator

Clemens Mundo, Concept Heidelberg

Speakers

Dr Katja Aschermann, Tetec AG
Vice President Quality

Dr Katja Aschermann is an accomplished leader in the biopharmaceutical industry with over 20 years of experience in various senior positions. Her extensive experience spans from transforming academic spin-offs into GMP companies to submitting regulatory dossiers to the EMA. She is a member of the ECA ATMP-Interest Group Board and has participated in the development of the "National Strategy for Gene and Cell-Based Therapies".

Melanie Braun, Labor LS
Head of Microbiological Services

As head of microbiological services, Melanie Braun is responsible for the areas of microbial identification, master bacteria management, industrial hygiene and culture media testing.

Stefan Gärtner, Labor LS
Head of Department – Sterile Products / Rapid and Alternative

After his qualification as biological laboratory technician at LS Stefan worked as technical specialist at LS. Since January 2015, he is head of a department Sterile Products / Rapid and Alternative at Labor LS.

Dr Armin Hauk, Sartorius Stedim Biotech GmbH
Principle Scientist E&L

After his PhD in 1995, Armin joined the central analytical department of Ciba-Geigy Inc., amongst others with focus on E&L investigations. From 2010 on Armin was active as consultant mainly in the area of E&L for Intertek in Basel. Since June 2016 Armin has a position at Sartorius-Stedim Biotech as Principle Scientist E&L.

Dr Ana Kuschel, West Pharmaceuticals Deutschland GmbH & Co. KG
Principal Scientific Affairs

As Principal Scientific Affairs Europe, Ana is providing technical support relating to West's packaging components and delivery systems for injectable drugs and healthcare products, as well as bridging scientific information through industry outreach. This is complementing her previous role as Manager Material Development, where she worked on both existing and new rubber formulations. Ana is also an active member of the ISO TC 76.

Anna Liznar, PathoQuest
Business Development Manager

Anna is RNA and NGS enthusiast and has worked in the field of RNAi, Transcriptomics, Genomics and now Quality Testing of Biologics with NGS at PathoQuest.

Raphael Parusel, Tetec AG
Deputy Head of Quality Assurance & PRRC

Raphael has extensive experience in medical microbiology. Since joining TETEC AG in 2021, he has held various roles, including Deputy Quality Management Representative (QMR) in 2022, QMR from 2024, and Deputy Head of Quality Assurance since 2023. As of August 2024, he is also the Person Responsible for Regulatory Compliance (PRRC).

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GERMANY

Reservation Form (Please complete in full)

Handling Biological Raw Materials & APIs
Live Online Training on 18/19 March 2025

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:
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2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
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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 of the Live Online Training

Tuesday, 18 March 2025, 09.00 h – 15.30 h
Wednesday, 19 March 2025, 09.00 h – 15.00 h
All times mentioned are CET.

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 – or search and register directly at www.gmp-compliance.org under the number 21968.

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.

You cannot attend the live online event?

We offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
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