ECA Academy
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GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Ghazaleh Gouya
Gouya Insights

Markus Haberger
Roche Diagnostics

Dr Andrea Hawe
Coriolis Pharma Research

Christian Mayer
AGES

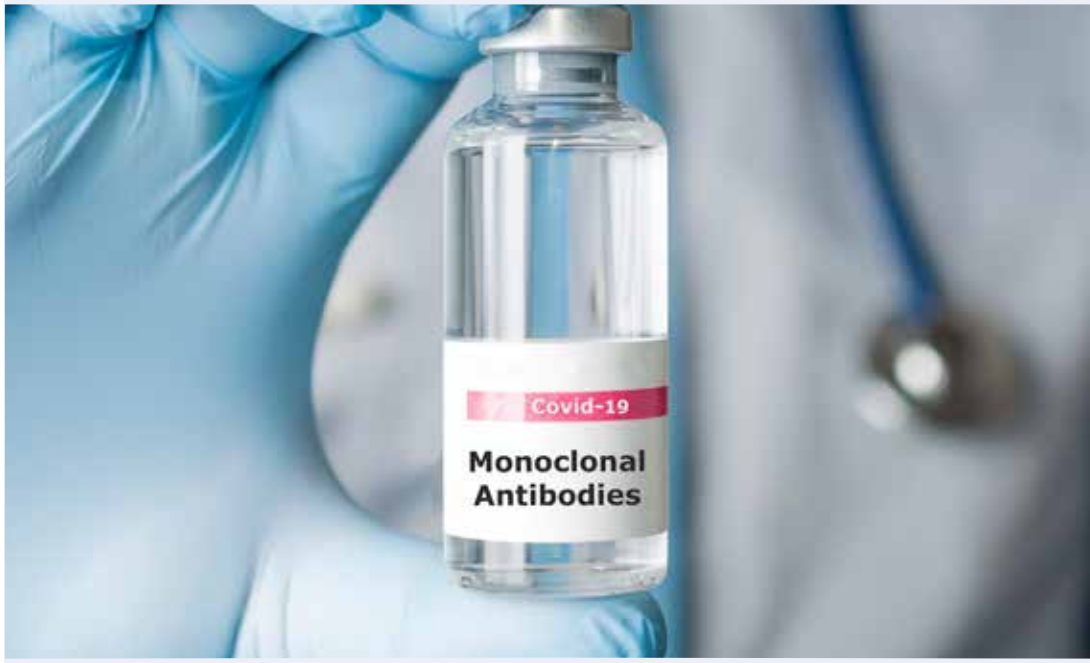
Dr Andreas Nechansky
VelaLabs

Markus Roucka
Tentamus

Monoclonal Antibodies

From Concept to Approval

Live Online Training on 22/23 October 2024



Highlights

- Bacterial vs Mammalian Cell Production
- Antigen Affinity Purification
- Analytical Concepts and Methods for Testing, LCMS and More
- Clinical Development Plan
- ADC & Bi-/Tri-specific Conjugates
- Regulatory Background Information

Objective

At the end of this course, participants will have a comprehensive understanding of monoclonal antibodies (mAbs). From the early development process, through upstream and downstream manufacturing, to different analytical approaches, clinical trials and stability studies. The course is designed to ensure that participants not only understand the theoretical underpinnings of mAb development, but also the practical and regulatory challenges that must be overcome to bring a therapeutic antibody from the laboratory to the clinic and ultimately to the market.

Background

Monoclonal antibodies (mAbs) are increasingly becoming a cornerstone of therapeutic strategies in a wide range of diseases, including oncology, rheumatology and infectious diseases. Their ability to target specific antigens with high precision makes them critical tools in the fight against complex diseases. The global market for monoclonal antibodies is expanding not only because of their efficacy but also because of technological advances in genetic engineering and bioprocessing.

The development of monoclonal antibodies involves a sophisticated and multidisciplinary approach that integrates the fields of molecular biology, genetic engineering, immunology and pharmacology. The complexity of the development process is compounded by the stringent requirements imposed by regulatory authorities to ensure the safety, efficacy and quality of these biopharmaceuticals before they reach the market.

Guidelines from regulatory agencies such as the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) provide structured pathways and requirements for the development and approval of monoclonal antibodies. These guidelines include detailed criteria for the manufacturing process, preclinical and clinical testing and submission of regulatory dossiers.

Given the rigorous and detailed nature of these guidelines, professionals involved in mAb development must have a deep understanding of both the scientific and regulatory landscape. It is essential that these professionals are familiar with critical guidelines such as ICH Q6B, which details test procedures and acceptance criteria for biotechnology and biological products, or ICH Q8(R2), which provides guidance on pharmaceutical development.

Target Audience

The programme is aimed at those working in research, clinical trials and anyone interested in developing monoclonal antibodies. By targeting this wide range of professionals, the training aims to create a knowledgeable and skilled workforce capable of advancing the field of monoclonal antibodies from the research phase through to clinical use and successful market entry.

Programme

World of mAbs: Introduction and Overview – From Idea to Product

- What are monoclonal antibodies (mAbs)?
- Conception to market – developing effective mAbs
- Areas of application: therapeutic applications, diagnostics, research

Analytical Concept for Fc and Fab

- Antibody structures: Fc and Fab analysis
- Ligand Binding Assay (LBA) and other techniques
- Bioassay validation

Production Processes of mAbs: From Upstream to Downstream

- Regulatory aspects
- Techniques and technologies
- Optimizing expression: Techniques for enhancing yield and quality
- Challenges and solutions in scale-up for commercial production
- Case studies

Production Processes of mAbs: Bacterial vs Mammalian Cell Production

- Choosing the right system: bacterial vs. mammalian cell lines
- Pros and cons: production strategies for monoclonal antibodies
- Evaluating hosts for optimal antibody yield

Purification Methods: Antigen Affinity Purification (Downstream)

- Principles of antigen-affinity purification: selectivity and specificity
- Technological advances in affinity media and ligand design
- Integration into downstream processing: purity, yield and scalability
- Optimization of purification processes for mAbs

Liquid Chromatography Mass Spectrometry (LCMS)

- LC-MS in mAbs characterization: sensitivity, specificity and throughput
- Comparative analysis: when to use LBA vs. LC-MS
- Glycosylation and its effect

Clinical Development Plan

- Blueprint for success: mapping the clinical trial journey
- Critical strategies for effective clinical development
- Navigating clinical development stages – Phase I - III

Formulation Strategies and Stability Testing for mAbs

- Developability assessment and early formulation screenings
- Phase appropriate formulation strategies for mAbs
- Conducting stability studies: protocols, parameters and analytical methods

ADC (Antibody Drug Conjugates) - Design and Application

- The anatomy of ADCs: linkers, drugs and antibodies
- Clinical applications of ADCs: successes and lessons learned
- Future directions: innovations in linker chemistry and targeted delivery

Bi- and tri-specific Conjugates - Potential and Challenges

- Designing bi- and tri-specific antibodies: concepts and constructs
- Therapeutic potential: targeting complex diseases with multifunctional antibodies
- Overcoming development challenges: manufacturing, stability and efficacy

Moderator

Clemens Mundo, Concept Heidelberg

Speakers

Dr Ghazaleh Gouya
Gouya Insights GmbH
Founder

As the founder of Gouya-Insights GmbH & Co KG, Ghazaleh Gouya Lechner provides strategic clinical development leadership to biotechnology, pharmaceutical, and medical device companies, addressing the complexities of clinical product development and regulatory compliance. Ghazaleh Gouya Lechner brings over 20 years of clinical research experience. She has played a pivotal role in numerous product development processes, significantly contributing to project strategy and protocol development, ensuring the right strategy for the right patients at the right sites, leading to successful marketing authorization.

Markus Haberger
Roche Diagnostics GmbH
Group Leader, Development Characterization Analytics

Since 2004, Markus has been with Roche in the Development Analytics Extended Characterization department. He started as a Technician and advanced to Principal Scientist in 2023. His expertise is in mass spectrometry, focusing on the identification and quantification of post-translational modifications. He specializes in intact mass analysis and has explored size exclusion, ion exchange, and affinity mass spectrometry to study the complex structures and functions of therapeutic proteins.

Dr Andrea Hawe
Coriolis Pharma Research GmbH
Chief Scientific Officer

Andrea Hawe is Co-Founder and Chief Scientific Officer of Coriolis Pharma, a science-driven contract research organization, supporting drug product development of biopharmaceuticals (protein, peptides, oligonucleotides ATMPs, vaccines, etc.), with focus on drug product development, formulation development, lyophilization technologies, and analytics (GMP and non-GMP). She is an expert for protein formulation and protein characterization and has published more than 60 articles in peer-reviewed journals.

Christian Mayer
AGES
Quality Assessor

For the past 15 years, Christian has been working as quality assessor at the AGES. Since then he has carried out numerous evaluations in the frame of centralized marketing authorization applications including lifecycle procedures, EMA and national scientific advice and clinical trial applications. Through this position as senior expert and coordinator of the expert group 'Biologicals – Quality' within AGES, he was involved in the quality assessment of a broad range of biological products. In 2014, he was appointed as the Austrian alternate member in the EMA's/CHMP's Biological Working Party (BWP) and since 2023, he has taken over the full membership in the BWP.

Dr. Andreas Nechansky
VelaLabs GmbH
Managing Director, QP

Dr Nechansky has over 20 years of professional experience in many different positions and companies such as Igeneon GmbH, VelaLabs, Eden Biologics, ABF Pharmaceutical Services. Since 2023 he is now Managing Director at VelaLabs GmbH. He has many years of experience in the field of antibody characterisation.

Markus Roucka
Tentamus
Head of Business Development

Markus started his career in the biotechnical R&D laboratories of Biomin GmbH, now DSM. Later he studied medical and pharmaceutical biotechnology at the University of Applied Science IMC Krems. He joined VelaLabs GmbH in 2008. Since than he had many stages starting from Head Laboratory to COO. In 2019 he took over the Managing Director position at VelaLabs until mid of 2023. His current position is now Head of Business Development at Tentamus Group focusing on the DACH region since July 2023.

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Reservation Form (Please complete in full)

Monoclonal Antibodies – From Concept to Approval, Live Online Training on 22/23 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
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 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 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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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 of the Live Online Training
Tuesday, 22 October 2024, 09.00 h – 15.30 h
Wednesday, 23 October 2024, 09.00 h – 15.00 h
All times mentioned are 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 conference 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 21299.

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.

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

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