



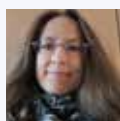
Speakers



Dr Kerstin Brack
Charles River Laboratories



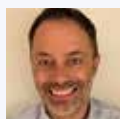
Dr Sabine Hauck
Chair of ECA ATMP Interest Group



Dr Ulrike Herbrand
Charles River Laboratories



Anna Liznar
PathoQuest



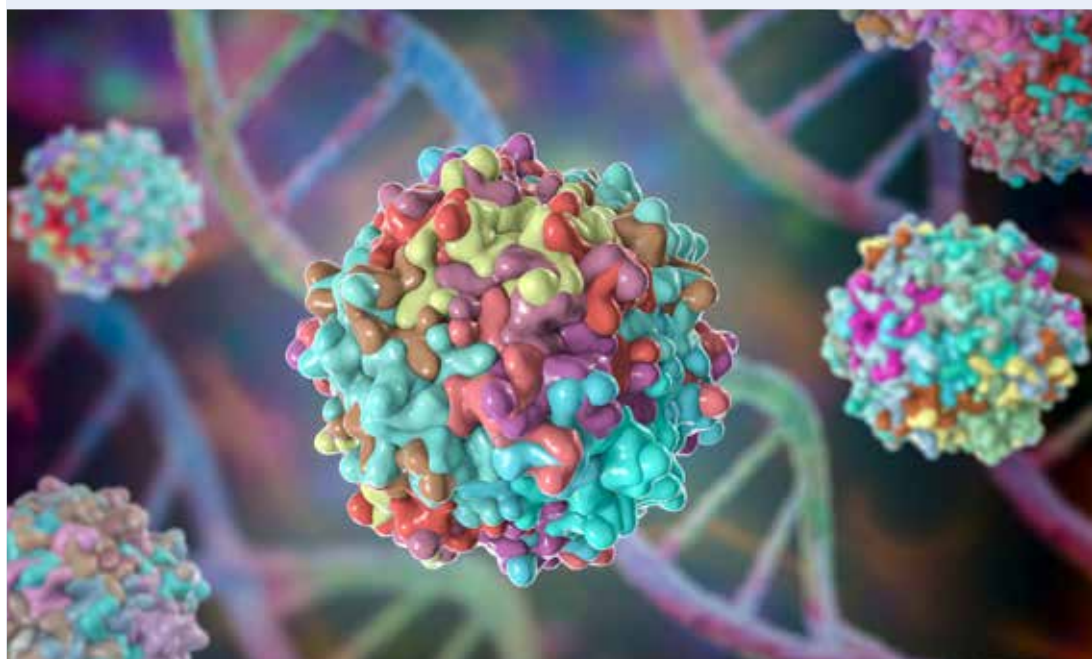
Dr Roland Pach
Roche

AAV Analytics

From Development to Batch Release



Live Online Training on 16 April 2026



Highlights

- Case Studies
- Establishing Specifications & Acceptance Criteria
- Method and Formulation Optimization
- Upscale/Scaling Production
- NGS

Suitable analytical methods to assess
AAV quality during development and
manufacturing

Objectives

Following a brief introduction to ATMPs and its regulations, this course will explore optimization strategies for the formulation, production, and analysis of adeno-associated viruses (AAVs). Participants will understand challenges and learn practical solutions for efficiency and compliance. The course highlights common obstacles and offers practical solutions demonstrated through case studies, providing insights into applying GMP principles in different scenarios.

In addition, expert speakers from manufacturing, research, and consultancy will share their experiences and lessons from GMP-compliant environments. Through their presentations, participants will gain a well-rounded understanding of the challenges and best practices in maintaining GMP compliance.

Background

Gene therapies are rapidly gaining popularity as a cutting-edge approach to treating a wide range of diseases, offering enormous potential to address conditions from degenerative diseases to rare congenital neurological disorders. These therapies have the potential to revolutionize medicine by targeting the underlying genetic causes of illnesses, providing long-lasting or even permanent therapeutic effects. Central to many DNA-based gene therapies is the use of viral vectors to deliver genetic material directly into the patient's cells, and among the various viral vectors available, the most commonly used and highly regarded is the adeno-associated virus (AAV).

The importance of AAV in the field of gene therapy cannot be overstated. Discovered in 1965, AAV has become the preferred vector due to its ability to efficiently transfer genetic material while exhibiting a relatively low immunogenic profile, meaning it is less likely to provoke an unwanted immune response. Additionally, AAV is known for its ability to transduce both dividing and non-dividing cells, making it a versatile tool for a variety of gene therapy applications. Its proven safety record, combined with its effectiveness in delivering therapeutic genes, has led to its widespread adoption in clinical trials and commercial gene therapies. AAV-based gene therapies are already showing promise in treating conditions such as spinal muscular atrophy, hemophilia, and certain inherited forms of blindness, highlighting their growing role in modern medicine.

However, as with any biopharmaceutical product, there are significant challenges associated with the development and production of AAV therapies, particularly in defining the appropriate Critical Quality Attributes (CQAs) that ensure the safety, efficacy, and consistency of the final product. Establishing these CQAs is a complex and highly regulated process, and failure to do so correctly can lead to inefficiencies, wasted resources, and even setbacks in the development process. Determining the best way to define and measure these CQAs—without wasting valuable time and financial resources—is a critical task for any organization working in AAV manufacturing.

This course will address these challenges head-on, providing valuable insights. It will explore strategies to optimize both the analytical methods and the manufacturing processes involved in the production of AAV-based gene therapies and their Quality Control. Participants will learn how to navigate these complexities efficiently and gain practical tools for improving the quality and scalability of AAV production, ultimately helping to bring these life-changing therapies to patients more quickly and reliably.

Target Audience

This course is addressed to all people involved in the day-to-day work of AAV with manufacturing, method development and optimisation and analysis. The course is designed so that participants with little or no experience, as well as those with years of experience, can learn new and important knowledge while working with AAV.

Moderator

Clemens Mundo, Concept Heidelberg

Programme

Introduction in ATMP and their Regulations

Dr Sabine Hauck

- EMA and ICH guidelines for ATMPs, focusing on Gene Therapy products
- GMP for ATMPs
- Pharmacopoeial texts for AAV (Pharm. Eur. 3186, 5.34 and 5.2.12, USP viral vectors)

AAV Bioprocess – Fundamentals & Trends

Roland Pach

- AAV platforms – Pro & Cons
- Manufacturing process
- CPP & cQAs
- Challenges & trends

Establishing Specifications for AAV Therapeutics – From Clinic to Commercial

Dr Kerstin Brack

- Unique characteristics of AAV therapeutic vectors and critical quality attributes
- Regulatory guidance documents for setting specifications
- Analytical procedures and phase-appropriate method qualification/validation
- How to establish specifications and acceptance criteria
- Key challenges

Identity Testing & Biosafety Testing of AAV with NGS

Anna Liznar

- Regulatory background of AAV quality control
- Virus detection for adventitious virus testing
- Genome identity & integrity testing

AAV Analytical Toolbox for Stability Assessment

Dr Sabine Hauck

- Selection of suitable methods
- Analysis of the stability indicating power
- Learnings for formulation development

Bioactivity for AAV Therapeutics

Dr Ulrike Herbrand

- Matrix approach
- MoA reflection
- Challenges related to references and control items



Dr Ulrike Herbrand
Charles River Laboratories
Scientific Director Global *in vitro* Bioassays

Ulrike Herbrand joined Charles River Laboratories in 2007. She is Scientific Director Global *in vitro* Bioassays and Head of the Bioassay Research & Development team at Charles River Laboratories' site in Erkrath, Germany. She gained a PhD in biological sciences during her time at the Max-Planck-Institute for Molecular Physiology in Dortmund (Germany) and worked five years at post-doctoral positions at medical research centers in the field of cancer research. She is an expert in mechanism of action-reflecting bioassays for protein therapeutics as well as for advanced therapy medicinal products.



Anna Liznar
PathoQuestUSP
Business Development Manager

Anna Liznar is a graduate from the University of Bayreuth in the field of RNA biochemistry. 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.

Speakers



Dr Kerstin Brack
Charles River Laboratories
Scientific Director, Global Biosafety

Dr Kerstin Brack works as a Scientific Director at Charles River Laboratories Germany GmbH since 2018 and is a subject matter expert for biosafety testing of biologicals. She holds a Diploma in Biology from the University of Bremen (Germany) where she subsequently also earned her PhD in Virology. In 2001 Kerstin joined NewLab BioQuality AG (now Charles River Laboratories Germany GmbH) as a Study Director in the Virology Department. Between 2004 and 2018 Kerstin headed the departments for biosafety testing and bioassay services at Charles River Laboratories Germany.



Dr Sabine Hauck
dequra pharma consult hauck
Freelance Consultant

Sabine Hauck has 20+ years of experience in the biotech industry, in which she held various positions in pharmaceutical development, quality assurance, regulatory affairs and corporate development. Her product experience spans from small molecules to cell therapies and includes a variety of dosage forms. After gaining experience in several biotech companies she is now providing freelance consulting and trainings for biotech and biopharma companies in the field of pharmaceutical development, quality assurance, and regulatory affairs. Sabine is also active as the chair of the ECA ATMP interest group.



Dr Roland Pach
Roche
Global Analytical Expert CMC Cell- & Gene Therapy & alternative formats

Prior Roche, he was leading the Analytical Development department at Berna Biotech and the QC department of Bio-Process Development at Merck Serono. Roland is the global CMC Analytical Technical Lead in the cancer vaccines and cell- & gene therapy (CGT) area of Roche more than 10 years. In his assigned area, he represents Roche in external development projects, industrial consortiums like CGT BioPhorum and numerous due diligences of in-licensing candidates or companies in the CGT fields. In his second role at Roche as global technical development leader, he had led successfully new formats like immunotoxins from pre-clinics into entry to human (EiH).

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.

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AAV Analytics – From Development to Batch Release
Live Online Training on 16 April 2026

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GERMANY

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- Cancellation until 4 weeks prior to the conference 10 %

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cellation 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.

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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 <https://www.gmp-compliance.org/privacy-policy>). 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

Thursday, 16 April 2026, 09.00 h – 15.30 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 € 790

APIC Members € 840

Non-ECA Members € 890

EU GMP Inspectorates € 445

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 22504.** To avoid incorrect information, please give us the exact address and full name of the participant.

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.

You cannot attend the live online event?

We also 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.

Conference Language

The official conference language will be English.

Organisation and Contact

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

CONCEPT HEIDELBERG

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