ECA Academy
Your GMP/GDP Information Source

Live Online Training

Speakers

Dr Anthony Blaszczyk
USP

Dr Sabine Hauck
Chair of ECA ATMP Interest Group

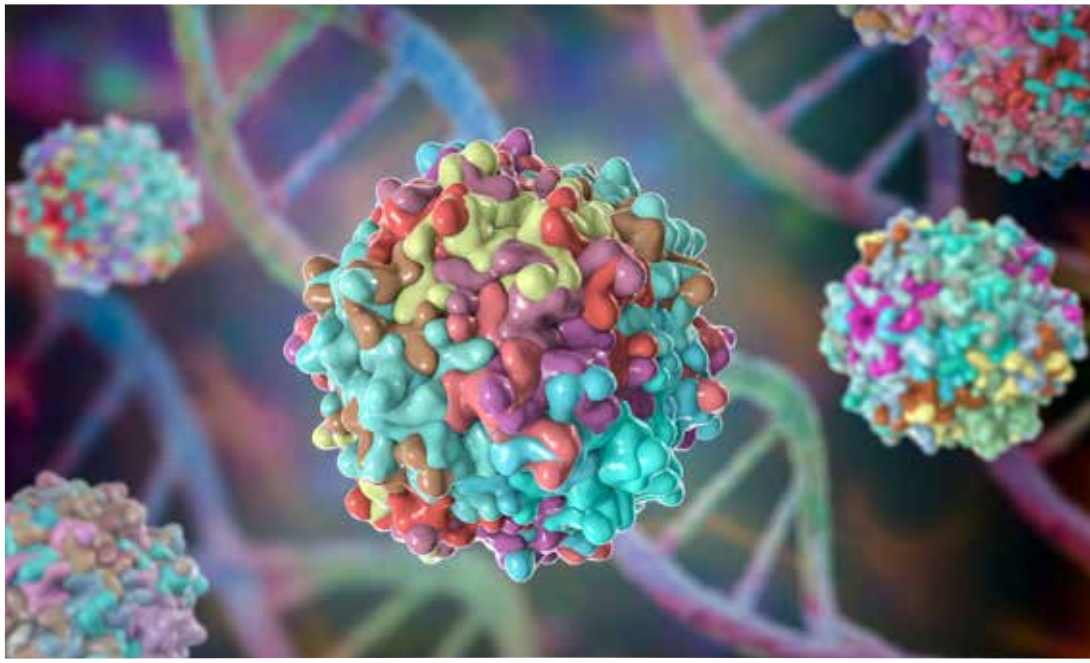
Dr Ulrike Herbrand
Charles River Laboratories

Christopher Perrin-Porzondek
Charles River Laboratories

Dr Rudolf Zirwes
Charles River Laboratories

SMART AAV Analytical Method Toolbox

Live Online Training on 25 April 2024



Highlights

- CQA
- Method and Formulation Optimization
- Upscale/Scaling Production
- Requirements and View of the Authority
- Testing of Impurities like Residual Nucleic Acid

Suitable analytical methods to assess AAV quality during development and manufacturing

Objectives

This course focuses on optimization possibilities of methods in the formulation, production and analysis of AAVs. Speakers from manufacturing, laboratory and authority will show their expectations as well as their experiences in GMP-compliant work.

Background

Gene therapies are becoming increasingly popular and offer great potential for treating diseases ranging from degenerations to congenital neurological disorders. Many DNA-based gene therapies use viral vectors to transfer the genetic material. The most common viral vector is the adeno-associated virus (AAV). Historically, this is not a new invention, it was already discovered in 1965.

With AAV, as with other products, it is always a challenge to define appropriate CQAs. But what is the best way to do this without wasting time and money? This question and how to make optimizations in analytics and manufacturing will be answered in this course.

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.

Moderator

Clemens Mundo, Concept Heidelberg

Programme

AAV Analytical Toolbox for Stability Assessment

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

Bioactivity for AAV Therapeutic

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

Development of USP Standards to Support AAV Therapeutics

- USP development of documentary standards
- USP development of physical standards
- Future direction of USP standard development for AAV

Building and Breaking AAV Processes

- How is development representative of future manufacturing scale?
  What data can we collect/analyze?
  How do we scale up?
- What tools do we have for making quick decisions?
  Are they worth the potential tradeoffs?
- What happens when something goes wrong?
  How can we be good stewards of time/resources?

Chemistry, Manufacturing and Control (CMC) Testing for AAV Therapeutics

- Identity testing
- Purity testing
- Safety testing

Speakers

Dr Anthony Blaszczyk
USP, Senior Scientist

Dr Anthony Blaszczyk is in the Pipeline Development group within USP's Global Biologics department. At USP, he works with scientific experts and stakeholders to develop new standards to support biopharmaceutical quality assessment and development. Prior to USP, Anthony worked at Catalent Cell and Gene Therapy, where he managed an analytical development team responsible for the development, qualification and transfer of methods. He obtained his Ph.D. in Biochemistry from Penn State University in 2018.

Dr Sabine Hauck
dequra pharma consult hauck

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 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.

Christopher Perrin-Porzondek
Charles River Laboratories, Director Research Services & Process Development

Christopher Perrin-Porzondek studied Biochemistry and Molecular Biology/Biotechnology. He has worked at VRL, Smithsonian Gardens and Vigene Biosciences before joining Charles River Laboratories in 2021. As Director in Research Service and Process Development, his responsibilities include administrative, budgetary and strategic planning, as well as technical, scientific and CMC consulting for client project development and research product manufacturing. He has specialized in the production of plasmid DNA, adeno associated virus, adenovirus and lentivirus during his career.

Dr Rudolf Zirwes
Charles River Laboratories, Global Coordinator Molecular Biology

Rudolf Zirwes joined Charles River Laboratories in 2007. He is Global Coordinator of Molecular Biology and Senior Scientist in the Research & Development team at Charles River Laboratories´ Erkrath site, Germany. He gained a PhD in cellular and molecular biology at the German Cancer Research Center (DKFZ Heidelberg). Rudolf has 20+ years of experience in the biotech industry, in which he held various positions in pharmaceutical drug discovery, development and quality control. His experience spans from small molecules to cell and gene therapeutics. In his current role, Rudolf is responsible for both local and global coordination and harmonization of assay development & validation activities for QC of advanced therapy medicinal products.

Your Benefit:
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.

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Reservation Form (Please complete in full)

SMART AAV Analytical Method Toolbox
Live Online Training on 25 April 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:
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- 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 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, 25 April 2024, 11.00 h – 18.00 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 € 690
APIC Members € 740
Non-ECA Members € 790
EU GMP Inspectorates € 395
The fee is payable in advance after receipt of invoice.

Registration

By e-mail 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.

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.

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