ECA Academy
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Speakers

Petra Falb
AGES

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Dr Bernd Renger
Bernd Renger Consulting

Dr Frank Sielaff
GMP Inspector

Dr Lyudmil Tserovski
BioNTech

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Genetically Modified Vaccines – Additional Guidance needed?

Live Online Training on 08 December 2021

Use of regulations and interaction with authorities

Highlights

- Regulatory Frame and Authority Expectations
- Case Study – mRNA Product – Regulatory Requirements and Hurdles
- Business and Healthcare Policy Perspectives - from Acceptability across the Entire Landscape of Stakeholders to the Contribution to Availability and Accessibility
- Quality and Facility - Requirements and Stumbling Blocks on the Way to Market Authorisation

Objectives

Genetic modification technologies were widely used for vaccine development during the COVID-19 pandemic, for other vaccines and for veterinary vaccines. Several products have been approved around the world. In the EU, products that protect against infection with an infectious organism are by definition vaccines. And as such, vaccines are excluded from the ATMP guidelines - even if technologically they use techniques known from gene therapy. Particularly in the case of approaches that were not previously approved as medicines, such as mRNA lipid nanoparticles, some companies face a regulatory environment that does not seem fully transparent to them and in which there appears to be a lack of appropriate guidance. This Live Online Training discusses the regulatory landscape for such genetically modified vaccines, especially when these gene therapy technologies overlap with traditional vaccine areas and vaccine regulations. This workshop will highlight the current regulatory situation and use case studies from manufacturers to show the challenges and hurdles in development, manufacturing and approval. It also seeks to identify the extent to which further guidance is needed beyond the existing guideline documents. One question could also be how this is viewed internationally when the requirements or classifications of the products differ, e.g. in Europe and in the USA.

Background

The quality of a medicinal product, and thus also that of a vaccine, is of crucial importance for its safety and efficacy and thus for its suitability for the patient. Given the growing recognition of the increasingly important role of biological medicines in healthcare worldwide, competent authorities have already published a whole range of guidelines and helpful documents. Products such as ATMPs, but also genetically modified vaccines, have the potential to transform patient and healthcare delivery worldwide. However, the development, characterisation and manufacture of these innovative medicines is particularly challenging due to their high complexity and emerging technologies. In the course of development, transfer and manufacture, new questions often arise that also need to be clarified from the regulatory side. Are further specifications from the authorities necessary for this? Where are there still gaps? What experience have manufacturers gained so far in the approval process? Especially with a view to worldwide use.

Target Audience

This Live Online Training is aimed at all staff and regulatory representatives involved in the development, manufacture, quality assurance and authorisation of vaccines and/or ATMP in general and gene therapy medicines in particular.

Programme

Welcome and Introduction
Dr Sabine Hauck and Axel H. Schroeder

Current Regulatory Framework for Genetically Modified Vaccines
Petra Falb, AGES

- Relevant guidelines
- Licensing regulatory background

Case Study – mRNA Product – Regulatory Requirements and Hurdles
Lyudmil Tserovski, BioNTech

- Basic mechanism of action of mRNA based vaccines and anti-cancer ATMPs
- GMP aspects of mRNA-based medicinal products (manufacturing and control)
- Regulatory aspects depending on the type of medicinal product (ATMP or Vaccine)
- Challenges concerning the supply chain and the QP certification

Regulatory GMP Landscape
Frank Sielaff, c/o Local Council Darmstadt

- Relevant GMP guidelines
- What is in focus of a GMP inspection and what is not?
- GMP challenges

Possible (Quality) Pitfalls on the Way to Marketing Authorisation
Bernd Renger, former Chair of the European QP Association

- What quality systems and GMP compliance level to expect
- API and formulated API (LNP)
- Novel excipients
  - Functional and structural lipids
  - Polymerosomes
- Oligodeoxynucleotide adjuvants

Vaccines and Gene Therapy - Same but Different
Peter Walters, CRB

- Way of manufacturing vs. route of administration vs. legally classification
- The complication that vaccine technologies have evolved, but are still regulated under different conditions
- How the future of the industry will possibly need to be updated in the wake of gene therapy innovation

Business and Healthcare Policy Perspectives
Pierre A. Morgon, PharmD, MBA, LL.M

- From acceptability across the entire landscape of stakeholders to the contribution to availability and accessibility

Speakers

Petra Falb, AGES

Vaccines expert (AGES-BASG) - Austrian CVMP Member (EMA) - CVMP Immunologicals Working Party (EMA)

Petra Falb studied at Veterinary University Vienna, Austria. From 1998 – 2001 she worked as scientist at the Institute for Virology and later at the Institute for pathology. 2001-2003 she was self employed as veterinary surgeon. In 2003 she joined the AGES with responsibilities in quality assessment of human and veterinary vaccines (national, decentralised and centralized procedures). Until 2016, her focus was on viral vaccines. In 2017 she took over new responsibilities for veterinary vaccines.

Pierre A. Morgon, PharmD, MBA, LL.M, MRGN Advisors

CEO & Founder

Pierre studied at the university Claude Bernard and Jean Moulin Lyon. Additionally he is trained in Marketing, Marketing Management and General Management. Today he is CEO of MRGN Advisors in Geneva, Switzerland. Additionally, he is director at the board of 8 companies, and a partner in private equity funds investing in life sciences.

Dr Bernd Renger, Bernd Renger Consulting

CEO and former Chair EQPA

Dr Renger started at Hoechst AG. Since then, he has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna and Vetter Pharma-Fertigung. He was a member of the European Compliance Academy (ECA) Advisory Board and is Immediate Past Chair of the European QP Association.

Dr Frank Sielaff, c/o Local Council Darmstadt

GMP Inspector

GMP Inspector at the Regierungspräsidium Darmstadt with focus on Inspection of drug manufacturers and laboratories in Germany and countries outside of the EU. Before joining the GMP-inspectorate Frank was several years employed in the pharmaceutical industry as Head of Quality Control and as Qualified Person.

Dr Lyudmil Tserovski, BioNTech

Qualified Person

Lyudmil studied mathematics with computer science as well as pharmacy at the Universities Darmstadt and Mainz. After 4 years of research and acquiring a PhD at the University Mainz he joined BioNTech IMFS in2017 as scientist in the QC RNA Manufacturing. Today, he is a QP for ATMPs at BioNTech SE.

Peter Walters, CRB

Director, Advanced Therapies

Peter studied Chemical Engineering at UC Davies. From 2004 to 2012 he worked at Pacira Pharmaceuticals. He joined CRB in 2012 as Process Engineer. Today, he is Director Advanced Therapy Medicinal Products (ATMPs).

Moderators

Dr Sabine Hauck,
Leukocare, Chair of the ECA ATMP Interest Group

Axel H. Schroeder,
Concept Heidelberg, Administration Manager of the ECA ATMP Interest Group

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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Reservation Form (Please complete in full)

Genetically Modified Vaccines – Additional Guidance needed?
Live Online Training on 08 December 2021, 12.00 - 17.00 h CET

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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Date of the Live Online Training
Wednesday, 08 December 2021,
12.00 - 17.00 h CET

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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 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.

Ordering Recordings
Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

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

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