GMP COMPLIANT MANUFACTURING OF COVID-19 VACCINES

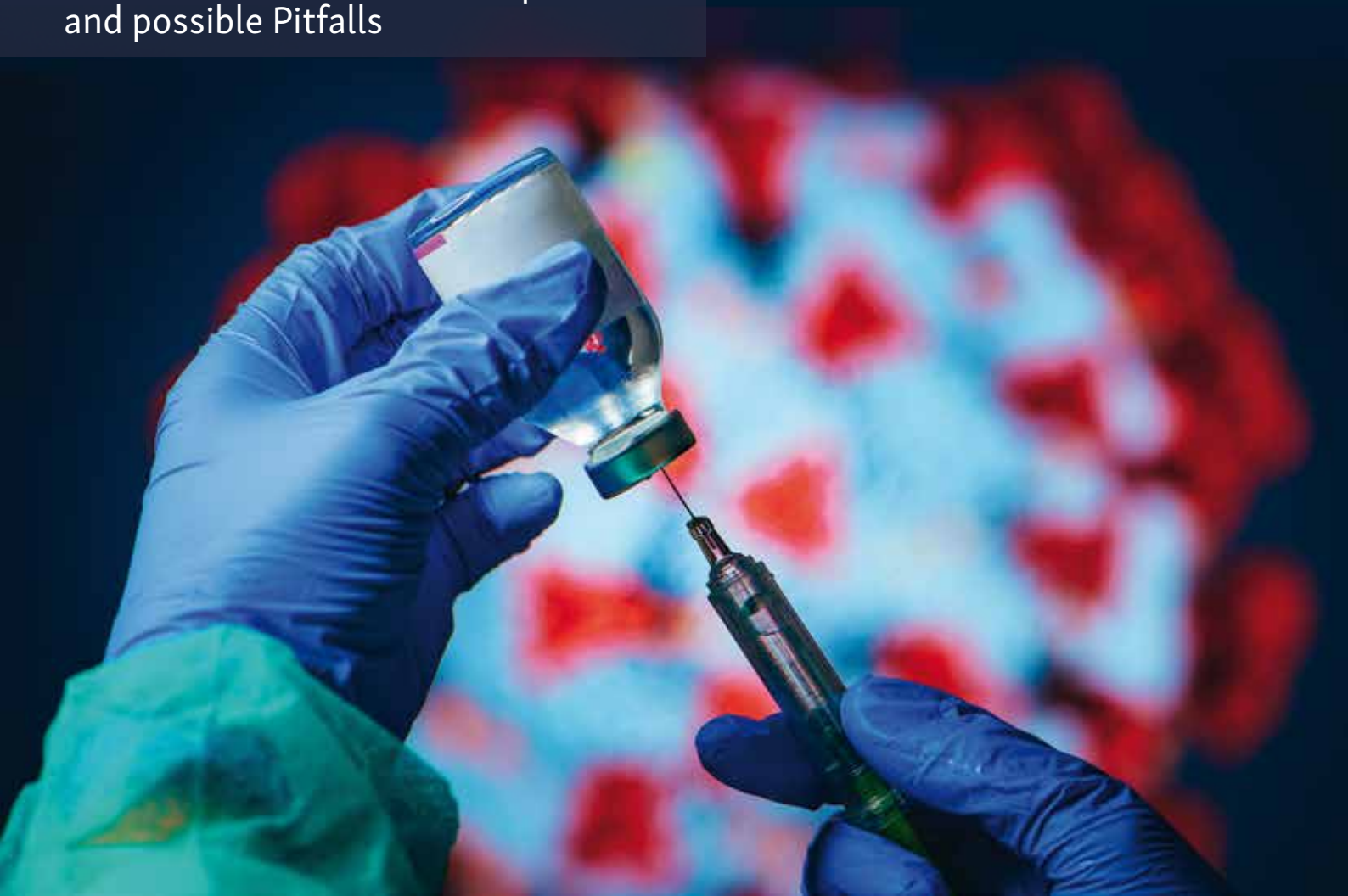
10/11 March 2021

PAUL-EHRLICH-INSTITUTE AND ECA JOINT WORKSHOP | LIVE ONLINE

Paul-Ehrlich-Institut

ECA Academy
Your GMP/GDP Information Source

A brief Overview on GMP Requirements and possible Pitfalls



Overview

Highlights

- GMP Guidelines
- Zoning and HVAC Systems
- Qualification of Production Lines
- Upscaling
- Upstream and Downstream
- Quality Aspects
- Characterisation, Control and Release
- Microbiological Safety
- Batch Release

Objectives

The objective is to provide a training opportunity for unexperienced staff and a discussion forum for experienced personnel on specific COVID-19 vaccine-related questions. Next to the above-mentioned topics the invited speakers will cover GMP issues, microbiological and viral safety aspects, QC and environmental monitoring aspects as well as important regulatory issues and framework.

Background

Vaccine development and manufacturing are crucial for control of the COVID-19 pandemic. Platform technologies have enabled rapid development of vaccines with demonstrated efficacy against COVID-19. However, large-scale manufacturing is prerequisite for meeting the global demand. This implies upscaling of manufacturing, meeting GMP requirements and switching of manufacturing in existing facilities. The workshop organized by PEI and the ECA Foundation will address these topics and provide an overview on GMP for vaccines and practical insights from experts in the field.

Target Audience

This workshop is aimed at all persons involved in vaccine licensing and production:

- GMP compliance in manufacturing
- The necessary room and technical requirements
- Upscaling of manufacturing
- Upstream and Downstream
- Inspections and audits
- Quality control, quality assurance and release issues

Moderators

Prof Dr Isabelle Bekeredjian-Ding
Paul-Ehrlich-Institute

Axel H. Schroeder
Administration Manager, Pharmaceutical Microbiology Working Group

Presentations

National, European, Old and New Responsibilities of the Paul-Ehrlich-Institute in Light of COVID-19

Prof Dr Isabelle Bekeredjian-Ding, Paul-Ehrlich-Institute

Regulatory GMP Requirements: Guideline Overview

Dr. Rainer Gnibl, GMP Inspector, Government of Upper Bavaria

- Requirements from drug law
- Applicable EU-GMP Guidelines
- GMP-Essentials for facility, equipment & process

HVAC Systems and Zoning

Part 1: GMP Compliance in Design and Construction

Robert Funcke, Infrasolution

- Construction Requirements
- Technical Solutions

Part 2: Zones and Ventilation Concepts in the Clean Room

Dr Jürgen Blattner, BSR Ingenieurbüro

- Zoning and pressure cascades
- Minimum requirements
- Combination of product and personal protection

Design and Qualification of Production Lines

Dr Daniel Minör, IDT Biologika

Containment, Biological Safety and Product Protection

Robert Schwarz, FH Campus Vienna formerly Baxter

- Containment, product safety versus environmental safety
- Primary containment and additional measures
- Negative pressure areas in aseptic manufacturing
- Decontamination of facilities
- Personnel as critical component in containment

Temperature-Controlled Transports of Medicinal Products

Peter Kralinger, Carrymed Pharma & Transport

- Insulated packaging for small and large quantities
- Road transport and air freight of cold chain products (2 – 8 °C)
- Transport and storage at ultra-frozen range (-70 °C)

Speakers of the Workshop

Development of Regulatory Requirements for COVID-19 Vaccines in an Emergency Situation – Focus on Quality

Dr Elena Grabski, Paul-Ehrlich-Institute

Platform Based Approach for Fast Track Development and Upscale of Manufacturing of an MVA Vaccine Candidate

Dr Simone Kardinahl, IDT Biologika

- IDT Biologika has been using its well established technology platform to jump start development of an MVA-base Covid-19 vaccine
- Highlights and Challenges of transferring a candidate into early development and later on into clinical manufacturing for Phase I and Phase II are presented
- Fast Track Analytical methods as well as additional extended characterization are supporting the development concept

GMP Issues for Upstream/Downstream Processing

Dr Joerg Weyermann, GSK Vaccines

- GMP requirements in manufacturing
- Issues and challenges during vaccine manufacturing
- New trends and techniques

COVID-19 Vaccines – Analytics & Process Transfer, Characterisation & Control

Dr Markus Fido, MFI Bio-Consulting

- Different vaccines – same goal
- Analytical product characterization during process development (USP/DSP)
- Product specification, release and stability

Microbiological Safety Testing – Accelerating Implementation of Rapid Sterility for Lot Release Testing

Stacey Ramsey, Charles River Laboratories

- Alternative Method Validation Journey
- Overcoming hurdles for rapid method implementation
- Case studies for completed projects and regulatory status

EU Control Authority Batch Release of Vaccines

Dr Volker Öppling, Paul-Ehrlich-Institute

- Principles of EU mutual recognition system
- Protocol review and testing by the agency
- COVID-19 related network activities

Prof Dr Isabelle Bekeredjian-Ding
Head of Microbiology, Paul-Ehrlich-Institute
Prof. Bekeredjian-Ding is physician by training with clinical specialization in Medical Microbiology, Virology and Epidemiology of Infection and a strong research background in immunology of infection. She was appointed Head of the Division of Microbiology at PEI in 2015. She is member of the ECA Foundation Regulatory Advisory Board on Pharmaceutical Microbiology, Member of the CHMP Vaccines Working Party at the EMA and Chair of the IMI2 Scientific Committee.

Dr Jürgen (Ing.) Blattner
CEO, BSR Ingenieurbüro
Jürgen studied at the technical University Karlsruhe with focus on particle measuring and filter technologies. After that he worked for Palas with responsibilities in filter testing, aerosol generation and measuring. 2003 he founded his own company BSR with activities and services in cleanroom qualification, monitoring and the necessary equipment.

Dr Markus Fido
CEO, MFI Bio-Consulting
Markus Fido holds a PhD in biochemistry & immunology. He has worked in different quality & product development departments at Baxter, Octapharma, & Novartis with increasing responsibility. In 2006 he has founded VelaLabs which he led as a CEO for 15 years, the last 5 years together with the new owner, the Tentamus Group. He is also in charge for Meridian Biopharma – acting in the field of cancer immune therapy. In May 2020 he started his consulting & training business with his new company, MFI Bio-Consulting.

Robert Funcke
International Sales, Infrasolution
Mr Funcke was Project Manager of some major TFS companies in Germany. He was realizing substantial cleanroom projects, both nationally and abroad, serving industrial clients in the field of electronics, pharmaceuticals and food.
He led caverion GmbH as managing partner for several years and joined Infrasolution in 2020. At InfraSolution AG, Mr Funcke takes care of the regional and international sales activities.

Dr Rainer Gnibl
GMP Inspector, Government of Upper Bavaria
Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

Dr Elena Grabski
Quality Assessor, Paul-Ehrlich-Institute
Elena studied biochemistry at Goethe University Frankfurt and did her PhD at the Institute of Experimental Infection Research, TWINCORE Center for Experimental and Clinical Infection Research GmbH, Hannover, Germany. She worked there as a PostDoc until 2016. In 2016, she moved to the Paul-Ehrlich-Institute, Section 'Viral Vaccines'.

Dr Simone Kardinahl
Vice President of Development, IDT Biologika
Simone Kardinahl is Vice President of Development at IDT Biologika GmbH and has over 20 years of experience in the pharmaceutical industry from different positions in Research, Development and Manufacturing of Biologics products. She studied Biochemistry at the University of Hannover and received her Ph.D. in Biochemistry from the University of Lübeck.

Peter Kralinger
Managing Director, Carrymed Pharma & Transport, Austria
Peter Kralinger is Managing Director of Carrymed, the first licensed pharma company providing international transport of temperature-sensitive pharmaceuticals. Before that he was in charge of the global transportation activities for all manufacturing sites in Europe of a large manufacturer of the pharmaceutical industry.

Dr Daniel Minör
IDT Biologika
Daniel Minör received his doctorate from the Heinrich Heine University Düsseldorf. His Thesis: Influence of intracellular nucleotide cofactors on redox reactions in recombinant whole cell systems.

Dr Volker Öppling
Paul-Ehrlich-Institute
After the study of Veterinary Medicine and his PhD he got appointment for specialist of Veterinary Microbiology in 1993. From 1990-2007 he was scientist in a section responsible for human bacterial (especially polysaccharide based) and fungal vaccines in the Department "Human Bacterial Vaccines" at the Paul-Ehrlich-Institute.

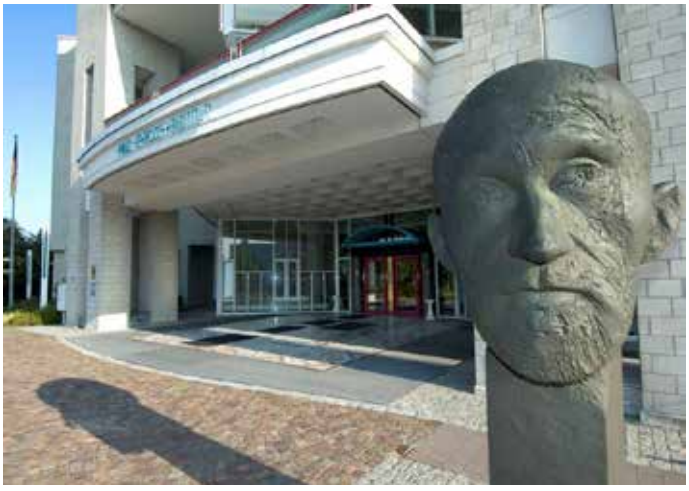
Stacey Ramsey, MS, SM (NRCM)
Senior Manager, Celsis Technical Services and Validation – Microbial Solutions, Charles River Laboratories
Stacey Ramsey is a career microbiologist with more than 15 years of experience in the pharmaceutical industry. She worked for the generics and contract pharmaceutical manufacturing company, Hospira, where she gained experiences in environmental monitoring, drug product testing, endotoxins testing, and process and method development and validation. Stacey relocated to North Carolina where she has also worked in contract labora-

tory testing, focusing on implementation of new processes, including rapid microbiology. Stacey joined Charles River in 2019 and located in Charleston, South Carolina, USA.

Robert Schwarz
Lecturer Qualification/Validation, Technical University Vienna
Robert Schwarz studied biotechnology and quality management. He joined Baxter in 2001 as coordinator of environmental monitoring. From 2005 he was validation specialist, responsible for equipment qualification, sterilisation validation and cleaning validation. Since 2010 he has been university lecturer in the field of biotech at the University of Applied Sciences in Vienna.

Dr Jörg Weyermann
Senior Quality Lead, GSK
Joerg Weyermann is a pharmacist by education. Currently he is the Quality Lead for the implementation of a new vaccine facility. Before he was responsible for different areas as Head Quality Assurance at GSK Vaccines, former Novartis Vaccines and Diagnostics GmbH. Until 2009 he was the Head Quality Operations for Sandoz Industrial Products GmbH. Before that he was Head Quality Control at Sandoz.

About the Paul-Ehrlich-Institute (PEI)



The Paul-Ehrlich-Institute is the Federal Regulatory Institute for Vaccines and Biomedicines. It reports to the German Federal Ministry of Health (Bundesministerium für Gesundheit) and serves as the German competent authority with responsibility for licensing of biomedicines and vaccines, approval of clinical trials, batch release of vaccines and other biomedicines, pharmacovigilance and regulatory research. The PEI offers national scientific advice and is involved in all regulatory issues concerning COVID-19 vaccines on national and EU levels.

Date of the Live Online Workshop

Wednesday, 10 March 2021, 14.00 – 18.00 h
Thursday, 11 March 2021, 14.00 – 18.00 h
All times mentioned are CET.

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and e-mail address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate plus VAT)

EUR 350.-
The conference 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.microbiology-conference.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.

Organisation and Contact

PEI and ECA have entrusted Concept Heidelberg with the organisation of this event.

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Reservation Form (Please complete in full)

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Live Online Workshop, 10/11 March 2021

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Important: Please indicate your company's VAT ID Number **Purchase Order No. if applicable**

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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
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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).

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