ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Biotech Manager

Speakers

Dr Eduard Ayuso
Dinamiqs

Dr Constanze Blume
BioNTech

Dr Karin Cooke
Gen-Plus

Dr Markus Dachtler
DiHeSys

Markus Grüll
Autolus

Thorsten Häfner
PSM

Small Batches

Special Handling and Production

Live Online Training on 12/13 March 2024

Highlights

- Various Case Studies on the Use of robotic Applications, Filling and the Path to Commercialisation from different Perspectives
- Handling with Batch Size 1
- Personalized Medicine
- Regulatory and CMC Aspects

Objectives

The training deals with the special features production and quality control of small and very small batches down to batch size 1. The pharmaceutical industry is increasingly faced with the following questions how these products can be economically manufactured and economically. The seminar provides answers to these questions and a precise overview of authorization issues, regulatory environment, manufacturing methods approaches, quality control through to the details from the transition from pre-clinical to commercial stage.

Background

While constant efforts are being made to increase the production of many medicinal products, this is not possible for all of them, as various further developments, such as improved diagnostics or personalized medicine, as well as economic constraints and the diversification of production for different target markets are leading to ever smaller batches down to a batch size of 1 in the case of patient-specific products. Due to developments in recent years and the increasing number of new personalized medicines, the issue of small batches with a worst-case batch size of 1 has become more important. The EDQM, the FDA and other institutions are attempting to create uniform regulations for personalized products with new draft guidelines. However, batch size is rarely considered.

The influence of batch size on the manufacture of a product is immense and affects several areas and should be considered at an early stage. These changes require new concepts in the areas of analysis, filling, production planning and processing and much more.

Target Audience

Employees in development, production and quality control of small batches, personalized medicine, specific ATMPs, contract manufacturing and testing.

Programme

Robotic Application in aseptic Contract Filling for Small Batches of ATMPs

Thorsten Häfner

- Latest system concepts
- Case Study: Advantages for product and employee protection with a focus on ATMPs

Small Batch Filling - the Path from Phase 1 to commercial Product

Thorsten Häfner

- Challenges in product developments in clinical trials
- Case Study: Clinical Phase to commercial filling – Lessons Learned & Best Practices

Personalized Medication – Part 1

Dr Markus Dachtler

- Digital printing in healthcare
- Printing technologies for personalized medication via 2D- and 3D-printing
- Use of 2D and 3D printers in pharmacies

Personalized Medication – Part 2

Dr Karin Cooke

- Manufacturing of intermediates for 2D and 3D printing
- QC in 2D and 3D printing (release, stability and IPC)
- Case study 1: 2D printed ODF containing Midazolam with personalized dosing
- Case study 2: 3D printed tablet (polypill)

The Journey of the first UK CAR-T Product from pre-clinical to commercial Stage

Markus Grüll

- Transition from R&D to GMP
- Conducting a global ATMP trial during COVID
- Buildout of own commercial GMP manufacturing site
- Pathway to Commercialisation under RMAT (FDA), ILAP (UK) and PRIME (EU) programmes

Manufacturing viral Vectors for rare Disorders

Dr Eduard Ayuso

- How to manage process development with time and budget limitations: a platform approach
- Analytical development, qualification of methods and product specifications
- Small but specialized fill & finish operations

mRNA-based Medicines - Regulatory and CMC Aspects
Dr Constanze Blume

- Platform approach – how to use for traditional and individualized products
- BioNTainer – decentralized manufacturing concept for pandemic preparedness and clinical material (Rwanda and Australia)

Speakers

Dr Eduard Ayuso, Dinamiqs
CEO
Dr Eduard Ayuso is the CEO of Siegfried DINAMIQS, a CDMO providing manufacturing services, process development, quality control and analytics solutions. He is an expert in the field of gene therapy using viral vector platforms, including their design, manufacture, and purification. He was previously the CTO at DiNAQOR, a genetic medicine platform company. He also served as Head of Innovative Vectorology at INSERM, and as the Scientific Director of the Translational Vector Core at the University of Nantes. Dr Ayuso earned his Ph.D. in Biochemistry and Molecular Biology and his degree in Veterinary Medicine from the Autonomous University of Barcelona.

Dr Constanze Blume, BioNTech
Senior Vice President Global Regulatory Affairs
Constanze Blume, PhD is SVP of Global Regulatory Affairs at BioNTech. She joined the company in September 2018 and established the Global Regulatory Affairs team. Since mid 2020 she supported as global regulatory lead the development, registration, and lifecycle of the COVID-19 mRNA vaccine (COMIRNATY) in collaboration with Pfizer. Currently, she is working on development projects in immuno-oncology incl. the individualized mRNA cancer vaccine platform and other projects such as BioNTainer. Before joining BioNTech Constanze gained experience in several areas of regulatory affairs, mainly oncology pipelines of biologics and IVD platforms as well as market access initiatives and assets transfers.

Dr Karin Cooke, Gen-Plus
Chief Scientific Officer
After completing her PhD in Analytical Sciences – Clinical Pharmacy, Karin Cooke has held various positions in pharmaceutical and nutraceutical product development and manufacturing in Austria, Germany and the USA. With almost 20 years of professional experience, she is now CSO at Gen-Plus GmbH and has been Director Business Developer North America at Conscio Pharma since 1 December 2023. She also works as a pharmaceutical consultant.

Dr Markus Dachtler, DiHeSys
CEO
From 2000-2004 Dr Markus Dachtler was employed as scientist at Unilever R&D, Vlaardingen, the Netherlands. From 2004-2015 he joined ratiopharm (since 2010 within Teva group), Ulm, Germany and worked in different departments (Stability control, R&D Project Management, General Management). In June 2015 Dr Markus Dachtler acquired Gen-Plus (now part of Conscio group) in Munich, Germany. He is also co-founder and CEO of the company DiHeSys Digital Health Systems. The company started its business in 2018 as healthcare provider for personalized medication delivering systems for 2D- and 3D Drug Printing (hardware, software, and printable drug formulation in cartridges).

Markus Grüll, Autolus
VP Head of Quality, QP
With more than 20 years of professional experience in various areas of clinical pharmacy and aseptic manufacturing, Markus Grüll has worked in different quality and production functions at companies such as Parexel. He joined Autolus in 2019 as Director QA/QP and is currently Head of Quality, responsible for QA, QC and GxP Systems, and leading the inspection readiness for upcoming GMP and GCP inspections by FDA, EMA and MHRA as part of the commercialisation process for Autolus' first commercial CAR-T cell product. He has also been responsible for the Quality oversight of the buildout of Autolus' own GMP manufacturing site 'The Nucleus'.

Thorsten Häfner, PSM
VP Business Development
Before Thorsten Häfner began his role as VP Business Development and authorized signatory at the German CDMO PSM GmbH in Schiffweiler in Saarland in 2023, he had previously worked for many years as Head of Product and Business Development at a German machine manufacturer for aseptic filling. His focus was on the development of system concepts that comply with the new EU GMP Annex 1, but also emphasize the use of robotics and minimize human intervention in the pharmaceutical process. At PSM, Thorsten Häfner is now the main point of contact for customer enquiries relating to aseptic contract filling and is also in charge of project management.

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Reservation Form (Please complete in full)

Small Batches
Live Online Training on 12/13 March 2024

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

City

ZIP Code

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E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
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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 %,
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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 July 2022).
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, 12 March 2024, 13.00 h – 17.45 h
Wednesday, 13 March 2024, 13.00 h – 16.30 h
All times mentioned are CET

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 € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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.

You cannot attend the Live 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.

Organisation and Contact

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

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WA/12122023