

Analytical Technologies Europe: Symposium on Analytical Sciences and Regulatory Trends in the Biopharmaceutical Industry 2023

Schedule

Tuesday, 9 May, 2023

09:30-17:00 Conrad Suite

Short Course: Characterization of Biopharmaceuticals

Eef Dirksen, Marta Germano, Sigrid Roosendaal

This pre-conference course addresses the different aspects which are relevant for the characterization of biopharmaceutical products according to regulatory guidelines and expectations.

NOTE: Registration for the short course is an additional fee and is not included in the regular registration fee.

The course will cover the entire process from defining a characterization strategy to writing of the characterization sections of regulatory files, taking into account the expectations at different phases of clinical development. Current regulatory guidelines, the advanced analytical technologies available for characterization, how characterization can support determination of critical quality attributes, and the different purposes of product characterization will be discussed.

This course is intended for scientists and others involved in CMC development of biopharmaceuticals. No specific analytical technology or regulatory expertise is required. It is expected that participants have some knowledge about biological molecules.

The aim of the course is to enable you to understand the concept of biopharmaceutical product characterization, develop and execute a characterization strategy, and be able to describe a characterization package in line with regulatory guidelines.

Wednesday, 10 May, 2023

08:30-09:00 Upper Lobby

Registration

Registration will be open until 17:00.

09:00-09:15 Le Jardin

Welcome and Introductions

Birgit Schmauser

09:15-10:10 Le Jardin

Keynote I

Birgit Schmauser

Mass Spectrometry of Oligonucleotides: Sequencing, Folding, Self-assembly and Interactions

Valérie Gabelica, *European Institute of Chemistry and Biology (IECB - CNRS, Inserm and University of Bordeaux)*

10:10-10:40 Upper Lobby

Networking Break

10:10-10:40 Upper Lobby

New Member Networking Break

10:40-12:25 Le Jardin

Session I: Gene Therapies and Vaccines

Carl Jone, Cari Sanger - van de Griend

Speakers:

Joost Snijder, *Utrecht University*

Ten Years of AAV Analysis by Native Mass Spectrometry

Maria Schwarz, *Solvias AG*

The Mystery of the LNPs - A Short Story of Capillary Electrophoresis, Nucleic Acid and Nanoparticles

Daan Crommelin, *Utrecht Institute for Pharmaceutical Sciences, UIPS*

mRNA-lipid Nanoparticle COVID-19 Vaccines: Structure and Stability

12:25-13:25 Roots Restaurant

Lunch

13:25-14:30 Rotterdam Room

Roundtable Session

Roundtable Topics:

1. Process Analytical Technology (PAT)
2. Platform Analytical Procedures – Does one size fit all?
3. Release vs Characterization Tests
4. Stability-indicating Methods
5. Career Development
6. Gene Therapies and Vaccines

14:30-15:00 Upper Lobby

Networking Break

15:00-16:45 Le Jardin

Session II: Analytical Challenges

Christof Finkler, Harold Taylor

Speakers:

Mercedes de Frutos, *Institute of General Organic Chemistry (IQOG-CSIC)*

Capillary Electrophoresis of Health-relevant Glycoproteins

Eline van den Berg, *Byondis B.V.*

Switching Positions: Assessing the Dynamics of Conjugate Heterogeneity in ADCs using CE-SDS

Gabor Jarvas, *University of Pannonia*

Protein Analysis by Native and SDS Capillary Gel Electrophoresis Coupled to Electrospray Ionization Mass Spectrometry using a One-dimensional Direct Online Connection

16:45-17:15 Le Jardin

Technical Seminar presented by Bruker

17:15-18:15 Upper Lobby

Exhibitor Reception

Thursday, 11 May, 2023

08:30-09:00 Upper Lobby

Registration

Registration will be open until 17:00.

09:00-09:05 Le Jardin

Daily Announcements

09:05-10:00 Le Jardin

Keynote Session II

Marta Germano

Advanced Approaches to Characterize Stability and Dynamics of Single Particles in Real-time
Wouter Roos, *Groningen University*

10:00-10:30 Upper Lobby

Networking Break

10:30-12:20 Le Jardin

Session III: Control Strategies

Marta Germano, Harold Taylor

Speakers:

Vanessa Wong, *AstraZeneca*

Development of an Analytical Toolbox for the Detection, Confirmation, and Characterisation of Partially Reduced Species in Monoclonal Antibodies

Lars Geurink, *Janssen Vaccines & Prevention B.V.*

AQbD Method Control Strategy

Bastiaan Duivelshof, *University of Geneva*

How to Use Protein Specific Retention Behaviour to Improve the Characterization of Therapeutic Antibodies

12:20-12:50 Le Jardin

Technical Seminar presented by Bio-Techne

12:50-13:50 Roots Restaurant

Lunch

13:50-15:35 Le Jardin

Session IV: Regulatory Trends

Mihaela Buda, Christof Finkler

Speakers:

Marcel Hoefnagel, *CGB-MEB*

Francesca Luciani, *National Centre for the Control and Evaluation of Medicines (CNCF)*

Robert Bream, *European Medicines Agency*

15:35-16:05 Le Jardin

Technical Seminar presented by Cygnus Technologies

16:05-17:05 Upper Lobby

Poster Session

18:00-22:00

Conference Event

We are excited to host all attendees for dinner at the Stadshaven Brouwerij. This unique waterfront gastropub and brewery is located in a 100-year-old, fully restored fruit warehouse and produces almost 2 million litres of craft beer annually. From Dutch classics to Asian ingredients and street-style dishes to gourmet, this gastropub combines popular comfort flavors from around the world. We will depart from the lobby of the Hilton Rotterdam at 18:00. Don't miss what is sure to be a special evening!

Friday, 12 May, 2023

08:00-09:00 Upper Lobby

Registration

Registration will be open until 15:00.

09:00-09:05 Le Jardin

Daily Announcements

09:05-10:20 Le Jardin

Emerging Professionals Showcase

Carl Jone, Cari Sanger - van de Griend

Speakers:

Anouk Arts, *Janssen Infectious Diseases and Vaccines*

Novel 2D-LC Method for Monitoring Adenovirus Degradation in Vaccine Products

Simeon Hubbard, *University of York*

Development of Workflows for O-glycan Profiling and Structural Characterisation of Biopharmaceuticals

Rebecca Wiesner, *University Braunschweig*

Capillary Zone Electrophoresis-UV: An Interlaboratory Study Investigating Various Monoclonal Antibodies, Instruments, and ϵ -aminocaproic Acid Lots

10:20-10:30 Le Jardin

Poster Award Presentation

10:30-11:00 Upper Lobby

Networking Break

11:00-12:00

Workshop: Surrogate Assays

Birgit Schmauser, Harold Taylor

12:00-13:00 Roots Restaurant

Lunch

13:00-14:45 Le Jardin

Session V: Novel Technologies & Improvements in Analytical Technologies

Marta Germano, Harold Taylor

Speakers:

Debbie van der Burg, *MPYA Sci&Tech*

Integrated Platform for In-line/At-line USP Analysis of mAbs and Nutrients

Marieke Klijn, *Delft University*

PAT for Data-driven Bioprocess Development

Kang Chen, *CDER, FDA*

Direct Assessment of Oligomerization of Chemically Modified Peptides and Proteins in Formulations using DLS and DOSY-NMR

14:45-15:00 Le Jardin

Closing Comments

Harold Taylor