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

### Schedule

**Tuesday, 9 May, 2023**

<table>
<thead>
<tr>
<th>Time</th>
<th>Location</th>
<th>Event</th>
</tr>
</thead>
</table>
| 09:30-17:00   | Conrad Suite                                                             | **Short Course: Characterization of Biopharmaceuticals**<br> 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**

<table>
<thead>
<tr>
<th>Time</th>
<th>Location</th>
<th>Event</th>
</tr>
</thead>
</table>
| 08:30-09:00   | Upper Lobby                                                               | **Registration**  
Registration will be open until 17:00. |
| 09:00-09:15   | Le Jardin                                                                 | **Welcome and Introductions**<br> Birgit Schmauser |
| 09:15-10:10   | Le Jardin                                                                 | **Keynote I**<br> 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**  
New Member Networking Break |
10:40-12:25  Le Jardin
Session I: Gene Therapies and Vaccines
Carl Jone, Cari Sänger - van de Griend
Speakers:
Joost Snijder, Utrect 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, UIIPS
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 Heterogeniety in ADCs using CE-SDS
Gábor Járvás, 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
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 Stadhaven 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 Sänger - 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
<table>
<thead>
<tr>
<th>Time</th>
<th>Location</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:30-11:00</td>
<td>Upper Lobby</td>
<td>Networking Break</td>
</tr>
<tr>
<td>11:00-12:00</td>
<td></td>
<td>Workshop: Surrogate Assays</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Birgit Schmauser, Harold Taylor</td>
</tr>
<tr>
<td>12:00-13:00</td>
<td>Roots Restaurant</td>
<td>Lunch</td>
</tr>
<tr>
<td>13:00-14:45</td>
<td>Le Jardin</td>
<td>Session V: Novel Technologies &amp; Improvements in Analytical Technologies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marta Germano, Harold Taylor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Speakers:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Debbie van der Burg, <em>MPYA Sci&amp;Tech</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Integrated Platform for In-line/At-line USP Analysis of mAbs and Nutrients</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Marieke Klijn, <em>Delft University</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PAT for Data-driven Bioprocess Development</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kang Chen, <em>CDER, FDA</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Direct Assessment of Oligomerization of Chemically Modified Peptides and Proteins in Formulations using DLS and DOSY-NMR</td>
</tr>
<tr>
<td>14:45-15:00</td>
<td>Le Jardin</td>
<td>Closing Comments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Harold Taylor</td>
</tr>
</tbody>
</table>