

**Quality requirements for nanomedicines:
which role for the European Pharmacopoeia?
7-8 June 2022, Strasbourg, France
Working language: English**

PROGRAMME

Tuesday, 07 June

09:15-10:00 *Registration*

Introduction Session, 10:00-12:30

- **10:00-10:10 Opening & Welcome address**
Petra Doerr, EDQM, Council of Europe
- **10:10-11:00 Cancer nanomedicines: Principles, progress, products, problems and prospects**
Twan Lammers, RWTH Aachen University, Germany
- **11:00-11:45 A short introduction to the European Pharmacopoeia (Ph. Eur.)**
Emmanuelle Charton & Dirk Leutner, EDQM, Council of Europe
- **11:45-12:15 Nano-related activities at the Ph. Eur. (NBC and vaccines)**
Gerrit Borchard, Chair of the Non-Biological Complex Drugs (NBC) Working Party, University of Geneva, Switzerland
Gwenaël Cirefice, Secretary to Group of Experts on Human Vaccines (15), EDQM, Council of Europe
- **12:15-12:30 Discussion**

12:30-14:00 *Lunch break*

mRNA Vaccines Session, 14:00-17:00

Moderator: Gerrit Borchard, Chair of the Non-Biological Complex Drugs (NBC)
Working Party, University of Geneva, Switzerland

- **14:00-14:30 Keynote lecture: The science behind mRNA vaccines**
Camilla Foged, University of Copenhagen, Denmark
- **14:30-15:00 CMC Considerations for mRNA Vaccines**
Romain Le Deun, Moderna, Switzerland
- **15:00-15:30 Questions and Answers**

15:30-16:00 *Coffee break*

- **16:00-16:30 Manufacturing Consideration for RNA-based Nanomedicines: Assembly, Downstream Processing and Analytics**
Martin Rabel, Precision Nanosystems ULC, Canada

- **16:30-17:00 Discussion**

17:00 *Close of first day*

Wednesday, 08 June

Other Nanomedicines Session, 09:00-12:30

Moderator: Gerrit Borchard, Chair of NBC Working Party, University of Geneva, Switzerland

- **09:00-09:30 Analytical challenges and current standardisation activities for nanomedicines**
Fanny Caputo, LNE, France
- **09:30-10:00 Regulatory challenges for nanomedicines**
Jon de Vlieger, Lygature, the Netherlands

Case studies

- **10:00-10:30 Development of nanomedicines through the clinic: a dendrimer conjugate case study**
Silvia Sonzini, AstraZeneca, UK

10:30-11:00 *Coffee break*

- **11:00-11:30 Liposomal formulations and nanosimilars**
Scott McNeil, University of Basel, Switzerland
- **11:30-12:00 The challenge of manufacturing complex nanomedicines: learnings from two decades of physicochemical iron carbohydrate characterisation**
Beat Flühmann, Vifor Pharma, Switzerland

- **12:00-12:30 Discussion**

12:30-14:00 *Lunch break*

Interactive Session: What does the future hold?, 14:00-16:00

Moderator: Daan Crommelin, University of Utrecht, the Netherlands

Brainstorming on:

- **Expectations of the European Pharmacopoeia (Ph. Eur.)**
- **How can standard setting through the Ph. Eur. support quality of nanomedicines?**

16:00 *Close of the symposium*