Nelson Labs
A Sotera Health company

# Open House Days 2024, Leuven

**Moderator: Dr. Carsten Worsøe (Novo Nordisk)**
**Location: Brabanthal, Brabantlaan 1 – 3001 Leuven**

| Time | Topic | Speaker |
|---|---|---|
| **8.30** | Registration | |
| **9.00** | Welcome | Eric Meyers /Piet Christiaens<br>**Nelson Labs** |
| **March 26 – Morning sessions** | | |
| **9.15** | **How to Implement USP<665> requirements before 2026** | Marine Lepoutre<br>**GSK** |
| **9.45** | **ELSIE Member Survey**: The implementation of USP<665> within its member companies | Dr. Alicja Sobantka<br>**Octapharma - ELSIE Member Company** |
| **10.15** | **PANEL DISCUSSION** on the implementation of USP <665> | - |
| **10.45** | BREAK | |
| **11.15** | USP <665> Focus on Component Qualification – What About Component Selection? | Dr. Simone Biel<br>Senior Regulatory Consultant<br>**Merck Life Science KGaA, Darmstadt, Germany** |
| **11.45** | Implementing X-Ray for Single Use Systems Sterilization: Current Status | Dr. Samuel Dorey<br>**Sartorius** |
| **12.15** | Considerations for Validation of Filters used in (Bio)Pharmaceutical Manufacturing (title TBC) | Frederick LaPlant<br>**3M** |
| **12.45** | Lunch | |
| **March 26 - Afternoon sessions** | | |
| **13.45** | Cytiva Approach for Extractables and Leachables Qualification and Risk Assessment of a Single-Use System: Case Studies | Patrick Evrard<br>**Cytiva** |
| **14.15** | Extractables & Leachables from Single-Use Systems and Their Assessment in Advanced Therapy Medicinal Product (ATMP) production. | Dr. Armin Hauk<br>**Sartorius** |
| **14.45** | BREAK | |
| **15.00** | The UCB approach to Qualification and Validation of Biopharmaceutical Manufacturing Equipment (Title TBC) | Isabelle Sbille<br>**UCB** |
| **15.30** | Qualification of Single Use Materials for Biopharmaceutical Manufacturing | Aidan Sexton<br>**Johnson & Johnson** |
| **16.00** | Leachable Risk Assessment Approaches: A Comparison of USP <665>, Biophorum, and other Methods for Assessing Leachable Risk in BioPharmaceutical Manufacturing Systems | Jason Creasey<br>**Maven E&L** |
| **16.30** | Transfer to Nelson Labs facilities for a **LAB TOUR** – followed by **RECEPTION** | |
| **19.30** | End Day 1 | |

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| **March 27 - Morning sessions** | | |
| **8.30** | Registration | |
| **9.00** | USP <665> and <1665>, Extractables for Components used in Pharmaceutical and Biopharmaceutical Manufacturing: Past, Present and Future(?). | Dr. Dennis Jenke, Principal Consultant **Nelson Labs** |
| **9.45** | Assisting Companies in the Qualification of Single-Use Materials: Overview of Different Steps to be Considered Beyond Analytical Chemistry Testing | Ir. Karen Pieters **Nelson Labs** |
| **10.30** | BREAK | |
| **10.45** | Extractables Testing of Bioprocessing Materials: From Conceptual Theory to Actionable Extractable Study Design – CASE STUDIES Showing the Practical Hurdles when Performing E-studies | Dr. Koen Smets **Nelson Labs** |
| **11.15** | Potential Designs for Leachable Studies on Biopharmaceutical Manufacturing Equipment | Dr. Pieter Van Wouwe **Nelson Labs** |
| **11.45** | Filter Integrity Testing of Sterilizing Grade Filters | Ir. Peter Cornelis **Nelson Labs** |
| **12.15** | Q&A | |
| **12.30** | Lunch | |
| **March 27 - Afternoon sessions** | | |
| **13.30** | Viral Clearance Testing for Filters | Tonya Morris **Nelson Labs** |
| **14.00** | Good Identification Practices in Non-Targeted Screening Analyses: the Key-Information to link a Compound to its Structure and Relevant Toxicological Information | Dr. Ward d'Autry **Nelson Labs** |
| **14.30** | Toxicological Safety Assessment of Process Equipment-Related Leachables (PERLs) in the Context of USP<665> | Ir. Kevin Breesch **Nelson Labs** |
| **15.00** | BREAK | |
| **15.15** | Panel Discussion – **Final Q&A Session** | Participants to be announced |
| **15.45** | Final Thoughts & Comments | |
| **16.00** | CLOSE | |