

22- 26 November 2021

Schedule - Analytical Procedure Life Cycle Management and Method Validation

Tuesday, 23 November 2021 (ALL TIMES IN CET)

09.00 – 09.15 h	Welcome and Organisations Axel H. Schroeder
09.15 – 09.30 h	Introduction Dr Joachim Ermer, Ermer Quality Consulting
09.30 – 10.00 h	USP 1220 Dr Joachim Ermer, Ermer Quality Consulting
10.00 – 10.30 h	Analytical Procedure Lifecycle Management, Stage 2 - Transfer of Analytical Procedures Ulla Bondegaard, Novo Nordisk
10.30 – 10.45 h	Coffee-break
10.45 – 11.15 h	Analytical development & control for complex therapeutics – an expedition via several set-ups Dr Markus Fido, MFI Bioconsulting
11.15 – 11.45 h	Established Conditions for Analytical Procedures & Application During the Analytical Life Cycle Management Isabelle Moineau, Aktehom /Jean Francois Dierick, GSK
11.45 – 12.15 h	Q&A
12.15 – 13.15 h	Lunch
13.15 – 13.45 h	How to Establish ATP for Small Molecules Patrick Jackson, GSK
13.45 – 14.15 h	Update TMU Xaver Schratt, GBA Pharma
14.15 – 14.45 h	Use of ATP to Guide Analytical Method Changes of Large Molecules Dr Gerald Gellermann, Novartis
14.45 – 15.00 h	Coffee Break
15.00 – 15.30 h	Analytical Procedure Lifecycle Management, Practical Implementation of Stage 3. Ulla Bondegaard, Novo Nordisk
15.30 – 16.00 h	Optimization, Qualification and Validation of FcγR binding using SPR Alexander Gill, Vela Labs

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16.00 – 16.30 h

**Deriving Fit-to-Purpose Validation Acceptance
Criteria Based on Actual Testing Procedures by HPLC**
Pavel Parkhomyuk, Teva

16.30 – 17.00 h

Q&A