Hosted by UNIVERSITÀ DI PAVIA

JOINT USP AND ACADEMIA WORKSHOP

Analytical Procedure Lifecycle and AQbD: ICH Q14/Q2(R2) and Compendial Approaches

SPEAKERS

Amanda Guiraldelli Mahr
Scientific Affairs Manager
US Pharmacopeia

Michaela Buda
Scientific Program Manager - EDQM

Francesca Luciani
Coordinator of the Biotech Section - Biological and Biotech Medicines Unit, ISS

Nikhil Rautela
Senior SCD Manager
US Pharmacopeia EMEA

AGENDA

Session Chair
Prof. Sandra Furlanetto, University of Florence

SESSION 1

- 8:00 - 9:00 am: Welcome Coffee
- 9:00 - 9:45 am: A Comprehensive Look at USP <1220> with Insights into ICH Q14 and Q2(R2)
- 9:45 - 10:15 am: Analytical Quality by Design and Pharmacopoeial Standards: Impact, Challenges and Opportunities
- 10:15 - 10:30 am: Q&A

Break

- 10:45 - 11:15 am: AQbD for Biologics Quality Control: Current Status and Ongoing Challenges
- 11:15 - 11:45 am: Quality Control at different stages of Therapeutic Monoclonal antibody manufacturing
- 11:45 - 12:00 pm: Q&A

Lunch

29 May 2024
8:00 am - 5:00 pm CST

Aula Magna, University of Pavia
Corso Strada Nuova, 65 - 27100
Pavia, Italy

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Sandra Furlanetto
Associate professor of Analytical Chemistry, University of Florence

Yulia Ivankina
Senior Expert Science & Technology, Novartis Austria

Claudia Magagnoli
Head, Global Phys-Chem Platform AR&D - Technical Research and Development, GSK Vaccines Italy

Jean-Francois Dierick,
Strategic Analytical Validation and Lifecycle Lead – Vx CMC analytical and statistics R&D, GSK Belgium

Andrea Gheduzzi
EMEA Principal LC Market Development Manager
Waters Italy

AGENDA

Session Chair
Amanda Guiraldelli Mahr, USP

SESSION 2

- 1:00 - 1:30 pm: Stability Indicating Procedure Development using AQbD principles
- 1:30 - 2:00 pm: Analytical Quality by Design and Biopharmaceuticals: a case study
- 2:00 - 2:30 pm: Reducing the risk of changing the analytical method for a commercialized mAb product using AQbD principles
- 2:30 - 2:45 pm: Q&A

Break

- 3:00 - 3:30 pm: AQbD as Strengthener for Analytical Development and Lifecycle
- 3:30 - 4:00 pm: Opportunities and Challenges from ICH Q2 (R2) and Q14 for the Analytical Lifecycle
- 4:00 - 4:15 pm: Q&A

Round Table

4:15 - 5:00 pm: Paradigm shift – Challenges and Benefits of implementing AQbD

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