

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
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US Pharmacopeia



Sandra Furlanetto
Associate professor of Analytical
Chemistry, University of Florence



Yulia Ivankina
Senior Expert Science &
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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
EMA 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 QbD 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 QbD principles
- 2:30 – 2:45 pm: Q&A
- **Break**
- 3:00 – 3:30 pm: QbD 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 QbD



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