

# 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

[Register Now](#)

Supported by:



FARMINDUSTRIA



Associazione Farmaceutici Industria  
Società Scientifica

Contact us for more info



[emea@usp.org](mailto:emea@usp.org)

# 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



**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**  
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 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



29 May 2024  
8:00 am – 5:00 pm CST



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

[Register Now](#)

Supported by:



FARMINDUSTRIA



Associazione Farmaceutici Industria  
Società Scientifica

Contact us for more info



[emea@usp.org](mailto:emea@usp.org)