



# 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**

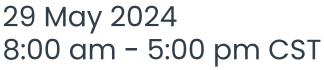
- 8:00 9:00 am: Welcome Coffee
- 9:00 9:45 am: A Comprehensive Look at USP
   <1220> with Insights into ICH Q14 and Q2(R2)
- 9:45 10:15 am: Analytical Quality by Design and Pharmacopoeial Standards: Impact,
   Challenges and Opportunities
- 10:15 10:30 am: Q&A

#### 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







Società Scientifica

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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
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



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



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

**Register Now** 









