

8th Annual Medicines Quality Workshop for Manufacturers

27-30 October 2025

AGENDA

Times are CET: Central European Time

Monday, 27 October 2025:

14:00-14:05: **Welcome**

14:05-14:10: 1-1 **Workshop agenda**

14:10-14:45 1-2 **Quality assessment - basic principles**

14:45-16:15 1-3 **API common deficiencies**

16:15-17:15 1-4 **Pharmaceutical development**

17:15-18:15 1-5 **Process validation**

Tuesday, 28 October 2025:

14:00-15:15: 2-1 **Specifications**

15:15-16:30: 2-2 **Stability studies**

16:30-18:00: 2-3 **Variations**

Wednesday, 29 October 2025:

14:00-16:00: 3-1 **Bioequivalence study**

16:00-16:15: Break (speaker will choose time)

16:15-18:00: 3-2 **Biowaiver application: BCS & additional strengths**

Thursday, 30 October 2025:

14:00-15:00: 4-1 **WHOPARS and Product Information**

15:00-17:00: 4-2 **WHO PQ Inspections and Findings**

17:00-17:30 4-3 **Update on ePQS and eCTD**

17:30-18:00: 4-4 **Collaborative Registration Procedure**

18:00-18:15: **Closing**