

9th Annual Medicines Quality Workshop for Manufacturers

28 September - 1 October 2026

AGENDA

Times are CET: Central European Time

Monday, 28 September 2026:

- 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 assessment**
- 16:15-17:15 **1-4 Pharmaceutical development**
- 17:15-18:15 **1-5 Process validation**

Tuesday, 29 September 2026:

- 14:00-15:15: **2-1 Specifications**
- 15:15-16:30: **2-2 Stability studies**
- 16:30-18:00: **2-3 Variations**

Wednesday, 30 September 2026:

- 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, 01 October 2026:

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 4-3 **Collaborative Registration Procedure**

18:00-18:15: Closing