# 9-12 June 2025

Times are CEST: Central European Summer Time

#### Monday, 9 June 2025

- 15:00-15:05 Welcome
- 15:05-15:10 Workshop agenda
- 15:10-15:30 Quality assessment basic principles
- 15:30 -17:00 API review and common deficiencies
- 17:00 -18:00 Pharmaceutical development

### Tuesday, 10 June 2025

15:00-16:00	Process validation
16:00- 17:15	Specifications
17:15 -18:15	Analytical methods and validation

## Wednesday, 11 June 2025

15:00-16:30	Assessment of a bioequivalence study
16:30-18:00	Assessment of a biowaiver application: BCS & additional strengths

## Thursday, 12 June 2025

- 15:00-16:15 Stability common issues
- 16:15-17:00 **Product information**
- 17:00-17:45 Collaborative Registration Procedure
- 17:45-18:00 Closing