

5th Biotherapeutic Product (BTP) and Similar Biotherapeutic Product (SBP) assessment training on 12 June 2026 (Virtual)

Times are CEST: Central European Summer Time

14:00 - 14:05 Welcome and program for the day

14:05 - 14:25 The Prequalification pilot project for Trastuzumab and Rituximab, its development and applications

14:25 - 14:50 Clinical requirements (SBP vs stand alone, PK/PD studies, clamp studies, safety studies, size

duration etc)

14:50 - 15:20 The Prequalification team medicine experience on BTPs/SBPs – practical examples – Clinical

15:20 - 15:50 Pharmacovigilance system and risk minimization plan focus on LMIC

15:50 - 16:20 The Prequalification team medicine experience on BTPs/SBPs – practical examples – Quality

16:20 - 16:50 A step-by-step biosimilarity exercise (SBP)/characterisation (stand alone product) approach

16:50 - 17:20 Process development and comparability (ICHQ5E) principles

17:20 - 17:50 Viral Safety

17:50 – 18:30 Q/A