

4th Biotherapeutic Product (BTP) and Similar Biotherapeutic Product (SBP) assessment training on 13 June 2025 (Virtual)

AGENDA

- 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**