

1st Biotherapeutic Product (BTP) and Similar Biotherapeutic Product (SBP) assessment training (Virtual)

18 June 2022

AGENDA

- 14:00 - 14:05: **Welcome and program for the day**
- 14:05 - 14:25: **The Prequalification pilot project for Trastuzumab and Rituximab and its development**
- 14:25 - 14:50: **The Prequalification team medicine experience on BTPs/SBPs practical examples - Quality**
- 14:50 - 15:20: **The Prequalification team medicine experience on BTPs/SBPs practical examples - Clinical**
- 15:20 - 15:50: **A step-by-step biosimilarity exercise (SBP)/characterisation (stand-alone product) approach**
- 15:50 - 16:20: **Process development and comparability (ICHQ5E) principles**
- 16:20 - 16:50: **Viral Safety**
- 16:50 - 17:20: **Clinical requirements (SBP vs stand alone, PK/PD studies, clamp studies, safety studies, size duration etc)**
- 17:20 - 17:50: **Pharmacovigilance system and risk minimization plan focus on LMIC**
- 17:50 - 18:30: **Q&A**