

PQT Medicines 4th Biotherapeutic Product (BTP) and Similar Biotherapeutic Product (SBP) Workshop for Manufacturers

27 September 2024

AGENDA

- 14:00-14:05: **Welcome and programme 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 Medicines experience on BTPs/SBPs – practical examples – Quality**
- 14:50-15:20: **The Prequalification Team Medicines 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**