

PQT Medicines 6th Biotherapeutic Product (BTP) and Similar Biotherapeutic Product (SBP) Workshop for Manufacturers

2 October 2026

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: Process development and comparability (ICHQ5E) principles

15:20-15:50: A step-by-step biosimilarity exercise (SBP)/characterisation (stand-alone product) approach

15:50-16:20: Viral Safety

16:20-16:50: The Prequalification Team Medicines experience on BTPs/SBPs – practical examples – Clinical

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