3rd Annual PQT/MED Biotherapeutic Product (BTP) and Similar Biotherapeutic Product (SBP) assessment training on 14 June 2024 (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 - The Prequalification Team - Medicines experience of BTPs/SBPs – practical examples – Quality
15:20 - 15:50 - Process development and comparability (ICHQ5E) principles
15:50 - 16:20 - Viral Safety
16:20 - 16:50 - Clinical requirements (SBP vs stand alone, PK/PD studies, clamp studies, safety studies, size duration etc)
16:50 - 17:20 - The Prequalification Team - Medicines experience of BTPs/SBPs – practical examples – Clinical
17:20 - 17:50 - Pharmacovigilance system and risk minimization plan - focus on LMICs
17:50 – 18:30 - Q&A