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