PQT Medicines biotherapeutics workshop for manufacturers - focus on insulin

01-02 October 2021

Agenda

*Times are CET: Central European Time*

**Friday, 01 October 2021:**

15:00-15:05: **Welcome**

15:05-15:10: 1-1 **Workshop agenda, including Day 1**

15:10-15:25 1-2 **Overview of the Insulin Market - WHO’s efforts to improving Access**

15:25-16:00 1-3 **The Prequalification pilot project for trastuzumab and rituximab**

16:00-16:20 1-4 **The Prequalification pilot project for human insulin**

16:20-16:50 1-5 **BTPs/SBPs – Quality (practical examples)**

16:50-17:00 Break (speaker will choose time)

17:00-17:30 1-6 **BTPs/SBPs – Clinical (practical examples)**

17:30-18:00 1-7 **GMP expectations linked to quality (process validation, methods qualification/validation etc.)**

18:00-18:30 1-8 **Questions and Answers**
Saturday, 02 October 2021:

15:00-15:05: 2-1 **Day 2**

15:05-15:35: 2-2 **A step-by-step biosimilarity exercise (SBP)/characterisation (standalone) approach**

15:35-16:05: 2-3 **A product development - quality overview (QTPP, characterization, product development strategies)**

16:05-16:35: 2-4 **Process development and comparability (ICHQ5E) principles**

16:35-17:05: 2-5 **Viral Safety**

17:05-17:35: 2-6 **Clinical requirements (SBP vs stand alone, PK/PD studies, clamp studies, safety studies, size duration etc)**

17:35-18:05: 2-7 **Pharmacovigilance system and risk minimization plan focus on LMIC**

18:05-18:30 2-8 **Questions and Answers**