WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR EUROPE

WELTGESUNDHEITSORGANISATION
REGIONALBÜRO FÜR EUROPA

ORGANISATION MONDIALE DE LA SANTÉ
BUREAU RÉGIONAL DE L'EUROPE

ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

First PQTm workshop for Russian - speaking participants
UN City, Marmorvej 51, 2100 Copenhagen, Denmark
19-20 May 2017

17 March 2017

Original: English with Russian translation

Provisional agenda

First PQTm workshop for Russian -speaking participants	
WHO Regional Office for Europe, Copenhagen	Auditorium 3
DAY 1: Monday 19 May 2017	
8:30-9:00	Welcome and introductions
9:00-9:15	Introduction to talks [Outline and objectives, intro to CTD]
9:15-10:00	Prequalification overview
10:00-10:20	Break
10:20 -11:30	Quality assessment principles [General challenges, approaches and tips for assessing the quality dossier (e.g. quality risk management, priority considerations)]
11:30-12:30	Lunch
12:30-14:30	API overview [Why assess the API? Where are the risks? Making use of previous approvals; Available guidance; Monographs; DMFs and CTD; DMF systems and documentation tracking/GMP]
14:30-15:00	break
15:00-17:00	Bioequivalence and biowaivers [When is BE necessary? What are the different approaches for establishing BE? Using pharmacokinetic BE: Optimal study design of a BE study, statistical considerations and acceptance criteria, and bioanalytical method considerations. BCS-based biowaivers, additional strength biowaivers, comparative dissolution studies for biowaivers, and comparator products for BE studies]

17:00-17:30	Open discussion/Q&A on the day's topics
DAY 2: Tuesday 20 May 2017	
8:30-08:45	Questions on Day 1 Material
8:45-09:45	Specifications [Why specifications are important. Tips for reviewing specifications. Common deficiencies.]
9:45-10:45	Methods/validation [How to review the standard test procedure; compendial methods vs non-compendial methods; key elements of validation of the methods (focus on HPLC)]
10:45-11:00	Break
11:00 -12:30	Solid oral product development [Why do we assess information on development pharmaceutics? Key elements, tips and examples on review of the submitted information.]
12:30-13:30	Lunch
13:30-15:30	Solid oral process validation [Key elements of validation, tips on how to assess validation protocol and validation report]
15:30-17:00	Stability [General requirements, how to summarize and evaluate data, the example of dissolution; examples and tips]
17:00-17:30	Open discussion/Q&A on the day's topics
17:30	Workshop close – submit your feedback form