

11th Annual PQT Medicines Quality Assessment Training

27-30 May 2019

Monday, 27 May 2019

- 08:30-09:00: Welcome and introductions
- 09:00-09:15: 1-1 **Training session outline and objectives**
- 09:15-10:00 1-2 **Prequalification: Overview and update**
- 10:00-10:20: Break
- 10:20-11:20 1-3 **WHOPARs, Product Characteristics and Product Information - Links between Quality and Clinical**
- 11:20-12:20 1-4 **Bioequivalence study design and assessment**
- 12:20-13:20: Lunch
- 13:20-14:35: 1-5 **Biowaivers**
- 14:35-15:45: 1-6 **Quality assessment principles/report writing**
- 15:45-16:05: Break
- 16:05-17:05: 1-7 **API assessment – common deficiencies**
- 17:05-17:35: 1-8 **Bioanalytical Method Validation**
- 17:35-18:00: Open discussion/Q&A on the day's topics

Tuesday, 28 May 2019

- 08:30-08:45: Questions on Day 1 Material
- 08:45-10:15: 2-1 **Dissolution testing**
- 10:15-10:35: Break
- 10:35-11:55: 2-2 **Pharmaceutical development of solid orals**
- 11:55-12:55: Lunch

- 12:55-14:10: 2-3 **Specifications**
- 14:10-15:25 2-4 **Stability**
- 15:25-15:45 Break
- 15:45-17:30 2-5 **Manufacture and validation of sterile solutions**
- 17:30-18:00: Open discussion/Q&A on the day's topics
- 19:00 Informal dinner

Wednesday, 29 May 2019

- 08:30-08:45: Questions on Day 2 Material
- 08:45-10:00: 3-1 **Variations**
- 10:00-11:30: 3-2 **Regulatory System Strengthening – benchmarking, technical assistance, capacity building and accelerated access to medicines**
- 11:30-13:00: Lunch (one-on-one leaders can schedule as most convenient)
- 13:00-.... One-on-one breakout sessions (feedback and guidance)

Thursday, 30 May 2019

- 09:00-11:45: Written examination on workshop topics / Workshop evaluation
- 11:45-12:00: Formal meeting close.