ISPE Technology Transfer training – Singapore May 6/7

2019 - Outline programme

Day 1

TIME	Ref	Topic
09.00		Opening remarks
09.10		Start TT Training
09.10 – 10.00	M0	Introduction & Objectives
10.00 – 10.30	M1	Introduction to TT Guide
10.30 – 11.00		Morning Break
11.00– 11.30	M2	Regulatory Aspects
11.30 – 12.00	H1	Breakout 1 – issues arising from what you have heard so far
12.00 – 13.00		Lunch
13.00 – 14.00	M3	Knowledge and quality aspects (for both Transfer & Management):
14.00 – 14.30	H2	Breakout 2 - Cause effect matrix (use of tools)
14.30 – 15.00		Afternoon Break
15.00 – 16.00	M2	TT Planning & Success Criteria
16.00 – 16.45	H3	Breakout 3 - Fishbone & Success criteria
16.45 – 17.00		Questions and wrap up Day 1

Outline programme _ Day 2

TIME	Ref	Topic
9.00 – 9.30		Review of Day 1
09.30 – 10.15	M5	Quality Risk Management
10.15 – 10.30	H4	Breakout 4 - FMEA
10.30 – 11.00		Break
11.00– 11.15	H4 – cont'd	Breakout 4 - FMEA
11.15 – 12.00	M6	Phases of Transfer Process
12.00 – 12.30	H5	Breakout 5 - Project Proposal
12.30 – 13.30		Lunch
13.30 – 14.00	H5 cont'd	Breakout 5 - Project Proposal
14.00 – 14.30	M7	Analytical Procedures TT
14.30 – 15.00		Break
15.00 – 15.30	H6	Breakout 5 - Analytical
15.30 – 16.15	M8 & M9	Drug Product TT (and Drug substance)
16.15 – 16.30	M10	Summary & Conclusion
16.30 – 17.00		Questions, actions & wrap-up