

Programme

Process Validation – Concepts and Application

Instructor: Enzo Passalia

Day 1: 08.30 – 16.30	
08.30 – 09.00	Registration – Breakfast buffet
09.00 – 10.15	Introduction and Regulations
10.15 – 10.30	Coffee/tea
10.30 – 12.20	Benefits of Process Validation, SOP, Site Master Validation Plan, and Process Risk Analysis
12.20 – 13.20	Lunch
13.30 – 14.30	Installation Qualifications (IQ) and discussion
14.30 – 14.45	Coffee/tea
14.45 – 16.30	Operational Qualifications (OQ) and discussion
Day 2: 09.00 – 15.00	
09.00 – 10.15	Performance Qualifications (PQ) and Software validation
10.15 – 10.30	Coffee/tea
10.30 – 12.00	Post-validation activities and process controls. Revalidation
12.00 – 12.20	Examples of FDA Warning Letters
12.30 – 13.20	Lunch
13.30 – 14.45	Workshop on process validation
14.45 – 15.00	Wrap-up
15.00 – 16.00	<i>Optional: One-to-one discussion and review of process validation documents/SOPs</i>