PHARMACEUTICAL GMP

ISPE Singapore Affiliate
30 October to 1 November 2017

PROGRAMME

Day 1

08.30 – 09.00  Course Registration
09.00 – 09.30  Session 1: Interactive Session: Welcome and Introduction
09.30 – 10.15  Session 2: History of GMP
10.15 – 10.35  Refreshment Break
10.35 – 11.15  Session 3: Quality Management Systems and GMP
11.15 – 11.45  Session 4: Buzz Group: Key Learning Objectives from the Course
11.45 – 12.30  Session 5: GMP Legislation in EU and USA – An Overview and Comparison
12.30 – 13.15  Lunch Break
13.15 – 14.00  Session 6: Buzz Group: EudraLex – Find It
14.00 – 14.30  Session 7: Deviation and Human Error
14.30 – 15.15  Session 8: Buzz Group: Deviations
15.15 – 15.30  Refreshment Break
15.30 – 16.15  Session 9 Buzz Group: Training
16.15 – 17.00  Session 10: Introduction to Quality Risk Management
17.00 – 17.30  Session 11: Premises: Introduction

Day 2

08.30 – 09.15  Session 12: Key GMP Issues for Premises and HVAC
09.15 – 10.15  Session 13: Buzz Group: Facilities Design
10.15 – 10.35  Refreshment Break
10.35 – 11.15  Session 14: Clean Room Design and Operation
11.15 – 12.00  Session 15: Buzz Group: Water
12.00 – 12.30  Session 16: Documentation

12.30 – 13.15  Lunch Break

13.15 – 14.00  Session 17: Buzz Group: Key Elements of Procedures and GMP
14.00 – 14.45  Session 18: Validation: The Basics
14.45 – 15.15  Session 19: Starting Materials and Supplier Assurance

15.15 – 15.30  Refreshment Break

15.30 – 16.00  Session 20: Buzz Group: Sampling and Testing Starting Materials and Supplier Assurance - Quality Management of Materials
16.00 – 16.30  Session 21: Introduction to Pharmaceutical Products
16.30 – 17.00  Session 22 Buzz Group: Solid Dose Supply
17.00 – 17.30  Session 23: GMP Aspects of Liquids, Creams and Ointments Manufacture

Day 3

08.30 – 09.30  Session 24: GMP Aspects of Tablet Manufacture
09.30 – 10.15  Session 25: Buzz Group: Audits and Self-Inspections

10.15 – 10.30  Refreshment Break

10.30 – 11.30  Session 26: GMP Aspects of Sterile Products
11.30 – 12.15  Session 27: GMP Aspects of Packaging

12.15 – 13.00  Lunch Break

13.00 – 14.00  Session 28: Good Control Laboratory Practice (GCLP)
14.00 – 14.45  Session 29: Complaints, Quality Defects and Recalls

14.45 – 15.00  Refreshment Break

15.00 – 15.45  Session 30: Change Management
15.45 – 16.15  Session 31: Measuring the Success of GMP
16.15 – 17.15  Session 32: Quiz
17.15 – 17.30  Session 33: Conclusion and Course Close