

PHARMACEUTICAL GMP

ISPE Singapore Affiliate
30 October to 1 November 2017

PROGRAMME

Day 1

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| 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 | <i>Refreshment Break</i> |
| 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 | <i>Lunch Break</i> |
| 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 | <i>Refreshment Break</i> |
| 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

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| 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 | <i>Refreshment Break</i> |
| 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	<i>Lunch Break</i>
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	<i>Refreshment Break</i>
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	<i>Refreshment Break</i>
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	<i>Lunch Break</i>
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	<i>Refreshment Break</i>
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