# Good Manufacturing and Laboratory Practices Workshop for Pharmaceutical, Biotech, and Medical Devices Professionals: Operational Excellence from R&D to GMP Compliance

*Session 1: 24 – 25 March 2026*

*Session 2: 7 – 8 April 2026*

**Mode:** *Virtual Zoom*

## WORKSHOP PROGRAMME

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**Learning outcomes**

At the end of this workshop, participants should be able to

- Understand global GMP and GLP regulations (FDA, EMA, PIC/S) and their operational applications across pharmaceutical, biotech, and medical device industries.
- Apply operational strategies for transitioning from R&D to GMP-compliant manufacturing, including scaling, documentation control, and quality systems integration.
- Manage operational risks through risk-based decision-making, effective deviation handling, and CAPA implementation to ensure regulatory compliance.
- Ensure product integrity by maintaining compliance in cleanroom environments, aseptic manufacturing, and environmental controls.
- Navigating GMP compliance challenges unique to medical device and biotech manufacturing, including upstream and downstream processes, gene therapies, and material management.
- Prepare for regulatory inspections by implementing audit readiness strategies, ensuring compliance with key focus areas (documentation, CAPA, traceability), and responding effectively to audit findings.
- Drive continuous improvement in GMP and GLP operations by leveraging operational metrics, and effective change control processes.

## Target Audience

- Pharmaceutical, Biotech, and Medical Device professionals in manufacturing, quality assurance, and regulatory affairs
- R&D teams transitioning to GMP-compliant environments and scaling for production
- Operational managers and supervisors in GMP manufacturing environments
- Quality control and quality assurance personnel responsible for operational compliance
- Regulatory affairs and compliance officers in the pharmaceutical and medical device sectors
- Laboratory managers and supervisors dealing with GLP and GMP regulations

# Good Manufacturing and Laboratory Practices Workshop for Pharmaceutical, Biotech, and Medical Devices Professionals

## Operational Excellence from R&D to GMP Compliance

### 24-25 March and 7-8 April 2026

**Session 1: Day 1 – 24 March 2026, Tuesday**

### Day 1: Operational Understanding of GMP and GLP in Pharma, Biotech, & Medical Devices

| Time | Topic | Speaker/Organisation |
|---|---|---|
| 8.30am | **Welcome and Workshop Briefing** | **Dr Rathi Saravanan**<br>Lead Education Associate<br>Centre of Regulatory Excellence (CoRE)<br>Duke-NUS Medical School |
| 8.45am | **Participants & Learning Management System Introduction** | **Dr Rathi Saravanan** |
| **Session 1: Advanced GMP Regulations and Operational Compliance** | | |
| 9.00am | **Comprehensive GMP Overview: Review of FDA, EMA, and PIC/S regulations, key compliance requirements, and industry-specific GMP practices across pharmaceutical, biotech, and medical device manufacturing.**<br>• Key compliance requirements for pharmaceutical, biotech, and medical device manufacturing.<br>• Differences in GMP practices across pharmaceutical, biotech, and medical device industries. | **Ms. Smitha Kenchath**<br>Consultant<br>SeerPharma (Singapore) Pte Ltd |
| 9.45am | **Operational Compliance & QMS Integration: Essential GMP documentation practices and the integration of Quality Management Systems (QMS) to ensure regulatory compliance and operational efficiency.**<br>• Essential GMP documentation practices to ensure regulatory compliance.<br>• Integration of Quality Management Systems (QMS) into operational processes | **Ms. Smitha Kenchath** |
| 10.45am | **Morning Break** | |
| 11.00am | **Case Study I**<br>• Challenges in Transitioning a University Research Lab to a GMP Facility and GMP Regulations & Operational Compliance | **Facilitated by Rathi Saravanan** |
| 12.30pm | **Lunch Break** | |
| **Session 2: GLP in Practice – Bridging Lab and Manufacturing Environments** | | |
| 1.30pm | **Application of GLP principles in R&D and lab operations, ensuring data integrity, laboratory management, and compliance.**<br>**Transition to GMP:** Addressing operational challenges in scaling from GLP to GMP for clinical trials and commercial production while | **Ms. Smitha Kenchath** |

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| | ensuring accuracy in analytical testing, validation, and stability studies. | |
| **2.30pm** | **Activity I**<br>• Assessing GDocP (Good Documentation Practices) in a Batch Record | **Rathi Saravanan** |
| **3.15 pm** | **Afternoon Break** | |
| **Session 3: Operational Challenges in the R&D to GMP Transition** | | |
| **3.30pm** | **Scaling from Research to GMP Production: Overcoming practical challenges during the transition, ensuring robust process validation, seamless documentation control, and aligning raw material and product specifications with GMP standards.**<br>• Addressing process consistency, regulatory compliance, and integration between R&D and GMP operations. | **Ms. Smitha Kenchath** |
| **4.30pm** | **Case Study II**<br>• How to Avoid Contamination and Mix-up<br>• Augmented Reality- Cleanroom Experiences, Operator challenges | **Rathi Saravanan** |
| **5.30pm** | **End of Day 1** | |

## Session 1: Day 2 – 25 March 2026, Wednesday

### Day 2: Operational Risk Management, Deviation Handling, and CAPA Implementation

| Time | Topic | Speaker/Organisation |
|---|---|---|
| 8.30am | **Registration** | |
| **Session 4: Risk-Based Quality Management and Operational Controls** | | |
| 9.00am | **Risk management strategies in the operational management of GMP processes**<br>• Operational application of risk-based decision-making tools (FMEA, risk assessments)<br>• Developing and implementing risk mitigation strategies in manufacturing processes | **Ms. Smitha Kenchath** |
| 10.00am | **Risk management strategies in the operational management of GMP processes (continued)**<br>Managing and reducing operational risks in production and lab settings | **Ms. Smitha Kenchath** |
| 10. 45am | **Morning Break** | |
| 11.00am | **Case Study III**<br>• FMEA Risk Assessment for a Pharmaceutical Manufacturing Process | **Rathi Saravanan** |
| 12.30pm | **Lunch** | |
| **Session 5: Deviations, Non-Conformances, and CAPA Management** | | |
| 1.30pm | **Managing Deviations and CAPA in GMP Operations: Implementing operational approaches for handling deviations, conducting root cause analysis, and developing effective CAPA plans.**<br>• Identifying systemic issues in manufacturing and testing processes and addressing them through targeted CAPA actions.<br>• Ensuring proper documentation of CAPA actions and timely, effective closure | **Ms. Smitha Kenchath** |
| 2.15pm | **Case Study IV**<br>• Root Cause Analysis & CAPA | **Rathi Saravanan** |
| 3.15 pm | **Afternoon Break** | |
| **Session 6: Ensuring Process Control and Compliance During Deviation Handling** | | |
| 3.30pm | **Managing Operational Impact of Deviations in GMP: Addressing the effects of deviations on product quality and regulatory compliance through corrective actions and monitoring CAPA effectiveness.**<br>• Implementing real-time corrective actions to prevent recurrence and ensuring effective investigation of non-conformances.<br>• Continuously monitoring the effectiveness of CAPA and reporting non-conformances in compliance with GMP standards | **Ms. Smitha Kenchath** |
| 4.30pm | **Case Study V**<br>• Applying QRM Principles to CAPA | **Rathi Saravanan** |
| 5.30pm | **End of Day 2** | |

## Day 3 – 7th April 2026, Tuesday

### Day 3: Regulatory Inspections, Audits, and Continuous Improvement in GMP Operations

| Time | Topic | Speaker/Organisation |
|---|---|---|
| **8.30am** | **Registration** | |
| **9.00am** | **Recap Quiz** | |
| **Session 7: Preparing for Regulatory Inspections and Audits** | | |
| **9.30am** | **Strategies for operational readiness for GMP and GLP inspections**<br>• Key aspects auditors focus on in operational GMP compliance (documentation, traceability, CAPA) | **Ms. Smitha Kenchath** |
| **10.15am** | **Managing and responding to audit findings**<br>• How to manage and respond to audit findings effectively<br>• Ensuring compliance during routine and unannounced regulatory inspections | **Ms. Smitha Kenchath** |
| **11.00am** | **Morning Break** | |
| **11.15am** | **Activity II**<br>• Simulated regulatory inspection, focusing on operational GMP readiness, CAPA | **Rathi Saravanan** |
| **12.30pm** | **Lunch** | |
| **Session 8: Operational Continuous Improvement in GMP Environments** | | |
| **1.30pm** | **Driving a culture of continuous improvement in GMP and GLP operations**<br>• Using operational metrics and key performance indicators (KPIs) to measure compliance and efficiency | **Ms. Smitha Kenchath** |
| **2.30pm** | **Continuous improvement methodologies in GMP settings**<br>• Leveraging Lean, Six Sigma, and other continuous improvement methodologies<br>• Implementing effective operational change control processes | **Ms. Smitha Kenchath** |
| **3.30pm** | **Afternoon Break** | |
| **3.45pm** | **Activity III**<br>• Culture of Continuous improvement | **Rathi Saravanan** |
| **5.30pm** | **End of Day 3** | |

## Day 4 – 8th April 2026, Wednesday

## Day 4: GMP Operational Challenges in Medical Device and Biotech Manufacturing

| Time | Topic | Speaker/Organisation |
|---|---|---|
| **8.30am** | **Registration** | |
| **Session 9: GMP in Medical Device Manufacturing – Operational Considerations** | | |
| **9.00am** | **Quality Management and Regulatory Compliance in Medical Device Manufacturing: Addressing medical device regulatory requirements in accordance with ISO 13485 and applicable regulations (e.g. FDA 21 CFR 820 / QMSR, EU MDR), ensuring product integrity, traceability, and effective quality control across the medical device lifecycle.**<br>• Maintaining product integrity through controlled environments, contamination control strategies, sterilisation processes (where applicable), and packaging controls, aligned with device risk classification and intended use.<br>• Ensuring effective quality control and lifecycle oversight from manufacturing through distribution, including complaint handling and post-market activities. | **Ms. Smitha Kenchath** |
| **9.45am** | **Risk Management Across the Medical Device Lifecycle: Implementing strategies to mitigate risks from design to post-market surveillance.**<br>• Identifying and addressing medical device–specific quality and compliance challenges within the QMS, including process changes, supplier controls, and production scale-up.<br>• Managing risks effectively to ensure ongoing regulatory compliance, product safety, and patient protection. | **Ms. Smitha Kenchath** |
| **10.30 am** | **Morning Break** | |
| **10.45am** | **Case Study VI**<br>• Medical Device Design, Development and Distribution | |
| **Session 10: Biotech Manufacturing – Operational GMP Compliance** | | |
| **11.30am** | **Introduction to Biotech Manufacturing and Key Operational Challenges in Biotech Manufacturing: Addressing complexities in manufacturing, and aseptic processes while ensuring GMP compliance.**<br>• Managing facility requirements, especially cleanroom environments, to maintain environmental control.<br>• Implementing effective materials management to support biotech production. | **Ms. Smitha Kenchath** |
| **12.30pm** | **Lunch** | |
| **1.30pm** | **Quality Assurance and Compliance in Biopharmaceutical Manufacturing: Ensuring GMP adherence for biologicals, gene therapies, validation, and batch release.**<br>• Managing aseptic manufacturing processes to maintain sterility and product integrity.<br>• Ensuring thorough validation and efficient batch release processes in biotech environments. | **Ms. Smitha Kenchath** |

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| **2.30pm** | **Case Study VII**<br>• Identify the Contamination sources and Establish Contamination Control Strategy (Breakout group discussion) | **Rathi Saravanan** |
| **3.45pm** | **Afternoon Break** | |
| **4.30pm** | **End of Course Assessment** | |
| **5.30pm** | **End of Workshop** | |