Quality Assurance and GMP Training Program

Instructor-Led Training
Physical Training and Online Training

YEAR 2025

The training program consists of 5 on-line courses and 9 physical courses. These courses cover the essential principles of Quality Assurance (QA), Good Manufacturing Practice (GMP), Validations, Supply chain Management, Medical Devices etc. Participants are expected to gain an understanding of current requirements and future international trends within the regulated industry. The courses consist of a lively combination of case study workshops and group presentation. The training has been adapted for delivery in an online, virtual classroom and physical training.

Trainers

The courses are both developed and delivered by SeerPharma. All SeerPharma trainers have academic qualification with at least a bachelor's degree, as well as a number of years of industry experience in Quality Management or Production Management in major and multinational companies. They have worked with various regulatory standards including the FDA, EU, PIC/S, TGA and ISO. The trainer for each course will have specific expertise in that subject matter.

SeerPharma is Asia-Pacific's leading premier training & consulting group for Quality and GMP compliance. Offering integrated consulting, training and software from MasterControl to pharmaceutical and medical device companies in the Asia Pacific region to help meet international GMP regulatory standards.

Aims and Objectives

The aim of the training program is to provide conceptual understanding of GMP, as well as to introduce the various current practices for implementation at the workplace.

Who Should Attend?

Key personnel in GMP & Quality Management, Managers, Engineers, Executives, Quality Practitioners, and any member of the pharmaceutical and related industry. Those from Research and Development, Quality and Production will find this program relevant and beneficial to their job function as well.

- E-Certificates endorsed by the National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia will be awarded to participants upon successful completion of each module.

Organised by:

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

Presented by:

SeerPharma® CONFIDENCE IN COMPLIANCE

Endorsed by:

National Pharmaceutical Regulatory Agency, MOH

For further details please visit www.mopi.org.my

COURSE OUTLINE

GMP Fundamentals: Key Concepts to Know (21 – 22 January 2025)

If you are responsible for any aspect of pharmaceutical product quality or GMP compliance, it is essential to understand your legal and ethical obligations. This requires a solid grasp of the regulatory environment, the purpose and requirements of a Pharmaceutical Quality System, and current Good Manufacturing Practice as outlined by PIC/S. To assist GMP-regulated organizations, this course will guide you through the key requirements of the current PIC/S Guide to GMP, Part I. Through case studies and real-world examples, you will learn how these requirements are applied within manufacturing environments, with a strong focus on ensuring product quality and preventing adulteration and misbranding.

Content:

Day 1:

Overview of the Global Regulatory Landscape

- Drug product lifecycle: stages of development, manufacturing, and distribution
- Types of Quality Systems and corresponding GMP standards
- Definition and purpose of GMP
- Key Compliance Priorities: Product identity, safety, purity, and efficacy
- Core GMP Requirements

GMP Basics:

- Personnel and Training
- Facility and Premises Management
- Production Areas
- Storage Areas
- Quality Control Areas
- Ancillary Areas and Support Systems
- Equipment Management
- Control over Production and Packaging
- Validation Processes
- Quality Control Responsibilities

Day 2:

Effective Good Documentation Practices

- GMP requirements for documentation
- Definition and purpose of Good Documentation Practice (GDocP)
- Importance of GDocP in maintaining data integrity
- Key do's and don'ts for GDocP
- Guidelines for designing SOPs, Work Instructions, and Forms

Implementing a Quality Systems Approach to GMP

- Understanding the Pharmaceutical Quality System
- Principles of Quality Risk Management
- Essential Quality System Components for Continuous Improvement
- Deviation Management
- Handling Complaints and Recalls
- Corrective and Preventive Actions (CAPA)
- Change Control
- Product Quality Review

Participants

This course is designed to equip personnel new to the pharmaceutical industry with a solid understanding of PIC/S GMP and Pharmaceutical Quality System requirements. It is also valuable for experienced GMP professionals seeking updates for current PIC/S GMP compliance, companies pursuing GMP certification (new or renewal) under PIC/S, and manufacturers involved in the secondary packaging of medicinal products.

COURSE OUTLINE

Revised

Quality Risk Management: A Comprehensive Training (26 – 27 February 2025)

Quality Risk Management (QRM) principles emphasize assessing risks to patient safety and product quality using scientific knowledge, data, and experience. Regulators expect QRM to be integrated into the Quality Management System (QMS) using a lifecycle approach that incorporates both formal and informal risk tools. This supports ICH Q9 elements, such as risk assessment, control, review, communication, and the acceptance of residual risks.

This interactive, advanced training uses case studies to equip participants with practical tools for applying QRM principles to real-world challenges, offering hands-on experience in conducting and facilitating risk assessments.

Day 1 Risk Management for Compliance

Within a Quality System (QS), making informed, scientifically sound decisions is critical for regulatory compliance and business efficiency. From tracking customer complaints to managing non-conformances, audit findings, or implementing corrective and preventive actions (CAPA), a well-defined Risk Assessment process enhances product quality, regulatory/GxP compliance, and mitigates legal risks. This training provides participants with the skills to engage in compliance-focused risk assessments, offering foundational insights into quality systems and structured risk evaluation methods.

Content:

- Quality Risk Management Framework
- Risk Management Objectives in GMP Compliance
- Key Quality Systems and Risk Assessment Applications
- Auditing
- Change Control
- Product Complaints and Adverse Drug Events (ADEs)
- Deviation Investigations
- CAPA

Day 2 Risk Management for Process

Since its introduction to GMPs in 2009, Quality Risk Management (QRM) has become a key component of pharmaceutical manufacturing operations. However, knowing which QRM tool to use, ensuring risk assessments add tangible value, and verifying appropriate manufacturing controls are essential. This session provides skills for effective process risk assessments, covering manufacturing process understanding, control, and structured risk evaluation.

Content:

- Manufacturing Process Considerations: Addressing complexities, potential issues, and risk factors
- Quality Risk Management Process Overview
- GMP Requirements for Risk Assessments
- The Quality Risk Management Toolbox: Tools and their applications
- Process Risk Assessment Techniques:
- Preliminary Hazard Analysis (PHA)
- Hazard Analysis and Critical Control Points (HACCP)
- Failure Mode and Effects Analysis (FMEA)

Participants:

This course is ideal for both newcomers to process risk assessment and experienced QRM practitioners. It benefits those interested in or responsible for risk assessments in quality compliance and/or manufacturing processes, providing a valuable skill set for managing compliance and manufacturing risks effectively.

COURSE OUTLINE

Behavioral GMP and Data Integrity: Reducing Human Error (22-23 April 2025)

Effectively managing deviations is essential for minimizing productivity losses. Deviation investigations often consume substantial time and frequently identify human error as the root cause, leading to common responses like additional training or procedural changes. However, these solutions often have limited effectiveness, and the issues tend to recur.

This course, centered on Behavioural Good Manufacturing Practices (bGMP), explores the underlying causes of non-compliance—whether from errors or deliberate actions—and provides strategies for meaningful improvement. Participants will examine three specific types of human error and learn when retraining is useful, while also understanding its limitations in preventing repeated issues.

Day 2 focuses on Data Integrity (DI), a cornerstone of regulatory compliance and quality management in the pharmaceutical industry. This session will cover DI principles, industry guidelines, and practical approaches to maintaining data integrity throughout pharmaceutical operations, including Quality Control (QC) and other departments. Real-world examples and case studies will illustrate best practices for upholding data integrity standards, equipping participants to manage DI complexities within their organizations.

Content

Day 1 Behavioral GMP and Managing Deviations

- Root Causes of Defective Products
- Understanding Human Error Types and Causes
- Behavioural Influences and Non-Compliance Factors
- Addressing Errors and Non-Compliant Behaviours
- Human Learning Stages and Error Types
- Identifying Factors that Contribute to Human Error and Non-Compliance
- Strategies for Managing Non-Compliance and Building a Quality Culture
- Supervisory and Management Roles in Compliance
- Reducing Learning and Inherent Errors
- Minimizing Potential Errors through Targeted Strategies

Day 2: Data Integrity

- Defining Data Integrity (DI) and Key Contributors to DI
- Regulatory Focus on Data Integrity and Security
- Data Criticality, Risk, and Its Management in a Quality System
- Integrating Data Integrity into QMS through a Risk-Based Approach
- Protection and Security of Raw Data and Original Records
- Developing Practical DI Audit and Remediation Strategies

Participants

This program is ideal for executives, managers, specialists, and supervisors responsible for GMP compliance, managing deviations, conducting failure investigations, and driving continuous improvement. Participants will gain actionable insights to strengthen compliance practices and maintain robust data integrity across their organizations.

COURSE OUTLINE

Revised

Qualification and Validation: Essential Implementation Strategies (27 – 28 May 2025)

This training course is designed to deepen your understanding of current requirements for the design, execution, assessment, and documentation of equipment qualification and validation. Discover how a science and risk-based approach to validation can enhance business efficiency, improve reliability, and strengthen processes, ensuring robust product quality. This approach not only adds tangible value to your organization but also reinforces patient safety measures. Gain insights into the latest industry standards and best practices, keeping you at the forefront of process integrity and effectiveness.

Content

Day 1: Core Validation Principles and Quality Risk Management (QRM) Application

Foundational Validation and Qualification Concepts

- Explore regulatory requirements and the scope of Qualification and Validation (Q&V).
- Understand the phases and stages of Q&V processes.
- Discuss validation planning essentials, regulatory demands, and the Q&V lifecycle.

Validation Planning Essentials

- Components of a validation program, including the Validation Master Plan (VMP) and Validation Project Plan (VPP).
- Application of Quality Risk Management (QRM) principles, focusing on a science and risk-based approach.
- Distinguish between critical and non-critical systems.
- Use tools like Failure Mode and Effects Analysis (FMEA) and Hazard Analysis and Critical Control Points (HACCP) in validation planning.

Day 2: Execution, Assessment, and Documentation of Equipment Qualification

- Equipment Qualification Essentials
- Key components of effective equipment qualification.
- Discussion on User Requirement Specifications (URS) and the stages of Qualification (IQ, OQ, PQ) per GMP requirements.
- New approaches in equipment qualification, emphasizing risk management.
- Protocol execution, evaluation, reporting, and deficiency management.
- Maintaining a Validated State
- Change management strategies to ensure patient safety and meet regulatory standards.
- Overview of the validation lifecycle and ongoing verification.
- Routine re-validation schedules and periodic reviews for compliance and performance optimization.

Participants

This course has been designed to provide personnel new to the Qualification and Validation (Q&V) principles and practices. It also applies to experienced GMP staff looking to update for compliance in the current Q&V requirements or practices.

COURSE OUTLINE

Computer Systems for Regulated Environment (17 – 18 June 2025)

Your company relies heavily on computer systems for its operations. With advancing technology and the industry's focus on "data integrity" (ensuring availability, authenticity, accuracy, and traceability of information), computerized systems are being adopted at a greater pace. In turn, regulatory bodies like TGA, FDA, and Medsafe are intensifying their scrutiny on computer system validation. Therefore, a risk-based approach to system validation is essential to achieve compliance. This course will equip you with critical insights into the validation of computerized systems, enabling your company to meet regulatory expectations while mitigating risks to product quality and patient safety.

Content

Day 1:

- Regulations and GAMP
  - Definition of validation as applied to computerized systems
  - Regulatory status and PIC/S
  - Introduction to the Principles of CSV
  - GAMP
- SDLC, Data Integrity and Risk Assessment
  - System Life Cycle Approaches
  - Development Models
  - More Principles of CSV
  - Mapping into Company Procedures
  - Data Integrity
  - Risk Assessment for Computerized Systems
- IT Infrastructure Qualification and Planning Phases
  - IT Infrastructure Qualification / Validation
  - Validation Master Planning
  - Legacy System Validation
  - Generating an Inventory of Systems
  - Validation Protocol
  - Spreadsheet Validation
  - Validation Plan
  - Cross Functional Plans

Day 2:

- Pre-Development Phases
  - Requirements Definition
  - Traceability
  - Audits
  - Design
- Development, Testing, Qualification and Use
  - Coding
  - Testing
  - Qualification
  - Decommissioning
- Electronic Records / Signatures – Cloud Computing
  - Detailed interpretation of Part 11
  - Implications for computerized systems in applying Electronic Records and Signatures
  - Applying principles to new and existing Systems
  - Reviewing Example Scenarios
  - Understand Cloud Computing Implications

Participants

You will benefit from this course if you are a key Quality, IT or Operational Subject Matter Expert (SME) or Manager likely to be involved in using, validating, approving, or purchasing computer systems.

COURSE OUTLINE

Revised

Introduction to Laboratory Controls: Managing OOS, OOT, OOE and Analytical Method Validation (09-10 July 2025)

Global GMP regulators continue to identify deficiencies in organizations related to Out-of-Specification (OOS) handling. Common findings include:

- **Inadequate Management**: Lack of SOPs or failure to follow them
- **Inadequate Investigations**: Insufficient depth or poor documentation
- **Inadequate Outcomes**: Testing into compliance without justifiable OOS invalidation

GMP inspectors are closely evaluating how companies manage OOS results, and a key goal of this course is to help participants understand current best practices for conducting OOS investigations. Additionally, Data Integrity (DI) is a critical area, especially in QC laboratories. Despite increased guidance from agencies like the FDA, WHO, MHRA, and PIC/S since 2016, demonstrating data integrity has long been a core GMP requirement.

This two-day course provides essential guidance for maintaining compliance in QC laboratories, with a focus on both OOS handling and Data Integrity. Successful validation of methods is crucial for QC labs and regulators alike, ensuring the reliability of test data. The course will cover key aspects necessary for method validation to meet regulatory standards.

Course Content

Day 1: Laboratory Controls and OOS/OOT Management

- Core elements and principles for establishing control and maintaining compliance in Quality Control/Analytical Laboratories (ISO 17025)
- Distinguishing Out-of-Specification (OOS), Out-of-Trend (OOT), and Out-of-Expectation (OOE) results
- Best practices for conducting OOS investigations, including re-testing and re-sampling
- Statistical approaches for trend analysis
- Perspectives from regulatory authorities

Day 2: Analytical Method Validation

- Introduction to analytical method validation
- Fundamental statistical tools for method validation
- Key performance characteristics of analytical methods
- Ensuring analytical methods are fit for purpose
- Designing a validation protocol for analytical methods

Participants

This course is ideal for regulated laboratory analysts, supervisors, managers, and anyone involved in GxP and laboratory practices. It will provide valuable insights into effective OOS management and data integrity compliance.

COURSE OUTLINE

Revised

Deviations and Investigation Management: Ensuring Effective CAPA (23 – 24 July 2025)

In the highly regulated pharmaceutical, biotech, and medical device sectors, the responsibility to investigate and understand the root causes of quality failures and production issues is critical to ensuring product safety and efficacy. However, regulatory inspections frequently highlight a recurring issue: the "failure to thoroughly investigate." This course aims to equip participants with the essential skills necessary for conducting comprehensive failure investigations and executing effective root cause analyses (RCA). Through the use of real-world scenarios drawn from industry experiences, participants will gain valuable insights into best practices for meticulous investigations. The course underscores the principle that a more structured and systematic investigation process leads to greater effectiveness and reliability in identifying and resolving issues.

Additionally, the program will explore the strategic application of the Corrective and Preventive Action (CAPA) system. Beyond merely fulfilling regulatory obligations, CAPA is presented as a dynamic tool for establishing a closed-loop mechanism for effective problem-solving. By adeptly integrating CAPA into your quality management framework, you can not only resolve immediate challenges but also foster a proactive culture that reduces the likelihood of future product quality issues and bolsters overall compliance. Practical examples and detailed case studies will illustrate the tangible benefits of implementing a robust and compliant CAPA system, showcasing how it can enhance operational excellence.

Course Content

Day 1: Root Cause Analysis (RCA)

- Introduction to the general principles of the 8D problem analysis methodology.
- Comparison and contrast of 8D with other methodologies such as Six Sigma DMAIC and PDCA (Plan-Do-Check-Act).
- Understanding the concept of variation within the problem-solving process.
- Detailed examination of the key steps involved in the 8D problem analysis methodology.
- Overview of common problem-solving techniques and tools.
- Hands-on exercise: Develop an 8D report for a selected real-world problem.

Day 2: Corrective and Preventive Action (CAPA)

- Overview of the regulatory framework surrounding CAPA requirements.
- Clear definitions of Corrective Action and Preventive Action within the context of quality management.
- Discussion on the integration of CAPA with essential quality system elements, including risk management.
- Linking the concepts of risk assessment and management with CAPA implementation.
- Understanding and applying the SMART (Specific, Measurable, Achievable, Relevant, Time-bound) principles to CAPA.
- Identifying the critical elements of a compliant and effective CAPA system.
- Practical exercise: Develop a CAPA plan based on findings from the RCA utilizing the 8D approach**.**

<u>Participants</u>

This course is tailored for professionals involved in failure investigations and the management of corrective actions across the pharmaceutical, biotech, and medical device industries. Whether you are new to formal problem-solving techniques and the CAPA process or an experienced professional seeking to enhance your knowledge, this program will provide significant value. A foundational understanding of regulatory Good Manufacturing Practice (GMP) and Quality Management System (QMS) requirements in these industries is expected to maximize the benefits of the course

COURSE OUTLINE

Revised

Process Validation: Statistical Applications and Best Practices (5 – 6 August 2025)

This comprehensive course is designed to deepen participants' understanding of Process Validation (PV) within the context of current regulatory frameworks. It goes beyond a mere review of foundational concepts and standard practices by offering practical guidance on the effective integration of Quality Risk Management (QRM) principles into the Process validation.

Throughout the program, participants will gain the skills necessary to strategically implement these principles, enabling them to create robust validation plans that not only satisfy existing regulatory requirements but also foster a proactive approach to quality assurance. By emphasizing the importance of a quality-centric mindset, the course aims to empower attendees with practical tools and insights that can be immediately applied to enhance their PV processes.

Moreover, participants will learn how to identify potential risks early in the validation lifecycle, utilize statistical tools for data analysis, and leverage best practices for continuous improvement. This course will also address real-world case studies, allowing attendees to engage in collaborative discussions and workshops that reinforce learning and facilitate knowledge exchange. Ultimately, the goal is to help participants elevate their compliance efforts and strengthen their organization's overall quality management system

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Content

Day 1: Principles of Process Validation

- Understanding the GMP rationale for process validation.
- Managing Variation, Process Capability Indices, and Sampling Considerations in the context of process validation.
- Overview of the validation life cycle and its significance.
- Insights into current regulatory perspectives and expectations.
- Exploration of evolving Quality Management philosophies.
- Discussion of real-life case studies and examples.

Process Design

- Introduction to Quality by Design (QbD) principles, including ICH Q8 and Q11 guidelines.
- Developing a Quality Target Product Profile (QTPP).
- Identifying and defining Critical Quality Attributes (CQA).
- Understanding Critical Process Parameters (CPP).
- Exploring Design Space and its implications for process validation.
- Establishing a robust Control Strategy.
- Emphasizing Continuous Improvement initiatives.
- Examining the connections between QbD, Control Strategy, and Process Design.

Day 2: Managing Data in Process Validation

- Gaining insights into process understanding and its role in effective validation.
- Evaluating the implications of validation deviations and their management.
- Utilizing Statistical Tools for data analysis in PV.
- Assessing Process Capability and Performance metrics.
- Participating in workshops that address common PV challenges and explore effective solutions.

Participants

This course is intended for validation professionals, as well as individuals responsible for approving process validation plans and projects. It is also suitable for anyone interested in the latest trends and methodologies in process validation that are rapidly gaining acceptance as industry standards.

COURSE OUTLINE

Revised

Cleaning Validation: Ensuring Compliance and Efficiency (19-20 August 2025)

For nearly two decades, the FDA's guidance document "Validation of Cleaning Processes (7/93)" served as the cornerstone reference for cleaning validation practices. However, between 2016 and 2020, there has been a significant increase in guidance publications from key industry organizations, including the EMA, PIC/S, PDA, ISPE, and WHO. This raises an important question: What do these numerous documents mean for you and your organization?

This training course aims to clarify the current "cleaning validation landscape" by examining recent changes in regulatory expectations and their implications for manufacturers. Participants will gain insights into the contemporary application of a science- and risk-based approach to cleaning validation and develop the skills necessary to create GMP-compliant cleaning validation (CV) protocols.

Key Learning Objectives:

- **Regulatory Evolution:** Explore the evolution of cleaning validation regulations over the years, highlighting key updates introduced by various regulatory bodies.
- **Practical Application:** Investigate real-world applications of a science- and risk-based approach to cleaning validation, drawing on industry best practices and case studies.
- **Interactive Discussions:** Participate in engaging discussions and collaborative case studies that reinforce understanding of the complexities within the updated cleaning validation framework.
- **GMP Compliance:** Learn effective strategies and techniques to ensure your cleaning validation protocols align with Good Manufacturing Practices (GMP) standards.
- **Industry Perspectives:** Acquire insights into how different companies are adapting to the evolving cleaning validation landscape, including perspectives from industry experts.

Course Content:

Day 1: The Principles of Cleaning Validation

- Understanding the regulatory foundation and GMP rationale for cleaning validation.
- Developing strategies for cleaning validation that comply with GMP standards.
- Establishing practical limits for cleaning residues and health-based exposure limits (HBEL).
- Key components of a cleaning validation protocol, supported by real-world industry examples.
- Techniques for sampling, inspection, and testing.

Day 2: The Practices

- Overview of current global regulations and requirements for cleaning validation.
- Designing cleaning processes and methods, including equipment design and qualification.
- Determining residue levels, analytical methods, and limit calculations.
- Documentation practices essential for supporting an effective cleaning program.
- Identifying common challenges and strategies for addressing failures during the cleaning process.
- Maintaining the validated state of cleaning processes.
- Strategies for presenting your cleaning validation strategy and data to regulatory authorities.
- Hands-on workshops addressing typical cleaning validation problems and solutions.
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<u>Participants</u>

This training is ideal for individuals in Quality or Validation Management roles or those directly responsible for preparing and executing cleaning validation studies within GMP facilities. It is suitable for Quality Assurance and Quality Control personnel, Operations and Manufacturing staff, Qualification & Validation experts, Engineering and Automation teams, R&D personnel, and anyone in the GMP industry seeking to expand their knowledge of cleaning validation processes..

COURSE OUTLINE

Revised

Managing Internal and External Audits: Strengthening Your Quality Management System (17 - 18 September 2025)

Conducting both internal and external audits is a vital component of establishing, sustaining, and enhancing your quality management system—an essential aspect of your organization's success. Whether you are part of a pharmaceutical company fulfilling the "self-inspection" requirements outlined in the PIC/S Guide to Good Manufacturing Practice (GMP) or a medical device manufacturer complying with the "internal audit" standards of ISO 13485, a well-structured audit program serves multiple purposes. It not only educates personnel but also reinforces accountability within the quality system, fostering a culture of continuous improvement and driving cost efficiencies.

The benefits derived from audits are significant, regardless of your organization's quality system maturity. If you are seeking ways to optimize and maximize the value of your internal and external audit programs, this course is tailored to help you achieve your Key Performance Indicators (KPIs).

Content

Day 1: Managing Internal and External Audits

- **The Critical Role of Audits in Quality Management:** Understand how both internal and external audits contribute to compliance and the overall improvement of your organization's quality management system.
- **Regulatory Standards and Guidelines:** Review the key regulatory frameworks that govern internal and external auditing, including GMP requirements and the ISO standards relevant to your industry.
- **Risk Assessment in Audit Practices:** Learn how to incorporate risk assessment principles into both internal and external audit processes to enhance their effectiveness.
- **Essential Documentation and Records:** Identify the types of documentation, records, and data necessary for conducting thorough audits.
- **Audit Scheduling and Risk-Based Prioritization:** Discover strategies for developing audit schedules that leverage risk management principles to prioritize both internal and external audits effectively.
- **Fundamental Auditing Techniques:** Gain mastery of the six fundamental steps of auditing, along with practical tips and techniques to improve your auditing processes.

Day 2: Corrective and Preventive Action (CAPA) in Auditing

- **Understanding CAPA:** Define Corrective and Preventive Action (CAPA) and explore its significance within the audit process.
- **Integrating CAPA into Audit Practices:** Learn how to effectively apply CAPA principles to both internal and external audits.
- **Applying Risk Management Principles:** Understand how to utilize risk management principles to enhance:
    - Audit observations
    - CAPA development and implementation
    - Audit verification and follow-up processes

Participants

This course is designed for operational personnel, including key operators, supervisors, and managers who are instrumental in implementing quality systems and audit programs. Participants will acquire the knowledge and skills needed to develop and maintain a comprehensive audit framework that fosters a culture of quality, compliance, and continuous improvement.

COURSE OUTLINE

Revised

Contamination Control: Developing a Robust Strategy (01-02 October 2025)

(Incorporation of Virtual Reality (VR) for Classroom Exercises).

The necessity to prevent or manage (cross-) contamination during the storage, handling, and processing of both sterile and non-sterile components, materials, and products is emphasized by the clear directives in Good Manufacturing Practices (GMPs). This is highlighted by numerous references in key regulatory documents, including over 40 in the PIC/S Guide to GMP for Medicinal Products Part I (PE 009-17) and more than 20 in FDA 21 CFR Part 211 CGMP for Finished Pharmaceuticals.

This comprehensive course aims to equip participants with the essential knowledge and skills needed for effective contamination control. Key objectives include:

- **Critical Understanding:** Recognize the significance of contamination control and its impact on product quality, safety, and regulatory compliance.
- **GMP Compliance:** Familiarize with GMP regulations requiring contamination control measures, referencing the PIC/S Guide and FDA 21 CFR Part 211.
- **Contamination Identification:** Learn to identify various contamination types and their major sources in the manufacturing environment.
- **Procedural Implementation:** Acquire skills to develop and implement robust procedures to mitigate contamination risks, ensuring GMP alignment.
- **Real-world Application:** Examine practical case studies demonstrating effective contamination control strategies in real manufacturing scenarios.
- **Continuous Improvement:** Understand how contamination control is integral to continuous improvement, supporting sustained compliance and operational excellence.
- **Regulatory Updates:** Stay updated on the latest changes in contamination control regulations to adapt to evolving industry standards.
- **Interactive Learning:** Engage in discussions and exercises to reinforce understanding and application of contamination control principles.

By the end of the course, participants will possess both theoretical knowledge and practical tools to implement and enhance contamination control measures in their manufacturing environments.

Day 1

- Introduction to Contamination Control
- GMP principles and requirements for contamination control
- Types of contamination and potential sources
- Risk assessment methodologies for analyzing major risks to products
- Strategies for effective contamination control
- Cleaning and Sanitation
- Appropriate cleaning agents and disinfectants for various manufacturing contexts
- Effective cleaning and sanitation techniques

Day 2

- Operating in a Cleanroom
- Cleanroom facilities, HVAC, and filtration principles
- International cleanroom standards
- Gowning procedures and operator qualifications
- Cleanroom conduct and operational controls
- Environmental monitoring (Focus on how to develop the Alert and Action Limits)
- HVAC and Controlled Environments
- Classification of cleanrooms
- Key design requirements for cleanrooms
- Principles of particle filtration and controlled facility design and operation
- GMP deficiencies
- Strategies for establishing alert & action levels for EM
- EM test methods and examples of where and when they will be used

Participants

This course is designed to give personnel at all levels—Operators, Officers, Supervisors, and Managers—a solid understanding of contamination and its control within a GMP environment. Participants from various departments, including Production, Manufacturing, Packing, Quality Control, Quality Assurance, and Engineering, will find this training beneficial.

COURSE OUTLINE

Supply chain management and Supplier QA program- Application of QRM principles (28 – 29 October 2025)

The pharmaceutical industry operates on a global scale, with active pharmaceutical ingredients, components, and products sourced through complex supply chains. To address the challenges posed by varying regulatory oversight, the US Government enacted the Drug Supply Chain Security Act (DSCSA), mandating a national track-and-trace system for medicines that includes electronic tracing throughout the supply chain. Since its enforcement by the FDA in 2015, this legislation has highlighted the need to maintain the integrity of the pharmaceutical supply chain.

At the same time, the European Union (EU) has strengthened its Good Distribution Practice (GDP) requirements, which have been in place for years. These regulatory developments emphasize the necessity for all personnel involved in the supply chain to understand their roles and actively support the implementation of a robust quality system. This training will focus on the following key areas:

- **Global Regulatory Landscape**: Gain insight into the evolving regulatory environment, including the DSCSA in the US and updated GDP requirements in the EU, and their impact on the pharmaceutical supply chain.
- **Compliance Enforcement**: Learn about the enforcement of these regulations by agencies like the FDA, underscoring the importance of compliance to ensure the safety and integrity of pharmaceutical products.
- **Educating Personnel**: Recognize the importance of training all supply chain personnel on their responsibilities, fostering a collective effort to uphold compliance and quality standards.
- **Risk Management Principles**: Understand how integrating risk management principles into the quality system can safeguard product quality and ensure a consistent supply to customers.
- **Continuous Improvement**: Explore how a comprehensive quality system promotes continuous improvement, helping organizations adapt to regulatory changes and enhance operational efficiency.

Day 1 Content

- You will gain a detailed understanding of responsible supply chain management principles and their implementation. Key topics include:
- Management responsibility
- Current and future regulatory and customer requirements
- Cold chain maintenance
- Process control and validation
- Good documentation and record-keeping practices
- Training
- Continual improvement
- Building a successful Supplier QA program—a strategic approach
- The session will provide an overview of current regulatory requirements and expectations, along with a six-step plan for managing supplier quality to reduce risks and enhance compliance.

Day 2 Content

- You will develop an appreciation for:
- Recent changes and enforcement trends in supplier management regulations
- Necessary SOPs and records for compliance and effective supplier qualification
- Six-step planning for managing supplier quality
- Identifying supplier risk factors
- Establishing supplier risk ratings and evaluation criteria
- Structuring and drafting the Supplier Quality Agreement
- Considerations for reduced testing
- Scenarios when the supplier operates within your organization

<u>Participants</u>

This course is ideal for anyone responsible for the quality and integrity of their organization's supply chain, particularly in areas related to the procurement, supplier quality assurance, distribution, and logistics of finished pharmaceuticals, pharmaceutical ingredients, and medical devices.

COURSE OUTLINE

Revised

Good Distribution Practices: Ensuring Compliance in Regulated Industries (11 - 12 November 2025)

This course is designed to introduce participants to the essential principles of Good Distribution Practice (GDP) within regulated industries. Its primary goal is to deepen understanding of management concepts related to the handling, storage, and distribution of medicinal products and medical devices.

Key Components and Objectives:

Introduction to GDP Requirements: Gain a comprehensive overview of the foundational requirements outlined in Good Distribution Practice, including the regulatory landscape and the significance of compliance.

Industry Relevance: Learn about the specific applicability of GDP principles to regulated sectors, emphasizing their critical role in ensuring the quality and safety of pharmaceuticals and medical devices.

Regulatory Compliance: Understand how adherence to GDP standards is vital for maintaining regulatory compliance and safeguarding the integrity of healthcare products throughout the distribution process.

Risk Management: Explore the integration of risk management principles within GDP, focusing on strategies to identify, assess, and mitigate risks associated with distribution.

Practical Implementation: Acquire actionable insights for implementing GDP requirements in everyday operations, with a strong emphasis on real-world applications and case studies.

Role of Technology: Recognize the importance of technology in enhancing GDP, including tracking systems, temperature monitoring, and other innovations that contribute to the integrity of the distribution process.

Course Content

Day 1:

GDP: Relationship and Integration with GMP

- Definitions and foundational concepts of Good Distribution Practice (GDP).
- Understanding the relationship between GDP and Good Manufacturing Practice (GMP) throughout the supply chain.
- Scope and application of GDP principles.
- Comparative analysis of requirements between GMP and GDP.

Understanding GDP Requirements

- Quality management principles specific to GDP.
- Roles and responsibilities of personnel involved in GDP compliance.
- Infrastructure considerations: premises and equipment.
- Importance of accurate documentation and operational procedures.
- Handling complaints, returns, suspected falsified products, and recalls.
- Managing outsourced activities and conducting self-inspections.
- Transportation requirements in GDP compliance.

Day 2:

Applying Risk Management in the Supply Chain

- Overview of the Quality Risk Management process.
- Practical approaches for implementing risk management strategies in GDP compliance programs.
- Utilizing Failure Mode and Effects Analysis (FMEA).

Overview of Cold Chain Management

- Definition of cold chain logistics and associated challenges.
- Regulations and guidelines related to GDP and cold chain management, including mapping requirements.
- Essential criteria for temperature-controlled storage areas.
- Cold area qualification activities, including mapping and the justification for re-qualification.
- How to conduct an effective temperature mapping

<u>Participants</u>

This course is suitable for Warehouse Managers, Supervisors, and operational personnel who are new to the industry. It also serves as refresher training for existing staff, as required by the PIC/S Guide to GDP. Participants will gain a solid understanding of the fundamental principles of GDP, current trends, and

COURSE OUTLINE

Revised

Effective Writing Practices in GMP: Enhancing SOPs, Reports, and CAPA Documentation (26 - 27 November 2025)

Well-crafted summary reports, investigation reports, technical SOPs, and other essential documents are crucial for helping employees understand information the first time they encounter it. Effective documentation streamlines communication and fosters a culture of compliance. Who wouldn't want to enhance compliance, shorten onboarding time, and minimize deviations caused by unclear procedures? If your job involves writing SOPs, would you appreciate straightforward guidance on getting started? Are your documents stuck in endless revisions, taking months to gain approval? Do you struggle with convoluted language or face data integrity issues? This training course is designed to tackle these challenges and enhance your skills in creating clear and effective Standard Operating Procedures (SOPs), data collection forms, and other critical documents.

By the end of the course, participants will be able to:

- **Draft SOPs** that provide clear, concise instructions for consistent procedures.
- **Develop data collection forms** that prioritize data integrity, ensuring accurate data capture.
- **Create documents ready for submission** after the first review, reducing turnaround times for approvals.
- **Produce reports with precise and relevant information** for effective decision-making.
- The course aims to build confidence in writing SOPs, data collection forms, and other documentation that is both easy to understand and applicable in everyday work.

Course Content

Day 1:

- **Eliminating unnecessary complexity**: Techniques for simplifying language and structure.
- **Streamlining content**: Best practices for organizing information logically.
- **Utilizing process mapping**: Visualizing processes for clearer documentation.
- **Writing clear instructional documents**: Guidelines for creating step-by-step SOPs.
- **Preparing effective data collection forms**: Designing forms that capture data accurately.
- **Crafting concise reports**: Summarizing findings effectively.

Day 2:

- **Writing Effective Documents:** Focus on clarity and conciseness.
- **Identifying the correct sequence of actions**: Logically arranging steps.
- **Ensuring consistency**: Maintaining uniform terminology and formatting.
- **Constructing SOPs in the proper format**: Adhering to organizational and regulatory standards.
- **Hands-on Writing Sessions:**
  - Create and edit SOP documents to meet required standards.
  - Write investigation reports (deviations, CAPA, OOS reports).
  - Design a SMART data collection form: Crafting forms that are Specific, Measurable, Achievable, Relevant, and Time-bound.
  - Effectively write summary reports (validation, technical reports).

Participants

This course is ideal for anyone who writes or reviews workplace documents, whether you're new to the process or experienced. It is particularly beneficial for Quality Assurance and Control personnel, Research and Development staff, and Training and Compliance officers.

Covering fundamental principles of effective technical writing and current trends in SOP writing, the skills learned are applicable across various industries, ensuring all employees contribute to a culture of quality and compliance

COURSE REGISTRATION

Registration Fee per participant per course:
(The fee includes complete set of course materials)

Virtual Training Fee
MOPI Member – 2 Days Course
30 days before commencement of course RM1,900.00
(RM2,052.00 inclusive 8% SST)
29 – 14 days before commencement of course RM2,100.00
(RM2,268.00 inclusive 8% SST)

Non-MOPI Member – 2 Days Course
30 days before commencement of course RM2,200.00
(RM2,376.00 inclusive 8% SST)
29 – 14 days before commencement of course RM2,400.00
(RM2,592.00 inclusive 8% SST)

Foreign Participant – 2 Days Course
30 days before commencement of course USD $1,000.00
(USD$ 1,080.00 inclusive 8% SST)
29 – 14 days before commencement of course USD $1,200.00
(USD$ 1,296.00 inclusive 8% SST)

Physical Training Fee
MOPI Member – 2 Days Course
30 days before commencement of course RM2,480.00
(RM2,678.40 inclusive 8% SST)
29 – 14 days before commencement of course RM2,680.00
(RM2,894.40 inclusive 8% SST)

Non-MOPI Member – 2 Days Course
30 days before commencement of course RM2,780.00
(RM3,002.40 inclusive 8% SST)
29 – 14 days before commencement of course RM2,980.00
(RM3,218.40 inclusive 8% SST)

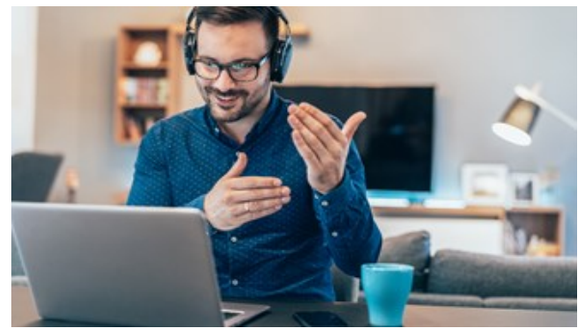
Foreign Participant – 2 Days Course
30 days before commencement of course USD $1,300.00
(USD$ 1,404.00 inclusive 8% SST)
29 – 14 days before commencement of course USD $1,500.00
(USD$ 1,620.00 inclusive 8% SST)

Payment must be made before the training

Seats are limited: Only 25 participants per class

TRAINING TIME SCHEDULE:
9.00AM – 5.00PM (in 2 days)

9.00AM – AM TOPIC
11.00AM – BREAK
11.15AM – AM TOPIC
1.00PM – LUNCH BREAK
2.00PM – PM TOPIC
3.00PM – BREAK
3.15PM – PM TOPIC
5.00PM – FINISH



BOOK YOUR SEAT NOW!!!

For further enquiries, please contact:
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Mezzanine Floor, Block A, No. 8, Jalan 19/1, Section 19,
46300 Petaling Jaya, Selangoer, West Malaysia
Tel: 03-7931 9003 Fax: 03-7932 2730
E-mail: mike@mopi.org.my and admin@mopi.org.my
www.mopi.org.my

ADMINISTRATION DETAILS:

Registration will be treated as confirmed only upon receipt of payment in full.

CANCELLATIONS & TRANSFERS:

- If you are a HRDF-registered employer, you may apply to HRDF for SBL-Khas training grant for the training.
- If you are not claiming or unable/unsuccessful to claim HRDF, full payment should be made in advance within 14 days of invoice issuance prior to the training event.
- All cheques should be crossed and made payable to **MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES**
  Banker Name : Malayan Banking Berhad Account Number : 5122 3139 2242
- If a registrant is unable to attend, a substitute candidate is welcome at no extra charge. Please provide the name and the title of the substitute participant at least 2 working days prior to the relevant course.
- Notice of cancellation by fax/email is required 14 working days prior to commencement of each module and refund less RM500 as administration charge will be made. However, a complete set of documentation will be sent to you.
- Regrettably, no refund can be made for cancellations received less than 10 working days prior to the commencement of each module. However, a complete set of documentation will be sent to you.
- MOPI / SeerPharma reserve the right to cancel or reschedule the training modules. All efforts will be taken to inform participants of any change. MOPI / SeerPharma however will not be held liable for reimbursement of any claims or expenses should cancellation or rescheduling occurs.

REGISTRATION FORM Subject to Administration details

☐ MOPI Member ☐ Non-Member ☐ Foreign

Please register the following participant(s) for the above program. (To be completed in BLOCK LETTERS)

HRDF Registered Employer [ ] Yes [ ] No Apply for HRD Claimable Course [ ] Yes [ ] No

HRDF Registered Number [ ]

1 Name_____

Designation_____

Email address _____

Contact Number _____

NRIC Number _____

☐ Vegetarian

2 Name_____

Designation_____

Email address _____

Contact Number _____

NRIC Number _____

☐ Vegetarian

Participant's Email Address must be in complete for online training

List of 2-Day Courses (please tick accordingly)	
☐ **GMP Fundamentals: Key Concepts to Know** **21 – 22 January 2025 (Tue – Wed) Physical Training**	☐ **Cleaning Validation: Ensuring Compliance and Efficiency** **19 – 20 August 2025 (Tue-Wed) Virtual Training**
☐ **Quality Risk Management: A Comprehensive Training** **26-27 February 2025 (Wed – Thu) Virtual Training**	☐ **Managing Internal and External Audits: Strengthening Your Quality Management System** **17 - 18 September 2025 (Tue - Wed) Physical Training**
☐ **Behavioral GMP and Data Integrity: Reducing Human Error** **22 - 23 April 2025 (Tue- Wed) Virtual Training**	☐ **Contamination Control: Developing a Robust Strategy** **01 – 02 October 2025 (Wed- Thur) Physical Training**
☐ **Qualification and Validation: Essential Implementation Strategies** **27 – 28 May 2025 (Tue-Wed) Physical Training**	☐ **Supply Chain Management & Supplier QA: Applying QRM Principles** **28 - 29 October 2025 (Tue- Wed) Virtual Training**
☐ **Computer Systems for Regulated Environments** **17 – 18 June 2025 (Tue- Wed) Virtual Training**	☐ **Good Distribution Practices: Ensuring Compliance in Regulated Industries** **11 – 12 November 2025 (Tue-Wed) Physical Training**
☐ **Introduction to Laboratory Controls: Managing OOS, OOT, OOE and Analytical Method Validation** **9 - 10 July 2025 (Wed- Thur) Physical Training**	☐ **Effective Writing Practices in GMP: Enhancing SOPs, Reports, and CAPA Documentation** **26 - 27 November 2025 (Wed- Thur) Physical Training**
☐ **Deviations and Investigation Management: Ensuring Effective CAPA** **23 – 24 July 2025 (Wed- Thur) Physical Training**	* * Dates and Instructors are subject to change depending on attendance feedbacks and instructor availability. In case of a change, updated dates and instructor profile will be advised to the organizer and the attendees prior to the start of each course
☐ **Process Validation : Statistical Applications and Best Practices** **5 – 6 August 2025 (Tue – Wed) Physical Training**	

Registration Submitted by:

Name _____

Designation _____

E-mail _____

Contact No / Mobile No _____

Company Stamp (with Address, Telephone & Fax Number)