Quality Assurance and GMP Training Program

Online, Instructor-Led Training And Physical Training

YEAR 2026

The training program consists of 9 physical courses and 6 on-line courses. These courses cover the essential principles of Quality Assurance (QA), Good Manufacturing Practice (GMP), Validations, Product Quality Reviews (PQR), Supply chain Management, Good Writing Practices, Laboratory Management, Contamination Control, Audit Management 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, NPRA, 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.

Organised by:

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

Presented by:

SeerPharma® CONFIDENCE IN COMPLIANCE

Endorsed by:

National Pharmaceutical Regulatory Agency, MOH

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

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

COURSE OUTLINE

Revised

GMP Essentials: Foundations for Operational Excellence (27 – 28 January 2026)

If you work in pharmaceutical manufacturing or GMP compliance, it is essential to understand your regulatory responsibilities, the structure of a Pharmaceutical Quality System, and the core expectations of Good Manufacturing Practice (GMP) under PIC/S. This course provides a practical, streamlined introduction to the key requirements in the PIC/S Guide to GMP Part I, supported by real-world examples to show how GMP principles protect product quality and prevent issues like adulteration and misbranding.

Day 1 — Global GMP Fundamentals

Regulatory Overview

- Product lifecycle: development → manufacturing → testing → distribution
- Key regulators and harmonized standards (PIC/S, FDA, NPRA, EMA, WHO)
- Quality System types and major GMP frameworks (PIC/S PE009, 21 CFR 210/211, EU GMP)
- Purpose of GMP: ensuring identity, safety, quality, strength, and efficacy
- Main inspection focus areas and compliance priorities

GMP Essentials

- Personnel roles, training, and qualification
- Facility design, cleanliness, and controlled flows
- Production and processing areas: contamination and mix-up prevention
- Storage and warehouse controls, including temperature management
- QC labs and analytical responsibilities
- Utilities and support systems (HVAC, water, gases)
- Equipment qualification, calibration, and maintenance
- Process and packaging controls across manufacturing
- Validation of systems, methods, and equipment
- QC duties: sampling, testing, batch documentation, and release

Day 2 — Documentation Excellence & Quality Systems

Good Documentation Practices (GDocP)

- GMP requirements for documentation and controlled records
- Purpose of GDocP and its link to data integrity (ALCOA+)
- Frequent documentation errors and how to avoid them
- Writing clear SOPs, work instructions, batch records, and forms
- Structuring documents for use, clarity, and audit readiness

Quality Systems Approach

- Pharmaceutical Quality System (ICH Q10) overview
- Quality Risk Management (ICH Q9) principles
- Core QMS processes for ongoing control:

– Deviations & non-conformances
– Complaints & recalls
– CAPA processes
– Change control
– Product Quality Review (PQR/APQR)

- How QMS components maintain a state of control and support continuous improvement

Participants

This course provides newcomers to the pharmaceutical industry with a strong foundation in PIC/S GMP principles and Pharmaceutical Quality System expectations. It is equally beneficial for experienced GMP professionals looking to stay current with PIC/S requirements, organizations preparing for new or renewed GMP certification, and manufacturers engaged in secondary packaging of medicinal products.

COURSE OUTLINE

New

Annual Product Quality Review (APQR): Concepts, Requirements & Best Practices (10 – 11 February 2026)

The Annual Product Quality Review (APQR) is a cornerstone of GMP compliance, providing ongoing assurance that processes remain in control, specifications remain appropriate, and products continue to meet quality, safety, and efficacy standards.

Yet many organisations still struggle with incomplete PQRs, poor data integrity, inadequate trending, unclear responsibilities, or ineffective use of statistics — all of which have been highlighted repeatedly in global regulatory findings.

This training programme provides a practical, end-to-end understanding of APQR requirements under PIC/S PE009-17, TGA interpretations, FDA expectations, and international best practices. Using real examples and cases from regulatory inspections, participants will learn how to plan, conduct, analyse, document, and defend an APQR that withstands regulatory scrutiny.

DAY 1 — Foundations & Requirements

Regulatory Basics

- PIC/S requirements
- API requirements
- Regulatory expectations & common findings

Planning the APQR

- Scope, grouping, schedule
- Roles & responsibilities (QA/QC/RA/Production)
- Compliance obligations & MA variations

Data Inputs & Integrity

- Ensuring complete, accurate data
- Mapping data sources & consolidation

Qualitative Review

- Deviations, CAPA, complaints
- Change controls, stability trends
- Supplier/API traceability
- Equipment/utility qualification

DAY 2 — Analysis, Trending & Reporting (Short Version)

Quantitative Analysis Qualitative Interpretation

- Trending CQAs & CPPs
- SPC basics: charts & rules- Capability (Cp/Cpk/Pp/Ppk)
- Identifying drift & need for revalidation
- Cross-functional trends, CAPA effectiveness
- Systemic vs isolated issues

Grouping & Frequency

- Scientific grouping criteria
- Review-by-exception
- FDA APR differences

APQR Reporting

- Required sections & structure, Writing conclusions & trends clearly
- CAPA recommendations

Participants:

This course is suitable for both participants new to Product Quality Reviews and experienced professionals involved in GMP compliance. It is particularly valuable for those responsible for compiling, reviewing, or interpreting PQR data across quality, manufacturing, QC, regulatory, or technical functions, equipping them with the skills needed to manage product and process risks effectively through robust annual reviews.

COURSE OUTLINE

bGMP- Human Factors in GMP & Data Integrity: Minimizing Errors Through Better Behaviors (31Mar-01 Apr 2026)

Effectively managing deviations is essential to maintaining productivity and a stable GMP environment. However, many investigations end with “human error” as the root cause, resulting in repetitive actions such as retraining or procedural updates. While these may offer temporary relief, they often fail to address deeper behavioural and systemic issues—leading to recurring non-compliances.

This course introduces Behavioural GMP (bGMP) as a practical framework for understanding why non-compliance occurs—whether due to unintentional mistakes or deliberate actions—and provides effective strategies to prevent recurrence. Participants will examine key human error types, understand where retraining is genuinely useful, and recognise its limitations when underlying behavioural factors are not addressed.

On Day 2, the focus shifts to Data Integrity (DI), a core pillar of regulatory compliance and a critical component of an effective Quality Management System. The session explores DI principles, global regulatory expectations, and practical methods for ensuring data reliability across the pharmaceutical lifecycle, including QC and other operational areas. Real examples and case studies will guide participants in identifying, preventing, and responding to DI issues.

Course Content

Day 1: Behavioural GMP & Managing Deviations

- Root causes of product defects
- Human error types and underlying causes
- Behavioural drivers leading to non-compliance
- Managing errors and non-compliant behaviours
- Human learning stages and related error patterns
- Identifying behavioural and systemic contributors
- Building a strong quality culture and reducing recurring issues
- Leadership roles in reinforcing compliance
- Strategies to minimise learning and inherent errors
- Targeted approaches for preventing future errors

Day 2: Data Integrity

- Core principles and contributors to Data Integrity
- Regulatory expectations for data governance and security
- Assessing data criticality, risk, and controls
- Embedding DI into the QMS using a risk-based framework
- Protecting raw data and original records
- Practical DI audit techniques, detection methods, and remediation strategies

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Participants

This program is designed for executives, managers, specialists, and supervisors involved in GMP compliance, deviation investigation, quality oversight, operations, and continuous improvement. Participants will gain practical tools and insights to strengthen GMP performance, reduce recurring issues, and uphold robust data integrity across their organisations.

COURSE OUTLINE

Revised

Qualification & Validation Masterclass: Practical Approaches for Implementation (21 – 22 Apr 2026)

This program delivers a comprehensive introduction to contemporary equipment qualification and validation practices. Over two days, participants will learn how to apply a structured, science-driven, and risk-based approach to planning, executing, and maintaining qualification activities across the equipment lifecycle. The course emphasises how strong validation programs enhance process reliability, optimise operational efficiency, strengthen regulatory compliance, and ultimately protect patient safety. Participants will also gain insight into current industry expectations, evolving regulatory trends, and practical tools that support sound validation decisions and defensible documentation.

Course Content

Day 1: Fundamental Validation Concepts & Applying QRM

Foundations of Qualification & Validation

- Overview of regulatory expectations and the breadth of Q&V activities
- Understanding lifecycle-based validation: from design to retirement
- Core elements of validation planning, documentation, and protocol architecture
- How validation integrates with the Pharmaceutical Quality System (PQS)

Building a Risk-Based Validation Strategy

- Key components of a validation program (VMP, VPP, system classification)
- Applying Quality Risk Management to determine validation scope and depth
- Identifying critical versus non-critical systems and functions
- Using tools such as FMEA, HACCP, and risk ranking to evaluate processes and controls
- Establishing science-based rationales for testing, sampling, and acceptance criteria

Day 2: Practical Execution, Assessment & Maintaining the Validated State

Equipment Qualification Framework

- Essential requirements for effective qualification activities
- Developing meaningful User Requirements Specifications (URS)
- Qualification stages (IQ, OQ, PQ): expectations, documentation, and decision-making
- Incorporating risk-based testing into qualification protocols
- Executing qualification studies, interpreting results, and managing deficiencies

Sustaining Validation Throughout the Lifecycle

- Managing changes and ensuring continued fitness-for-use
- Periodic review, requalification triggers, and ongoing verification strategies
- Maintaining the validated state through robust controls and monitoring
- Aligning lifecycle activities with patient safety, regulatory expectations, and business continuity

Participants

This course is ideal for individuals new to qualification and validation, as well as experienced GMP professionals seeking refreshed knowledge on current regulatory expectations, lifecycle validation, and modern risk-based approaches. It is particularly valuable for QA, validation, engineering, technical operations, and manufacturing personnel involved in equipment and process qualification activities.

COURSE OUTLINE

Revised

Supply Chain Quality & Supplier Oversight and Qualification: Risk-Based Approaches in Practice (19 – 20 May 2026)

The pharmaceutical supply chain spans multiple countries and partners, creating challenges in traceability, quality oversight, and regulatory compliance. Global regulators have responded by strengthening requirements to protect product integrity. In the U.S., the Drug Supply Chain Security Act (DSCSA) introduced a national electronic track-and-trace system, while the EU continues to reinforce its Good Distribution Practice (GDP) standards. These developments emphasise that all personnel involved in procurement, distribution, logistics, and supplier oversight must understand their responsibilities and contribute to a strong quality system.

This training provides a practical overview of global supply chain expectations, key regulatory frameworks, and risk-based strategies that help organisations maintain compliant and reliable distribution practices.

Key Learning Areas

- Overview of DSCSA, EU GDP, and international supply chain regulations
- How agencies such as FDA and EU authorities enforce compliance
- Roles and responsibilities across the supply chain
- Integrating risk management into distribution and supplier oversight
- Strengthening the Quality System to support continuous improvement

Day 1 Content

- Management responsibility in supply chain quality
- Current and emerging regulatory/customer requirements
- Cold-chain handling and storage controls
- Distribution process control and validation
- Documentation and record-keeping expectations
- Training and competency management
- Continuous improvement foundations
- Building an effective Supplier QA program (six-step approach)

Day 2 Content

- Recent regulatory trends in supplier management
- Essential SOPs and records for qualification and oversight
- Applying the six-step supplier quality planning model
- Identifying supplier risks and assigning risk ratings
- Developing Supplier Quality Agreements
- When reduced testing may be justified
- Managing suppliers operating within your own facilities

Participants

Designed for professionals involved in supply chain quality, procurement, supplier QA, logistics, warehouse operations, and distribution of pharmaceuticals, ingredients, and medical devices.

COURSE OUTLINE

Revised

Quality Risk Management Deep Dive: Tools, Techniques & Applications (03 - 04 Jun 2026)

Quality Risk Management (QRM) provides a structured, science-driven way to evaluate and control risks that may impact patient safety, product quality, or regulatory compliance. Regulators increasingly expect QRM to be embedded throughout the Quality Management System, using both formal and informal tools aligned with ICH Q9 principles—risk assessment, risk control, risk review, communication, and acceptance of residual risk.

This advanced, practical training uses real case studies to help participants confidently apply QRM concepts to quality system issues and manufacturing processes. Through interactive exercises, attendees will gain hands-on experience selecting appropriate tools, conducting risk assessments, and interpreting outcomes that support robust decision-making.

Day 1 — QRM in Quality & Compliance

Quality systems rely on well-informed, evidence-based decisions. Whether addressing customer complaints, deviations, audit findings, or CAPA, a structured risk assessment process strengthens compliance and supports consistent product quality. Day 1 focuses on applying QRM tools within key GxP processes and improving the quality of compliance-related decisions.

Topics include:

- QRM framework and core concepts
- How risk supports GMP compliance and decision-making
- Applying risk assessments within key quality systems:
    - Audits
    - Change Control
    - Complaints & Adverse Events
    - Deviations & Non-conformances
    - CAPA

Day 2 — QRM for Manufacturing & Process Risk

QRM has become integral to pharmaceutical manufacturing since its adoption into GMPs. Day 2 provides a practical understanding of when and how to use the right tools, ensuring risk assessments add real operational value. Participants will learn how to evaluate process risks, identify controls, and build risk-based justification for manufacturing decisions.

Topics include:

- Understanding process risks and critical factors
- Overview of GMP expectations for process risk assessments
- Selecting from the QRM toolbox: choosing the right tool for the problem
- Practical application of key tools:
    - Preliminary Hazard Analysis (PHA)
    - Hazard Analysis & Critical Control Points (HACCP)
    - Failure Mode & Effects Analysis (FMEA)

Participants

This course is suitable for personnel new to risk assessment as well as experienced QRM practitioners. It is especially valuable for individuals involved in quality systems, regulatory compliance, manufacturing operations, or anyone responsible for evaluating and managing risks that impact product quality and patient safety.

COURSE OUTLINE

Revised

Process Validation Excellence: Statistics, Sampling & Lifecycle Strategies (14 – 15 July 2026)

Process Validation (PV) is a critical element of pharmaceutical manufacturing, ensuring that processes consistently deliver products of the intended quality. This program provides a practical and modern interpretation of PV by aligning regulatory expectations with Quality Risk Management (QRM) and data-driven decision-making. Instead of focusing solely on traditional validation concepts, the course highlights how QRM, science-based evaluation, and lifecycle thinking can be effectively embedded into PV activities.

Participants will learn how to plan and execute validation using a strategic, risk-based approach—strengthening process understanding, improving control strategies, and ensuring long-term process robustness. Through targeted discussions, real examples, and workshop exercises, the program equips attendees with tools to identify risks early, interpret data using statistical methods, and drive continuous improvement. By the end of the course, participants will be able to develop validation programs that are compliant, efficient, and aligned with current industry expectations.

Course Content

Day 1: Foundations of Process Validation

- The purpose of process validation within GMP
- Understanding process variation, capability indices, and sampling concepts
- Regulatory viewpoints and expectations for lifecycle-based PV
- Evolving approaches to modern Quality Management
- Case studies illustrating real validation challenges

Process Design Essentials

- Quality by Design (QbD): principles, ICH Q8 & Q11 overview
- Defining the Quality Target Product Profile (QTPP)
- Determining Critical Quality Attributes (CQAs)
- Identifying Critical Process Parameters (CPPs)
- Establishing Design Space and its impact on validation strategy
- Developing effective control strategies
- Integrating continuous improvement within the PV lifecycle
- Linking QbD, design activities, and process control

Day 2: Data, Evaluation & Validation Lifecycle Management

- Building process understanding to support validation decisions
- Managing validation deviations and assessing their impact
- Using statistical tools to analyse validation data
- Process capability and performance evaluation
- Workshops on common PV issues and practical problem-solving

Participants

This course is ideal for professionals involved in validation activities, those responsible for reviewing or approving validation deliverables, and individuals seeking up-to-date knowledge on modern PV practices. It is also well suited for anyone interested in emerging trends and regulatory expectations related to lifecycle validation.

COURSE OUTLINE

Revised

Cleaning Validation Mastery: Risk-Based Methods for Compliance and Efficiency (28 – 29 Jul 2026)

Cleaning validation has long been a critical focus area for regulators, with the FDA's 1993 guidance serving as the primary reference for many years. In recent times, however, the regulatory landscape has evolved rapidly. Between 2016 and 2020, organisations such as EMA, PIC/S, PDA, ISPE, and WHO released updated expectations that reflect a more scientific and risk-based approach. With so many new documents and perspectives emerging, companies are now challenged to understand what these changes mean for their cleaning programs.

This course provides a clear, practical overview of today's cleaning validation expectations, helping participants interpret new regulatory themes and apply them effectively in GMP environments. Through examples, discussions, and workshops, attendees will learn how to plan, execute, and maintain a cleaning validation program that meets global regulatory standards and supports product and patient safety.

Key Learning Objectives

- **Regulatory Progression:** Understand how cleaning validation expectations have developed and how recent global guidelines align or differ.
- **Risk-Based Application:** Learn how to apply science-based, risk-oriented principles to modern cleaning validation.
- **Hands-On Learning:** Work through real examples to understand the challenges and practical decision-making involved.
- **GMP Alignment:** Build strategies for developing cleaning validation protocols that stand up to regulatory scrutiny.
- **Industry Insights:** Explore how various organisations are implementing updated approaches and adapting their cleaning strategies.

Course Content

Day 1 — Foundations of Cleaning Validation

- The GMP rationale and regulatory drivers behind cleaning validation
- How to design cleaning validation strategies aligned with compliance requirements
- Establishing residue limits, including HBEL-based approaches
- Essential elements of a cleaning validation protocol with industry illustrations
- Sampling, inspection, and testing methods for cleaning verification

Day 2 — Practical Implementation

- Overview of global cleaning validation requirements and expectations
- Designing robust cleaning processes, including equipment considerations
- Residue determination, analytical methods, and limit calculations
- Documentation and recordkeeping needed for a defensible cleaning program
- Common causes of cleaning failures and how to resolve them
- Maintaining the validated state and lifecycle management
- Presenting cleaning validation data effectively to regulators
- Workshop sessions focused on real-world problem solving

Participants

This course is suitable for professionals involved in cleaning validation activities or oversight, including Quality Assurance, Quality Control, Manufacturing/Operations, Validation and Qualification teams, Engineering, Automation, and R&D personnel. It is ideal for those seeking a comprehensive understanding of modern cleaning validation expectations in GMP-regulated environments.

COURSE OUTLINE

Revised

Contamination Control Systems: Building a Modern Holistic Strategy (26-27 Aug 2026)

Enhanced with Interactive Cleanroom Augmented Virtual Reality Demonstrations

Contamination control is a core requirement in all GMP-regulated environments, applying to the handling, storage, and processing of both sterile and non-sterile materials and products. Global regulations such as PIC/S PE 009-17 and FDA 21 CFR Part 211 contain extensive requirements aimed at preventing contamination, highlighting its critical role in protecting product quality and patient safety.

This course provides a practical, streamlined understanding of contamination risks and the controls needed to manage them effectively. Through case examples and guided discussions, participants will learn how to identify contamination sources, apply risk-based controls, and implement procedures consistent with current GMP expectations.

Key Learning Outcomes

- Understand the importance of contamination control in relation to GMP and product quality
- Review key regulatory expectations from PIC/S and FDA
- Identify contamination types and common sources
- Learn practical strategies to prevent and control contamination
- Apply cleaning and sanitation principles effectively
- Gain exposure to cleanroom operations and environmental control requirements
- Understand how to set alert/action limits for environmental monitoring
- Strengthen contamination control programs through real-world examples.

Course Content

Day 1 — Contamination Control Essentials

- GMP principles on contamination prevention
- Types of contamination & major sources
- Risk assessment for contamination hazards
- Practical contamination control strategies
- Cleaning & sanitation fundamentals
- Choosing disinfectants and applying cleaning techniques

Day 2 — Cleanroom & Environmental Control

- Cleanroom operations, facility design, HVAC basics
- International cleanroom standards
- Gowning, operator behaviour, and qualification
- Cleanroom discipline & operational controls
- Environmental Monitoring: alert/action limits, methods, and examples
- Cleanroom classification & controlled environment design
- Common GMP deficiencies and how to avoid them

Participants

Ideal for Operators, Supervisors, Officers, and Managers across Production, Packaging, QA, QC, Engineering, and other GMP-regulated departments seeking a solid understanding of contamination control and cleanroom operations.

COURSE OUTLINE

Revised

Audit Readiness & Execution: Managing Internal , External, Regulatory and Supplier Audits Effectively (02- 03 Sep 2026)

Auditing is a fundamental pillar of an effective Quality Management System (QMS). Whether performed to meet PIC/S GMP self-inspection requirements, ISO 13485 internal audit obligations, or supplier audit expectations, a well-designed audit program plays a critical role in sustaining compliance and ensuring the reliability of operations. Robust audits do far more than identify gaps—they strengthen organisational accountability, promote transparency, reinforce good practices, and help prevent issues before they escalate. When executed effectively, audits also serve as a powerful learning tool, enabling teams to understand processes more deeply and contribute to a culture of continual improvement.

This course offers a comprehensive, practical framework for planning, conducting, and evaluating both internal and external audits. Participants will learn how to align their audit processes with regulatory requirements, integrate risk-based decision-making, and gather objective evidence that withstands regulatory scrutiny. The training further emphasises how to document findings clearly, evaluate their impact, and connect them to meaningful and sustainable corrective and preventive actions (CAPA). By the end of the program, participants will understand how an effective audit cycle contributes to long-term compliance, operational excellence, and a proactive quality culture.

Course Content

Day 1 — Managing Internal & External Audits

- The role of internal, external, and supplier audits in maintaining QMS effectiveness
- Understanding regulatory frameworks: PIC/S GMP, ISO 13485, ICH Q10, and other relevant standards
- Integrating Quality Risk Management into audit planning and execution
- Techniques for gathering objective evidence: documentation review, interviews, walk-throughs, and observations
- Audit preparation: defining scope, understanding processes, and preparing checklists
- Essential documentation for strong audits: protocols, notes, reports, and records
- Developing risk-based audit schedules to prioritise high-impact areas
- Key auditing skills: communication techniques, questioning strategies, and professional behaviour
- Writing clear, defensible audit findings and classification of observations

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Day 2 — CAPA & Risk-Based Follow-Up

- Purpose, structure, and regulatory expectations for CAPA within a QMS
- Linking audit findings to effective corrective and preventive actions
- Using risk-based tools to assess the severity and impact of audit observations
- Ensuring CAPAs are SMART, evidence-based, and appropriately justified
- Techniques for root cause analysis and linking RCA outcomes to audit CAPAs
- Verification and effectiveness checks: ensuring CAPAs deliver the intended improvements
- Establishing a closed-loop audit process that feeds back into continuous improvement
- Best practices for documenting CAPA activities, timelines, and follow-up
- Preparing for regulatory inspection queries related to audit and CAPA processes

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Participants

This program is ideal for operators, supervisors, managers, and professionals involved in quality systems, self-inspections, supplier audits, or regulatory compliance. It provides valuable skills for those responsible for planning audits, conducting assessments, documenting findings, or managing CAPA activities. Participants will leave with the knowledge and confidence needed to build and sustain an effective audit framework that enhances compliance, strengthens oversight, and drives continuous improvement across the organisation.

COURSE OUTLINE

Computer Systems for Regulated Environments (30 Sep – 01 Oct 2026)

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

Laboratory Quality Systems and Method Validation: Managing OOS/OOT/OOE and Ensuring Method Compliance (13 – 14 Oct 2026)

Global GMP authorities continue to highlight recurring gaps in how organisations manage Out-of-Specification (OOS) results. Despite long-standing regulatory expectations, many laboratories still struggle with consistent, science-based investigation practices. Common inspection findings include:

• **Poor Oversight:** Inadequate or outdated SOPs, unclear instructions, or failure to follow established procedures

• **Weak Investigations:** Superficial or incomplete root-cause analysis, missing justifications, or inadequate documentation

• **Improper Conclusions:** "Testing into compliance," inappropriate averaging, or invalidating results without scientifically defensible rationale

Regulators now place even greater scrutiny on the handling of OOS data because unreliable investigations can mask real quality issues and compromise product safety. At the same time, **Data Integrity (DI)** continues to be a major enforcement priority. Agencies such as the FDA, WHO, MHRA, and PIC/S have issued extensive DI guidance—yet DI has always been a foundational GMP requirement, particularly within analytical laboratories where accuracy and traceability are critical.

This two-day course provides practical, hands-on guidance to help QC laboratories maintain regulatory compliance. The program covers best practices for investigating OOS, OOT, and OOE results, key expectations for Data Integrity controls, and essential principles of analytical method validation. Participants will learn how to generate trustworthy data, respond correctly to unexpected results, and design validation approaches that meet current regulatory standards.

Course Content

Day 1 — Laboratory Controls & OOS/OOT Management

• Key principles for establishing strong laboratory controls (aligned with ISO 17025)
• Definitions and differences: OOS vs Out-of-Trend (OOT) vs Out-of-Expectation (OOE)
• Step-by-step workflows for conducting structured OOS investigations
• Proper use of retesting, resampling, and hypothesis testing
• Statistical tools and trending techniques for detecting shifts and anomalies
• Regulatory expectations and common inspection observations related to OOS handling

Day 2 — Analytical Method Validation

• Introduction to analytical method validation and global regulatory expectations
• Essential statistical tools that support method qualification and verification
• Understanding method performance characteristics (accuracy, precision, linearity, range, robustness, etc.)
• Establishing scientifically justified acceptance criteria
• Designing, documenting, and executing a compliant method validation protocol

Participants

This program is ideal for laboratory analysts, supervisors, managers, QA personnel, and professionals working in GxP-regulated testing laboratories. It provides practical, actionable knowledge to strengthen OOS/OOT investigations, reinforce Data Integrity controls, and ensure analytical methods are fit for purpose and compliant with regulatory standards.

COURSE OUTLINE

Revised

Good Distribution Practices (GDP): Quality & Compliance Across the Distribution (27 - 28 Oct 2026)

Good Distribution Practice (GDP) is an essential component of ensuring that medicinal products and medical devices are handled, stored, and transported in a manner that protects their quality and integrity. This course provides a practical introduction to GDP principles and demonstrates how they apply within regulated industries. Participants will gain a clear understanding of the quality, regulatory, and operational requirements that support a compliant distribution system.

The program also explores how risk management, structured procedures, and modern technologies contribute to a reliable supply chain. Real-world examples and discussions will reinforce how GDP requirements can be effectively implemented in day-to-day operations.

Key Learning Objectives

- **Foundational Knowledge:** Understand the core principles and legal expectations of GDP.
- **Industry Application:** Learn how GDP requirements support the quality and safety of pharmaceuticals and medical devices.
- **Regulatory Compliance:** Recognize the importance of GDP in meeting global health authority expectations and maintaining product integrity.
- **Risk-Based Thinking:** Explore practical methods for identifying and managing risks in distribution operations.
- **Operational Implementation:** Gain insights into applying GDP requirements across warehousing, storage, documentation, and transport.
- **Technology Integration:** Discover how digital tools, temperature monitoring, and tracking systems improve compliance and oversight.

Course Content

Day 1 — Fundamentals of GDP- GDP & Its Relationship to GMP

- Definitions and scope of Good Distribution Practice
- Connection between GMP and GDP across the product lifecycle
- Differences and overlaps between the two standards
- Where GDP requirements apply in the supply chain

Understanding Core GDP Requirements

- Quality management elements specific to GDP
- Roles and responsibilities of GDP personnel
- Facility and equipment considerations
- Documentation, SOPs, and recordkeeping
- Handling complaints, returns, falsified products, and recalls
- Managing outsourced activities and conducting self-inspections
- Transport requirements and best practices

Day 2 — Risk Management & Cold Chain Handling- Applying Quality Risk Management (QRM)

- Overview of the QRM process
- Practical methods for applying risk tools within GDP
- Use of FMEA for identifying and mitigating distribution risks

Cold Chain Management

- Understanding temperature-sensitive logistics and challenges- GDP and regulatory requirements
- Temperature-controlled storage principles
- Qualification activities: mapping, monitoring, and re-qualification-
- **Participants**

This program is ideal for Warehouse Managers, Supervisors, and frontline operational staff who are new to GDP. It also serves as valuable refresher training for existing personnel, as recommended in the PIC/S Guide to GDP. Participants will leave with a strong grasp of GDP fundamentals, current industry expectations, and strategies to minimize errors in distribution activities.

COURSE OUTLINE

Revised

Effective Writing Practices in GMP: Crafting Clear SOPs, Technical Reports & CAPA Documentation (25 - 26 Nov 2026)

Clear, well-structured documentation is essential to ensuring that employees understand processes correctly the first time they read them. Strong writing supports consistent execution, reduces errors, and strengthens a culture of GMP compliance. When SOPs, batch records, Quality Agreements, investigation reports, and technical documents are written effectively, they shorten onboarding time, minimise deviations, and help teams work with confidence.

If you are responsible for drafting or reviewing operational documents, you may often face challenges—unclear instructions, overly complex language, lengthy review cycles, or data integrity issues. This course is designed to address these common problems by strengthening your ability to develop SOPs, data collection forms, Quality Agreements, batch manufacturing records, and technical reports that are accurate, readable, and compliant.

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

- Write SOPs that give clear, direct instructions for consistent execution.
- Design data collection forms that support complete, accurate, and reliable data.
- Develop batch manufacturing records that are logical, error-resistant, and easy to follow.
- Create well-structured Quality Agreement sections that clearly define roles and duties.
- Produce concise reports that support decision-making and withstand review.
- Confidently prepare documentation that is easy to understand and ready for approval with fewer revision cycles.

Course Content

Day 1

- Removing unnecessary complexity: simplifying wording and document structure
- Organising information logically for better document flow
- Using process maps to visualise workflows before writing
- Developing step-based, user-friendly SOPs
- Designing data collection forms that protect data integrity
- Preparing concise, purposeful technical and summary reports
- Introduction to writing batch manufacturing records and what regulators expect

Day 2

- Writing clear, consistent, and concise technical documents
- Determining the correct sequence of actions for SOPs and batch records
- Maintaining uniform terminology, formatting, and style
- Constructing documents that meet organisational and regulatory formats
- Hands-on writing practice:

– Drafting and refining SOPs
– Writing investigation reports (deviations, CAPA, OOS)
– Creating SMART data collection forms
– Developing clean, accurate batch records
– Writing sections of Quality Agreements
– Preparing strong summary and technical reports

Participants

This course is ideal for anyone involved in drafting or reviewing operational documents—whether beginners or experienced writers. It is especially valuable for QA and QC teams, manufacturing and R&D personnel, and staff responsible for compliance or training. The principles taught apply across regulated industries and support a consistent culture of clarity, quality, and GMP compliance.

COURSE OUTLINE

Revised

Deviation Handling & Root Cause Mastery: Driving Stronger CAPA Outcomes (08 - 09 Dec 2026)

The pharmaceutical, biotechnology, and medical device industries operate under stringent regulatory expectations, where the ability to properly investigate quality failures, deviations, and production issues is essential to protecting patient safety and maintaining product reliability. Yet, one of the most frequent deficiencies cited during FDA, EMA, MHRA, and PIC/S inspections is the **"failure to thoroughly investigate."** This course is designed to equip participants with the competencies needed to perform robust root cause analysis (RCA), document investigations effectively, and apply structured problem-solving methods that withstand regulatory scrutiny. Using real industry scenarios and practical examples, the training emphasizes how disciplined, systematic approaches lead to more accurate conclusions and prevent recurrence of issues. The program also provides an in-depth look at the strategic use of Corrective and Preventive Action (CAPA). Rather than treating CAPA as a purely procedural obligation, the course shows how a well-designed CAPA system functions as a closed-loop control mechanism—driving sustainable improvements, reducing repeat failures, and reinforcing the overall Quality Management System (QMS). Updated industry expectations, including integration with risk management, data integrity, and lifecycle principles, are also covered.

Course Content

Day 1 — Root Cause Analysis (RCA)

- Introduction to structured problem-solving and the 8D methodology
- Comparing 8D with Six Sigma DMAIC and PDCA lifecycle approaches
- Understanding variation and its impact on problem definition and analysis
- Step-by-step walkthrough of all 8D phases, from containment to prevention
- Overview of common RCA tools (Fishbone, 5 Whys, Fault Tree Analysis, Is/Is Not, Pareto, etc.)
- Practical workshop: Develop a complete 8D report using a real investigation scenario

Day 2 — Corrective and Preventive Action (CAPA)

- Review of current regulatory expectations for CAPA (FDA 21 CFR, EU GMP, ISO 13485, PIC/S, ICH Q10)
- Clear differentiation between Corrective Action and Preventive Action
- How CAPA links with key QMS elements: deviations, complaints, audit findings, change control, and risk management
- Applying risk assessment (FMEA, risk prioritization, severity/occurrence/detectability) to CAPA decisions
- Incorporating SMART criteria into CAPA planning and documentation
- Critical components of a compliant, effective CAPA system
- Hands-on exercise: Build a CAPA plan based on RCA findings from the Day 1 workshop

Participants

This course is designed for professionals responsible for deviations, investigations, problem-solving, or CAPA within pharmaceutical, biotech, and medical device manufacturing. It is valuable for both newcomers to structured problem-solving and experienced staff seeking to strengthen their investigation and CAPA practices. A basic understanding of GMP and QMS frameworks will help participants gain maximum benefit from the program.

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 RM2,300.00
(RM2,484.00 inclusive 8% SST)
29 – 14 days before commencement of course RM2,500.00
(RM2,700.00 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 RM2,900.00
(RM3,132.00 inclusive 8% SST)
29 – 14 days before commencement of course RM3,100.00
(RM3,348.00 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)

Seats are limited: Only 30 participants per class

Payment must be made before the training

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:
Mike,
Malaysian Organisation of Pharmaceutical Industries,
Global Business & Convention Centre,
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

List of 2-Day Courses (please tick accordingly)	
☐ **GMP Essentials: Foundations for Operational Excellence** **27 – 28 January 2026 (Tue – Wed) Physical Training**	☐ **Contamination Control Systems: Building a Modern Holistic Strategy** **26 - 27 Aug 2026 (Tue-Wed) Physical Training**
☐ **Annual Product Quality Review (APQR): Concepts, Requirements & Best Practices** **10- 11 February 2026 (Tue-Wed) Physical Training**	☐ **Audit Readiness & Execution: Managing Internal , External, Regulatory and Supplier Audits Effectively** **2 – 3 Sept 2026 (Wed-Thur) Physical Training**
☐ **bGMP- Human Factors in GMP & Data Integrity: Minimizing Errors Through Better Behaviors** **31Mar - 01 Apr 2026 (Tue- Wed) Virtual Training**	☐ **Computer Systems for Regulated Environments** **30 Sep – 01 Oct 2026 (Wed - Thu) Virtual Training**
☐ **Qualification & Validation Masterclass: Practical Approaches for Implementation** **21-22 Apr 2026 (Tue-Wed) Physical Training**	☐ **Laboratory Quality Systems and Method Validation: Managing OOS/OOT/OOE and Ensuring Method Compliance** **13 - 14 October 2026 (Tue- Wed) Physical Training**
☐ **Supply Chain Quality & Supplier Oversight % Qualification: Risk-Based Approaches in Practice** **19 – 20 May 2026 (Tue- Wed) Virtual Training**	☐ **Good Distribution Practices (GDP): Quality & Compliance Across the Distribution** **27 – 28 Oct 2026 (Tue-Wed) Physical Training**
☐ **Quality Risk Management Deep Dive: Tools, Techniques & Applications** **3 - 4 Jun 2026 (Wed- Thur) Virtual Training**	☐ **Effective Writing Practices in GMP: Crafting Clear SOPs, Technical Reports & CAPA Documentation** **25 - 26 November 2026 (Wed- Thur) Virtual Training**
☐ **Process Validation Excellence: Statistics, Sampling & Lifecycle Strategies** **14 – 15 July2026 (Tue- Wed) Physical Training**	☐ **Deviation Handling & Root Cause Mastery: Driving Stronger CAPA Outcomes** **8 - 9 Dec 2026 (Tue-Wed) Physical Training**
☐ **Cleaning Validation Mastery: Risk-Based Methods for Compliance and Efficiency** **28 - 29 Jul 2026 (Tue – Wed) Virtual 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

Registration Submitted by:

Name _____

Designation _____

E-mail _____

Contact No / Mobile No _____

Company Stamp (with Address, Telephone & Fax Number)