Quality Assurance and GMP Training Program

Online, Instructor-Led Training And Physical Training

YEAR 2023

The training program consists of 12 on-line courses and 3 physical courses. These courses cover the essential principles of Quality Assurance (QA) and Good Manufacturing Practice (GMP). 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 Australia's and Asia Pacific's premier training & consulting group offering integrated consulting, training and technical services to Australia and the Asia Pacific region to meet all international 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

GMP – What You Need to Know (16 – 17 January 2023)

If you are responsible for any part of pharmaceutical product quality or GMP compliance, you must understand your legal and ethical obligations. To understand your obligations, you must understand the regulatory environment, intent and requirements of a Pharmaceutical Quality System, and current Good Manufacturing Practice as defined by PIC/S. To support GMP-regulated organisations, this course will help by stepping you through the various requirements of the current PIC/S Guide GMP Part I. Using case studies and examples drawn from industry and consulting experience, you will learn the requirements and how they are applied to your manufacturing environment(s), with a focus on ensuring product quality and the prevention of adulteration and misbranding.

Content:

Day 1:

Overview of the Global Regulatory Environment

- Drug product lifecycle - development, manufacturing, and distribution
- Types of Quality System versus applicable GMP Standard(s)
- The meaning of GMP
- Compliance Focus and Product Identity-Safety-Purity-Efficacy
- Fundamental Requirements for GMP

GMP Basics:

- Personnel and Training
- Premises/Facility Control
  - Production Areas
  - Storage Areas
  - Quality Control Areas
  - Ancillary Areas and supporting systems
- Equipment Management
- Production and Packaging Control
- Validation
- Quality Control Functions

Day 2:

Good Documentation Practices

- GMP requirements on 'Documentation'
- What is Good Documentation Practice (GDocP)?
- The significance of GDocP in ensuring data integrity
- Common do's and dont's of GDocP
- Tips on designing SOPs, WIs, and Forms

A Quality Systems Approach to GMP

- What is a Pharmaceutical Quality System?
- Quality Risk Management
- Key Quality System Elements for Continual Improvement
  - Deviation Handling
  - Complaints and Recalls
  - Corrective and Preventive Action
  - Change Management
  - Product Quality Review

Participants

This course has been designed to provide personnel new to the pharmaceutical industry with a good understanding of PIC/S GMP and Pharmaceutical Quality System requirements. It also applies to experienced GMP staff looking to update for compliance in the current PIC/S GMP, companies that require GMP certification (new/renewal) in PIC/S, or manufacturers who do secondary packaging of medicinal products.

COURSE OUTLINE

Changes to Annex 1 – Manufacture of Sterile Medicinal Products (20 – 21 February 2023)

The European Union (EU) published its eagerly anticipated revision of Good Manufacturing Practice (GMP) Guideline, Annex 1 - Manufacture of Sterile Medicinal Products in August 2022. The previous version (16 pages) has been in effect for 14 years, from 2008, and the changes are significant with the document growing >300% (now 58 pages); some consider it a rewrite.

The new requirements will take effect 25 August 2023* in the EU and PIC/S announced in September 2022 that it will apply the same dates of entry into operation.

*except for point 8.123 which is postponed until 25 August 2024.

You will gain knowledge of the new requirements and obtain a framework for managing your transition to comply with the new version of Annex 1 - Manufacture of Sterile Medicinal Products.

Content:

- New structure of Annex 1
- Major Changes for
    - Quality Risk Management
    - Contamination Control Strategy (CCS)
    - Production and new technologies
    - Personnel controls such as gowning and training
    - Environmental Monitoring (EM) and the importance of trending
    - Premises including cleaning and disinfection
    - Equipment and utilities, including water systems

Participants

This course has been designed for all personnel involved in the sterile manufacturing industry who follow the PIC/S GMP Annex 1 guideline.

Format and Course Length

Risk Management – Compliance and Process (13 - 14 March 2023)

Day 1 Risk Management for Compliance

Within a Quality System (QS), the ability to make sound decisions based on facts and good science is key to being compliant with the regulatory requirements as well as being economical to the business. Whether it is tracking customer complaints, identifying non-conforming materials or products, managing audit findings, or implementing appropriate corrective and preventive actions (CAPA), having a well understood and integrated Risk Assessment process in place can improve product quality and regulatory or GxP compliance, and reduce legal liability. This training is designed to provide you with relevant knowledge and skills to effectively participate in quality and compliance-related risk assessments. It will provide you with a general understanding of quality systems and processes, as well as an understanding of the Risk Assessment Process that provides the basis from which to conduct a structured risk evaluation.

Content:

- Quality Risk Management Framework
- The goal of risk management in managing GMP compliance
- The key systems – how they integrate and where risk assessment can be applied to appropriate sub-systems, such as

- Auditing
- Change Control
- Product Complaints and ADEs
- Deviation Investigation
- CAPA

Day 2 Risk Management for Process

Quality Risk Management (QRM) was introduced to the GMPs in 2009 and should now be an integrated part of your daily pharmaceutical manufacturing operations…but is it? Do you know which QRM tool to use in different situations? Are you satisfied that the time and effort in conducting risk assessments is adding real value to your business? Are you confident that your risk evaluation has identified the appropriate level of manufacturing controls? This training can help by providing you with relevant knowledge and skills to effectively participate in process risk assessments. You will gain a general understanding of manufacturing processes and how they are controlled, as well as an understanding of the Risk Assessment Process to ensure you have a basis from which to conduct a structured risk evaluation.

Content:

- Manufacturing considerations: what can go wrong, complex processes and systems
- Overview of the Quality Risk Management Process
- GMP requirements for risk assessments
- The Quality Risk Management Toolbox: what to use and when
- Conducting Process Risk Assessments, considering:
  - Preliminary Hazard Analysis (PHA)
  - Hazard Analysis and Critical Control Points (HACCP)
  - Failure Mode and Effects Analysis (FMEA)

Participants:

This course is designed for both personnel new to process risk assessment as well as more experienced QRM practitioners. You will benefit from this course if you have a simple interest in or have any level of responsibility for risk assessments of quality compliance and/or manufacturing processes.

Good Writing Practice for efficiency and error proofing (08 May 2023)

• Do your documents go through endless revisions before being finally approved months after the review date?
• Are you tired of wading through waffle to get to the information you need?
• Do you have problems with Data Integrity?
• Do you suffer from writer's block?

Get straight to the point with this training course that has been specifically designed to develop and improve your skills in writing effective SOPs, data collection forms and other documents.

Objectives

At the end of the course you should be able to:
• Write SOPs that provide unambiguous instruction
• Design data collection forms that promote data integrity
• Prepare documents that are ready for approval first time
• Prepare reports that contain the right amount of the right information

Ultimately you will come away with the confidence to write SOPs, data collection forms and other documentation that can be easily used and understood.

COURSE OUTLINE

Content

In this one-day course you will learn about good writing practices such as,

- Pruning the 'deadwood'
- Reducing complexity
- Using process mapping to structure documents
- Writing clear instructional documents (e.g. SOPs)
- Preparing data collection forms
- Writing concise reports

Participants

This course is suitable for anyone who writes or reviews workplace documents, whether you are new to this or have been writing for years. It covers fundamental principles of good technical writing as well as current trends in, and tools for, SOP writing. The applicability of this course extends beyond the life sciences industries to any business where documents play a fundamental role.

Qualification and Validation – Getting the essentials for implementation (22 – 23 May 2023)

Charged with the responsibility for Q&V, you will be confronted with a plethora of standards, guidelines, terms, and techniques. Understanding the language and the various validation methodologies (along with when and where to use them), is essential for success in this rapidly changing environment. There are many different paths you can take to achieve a qualified/validated state. Sometimes you get there by good luck, sometimes you make a few wrong turns. This course looks at the essential concepts that you need for effective implementation of qualification/validation activities.

Content

Day 1 Introduction to Validation Principles and Application of QRM

- Fundamental Principles of Q&V
  - Regulatory requirements of Q&V
  - Scope of Q&V
  - Sequence and stages of Q&V
- Validation Planning
  - What is in a validation program?
  - Validation master plans (VMP), project plans (VPP) and other documents
  - Applying QRM Principles to Validation and increase the efficiency (science and risk-based approach to validation)
  - Critical and non-critical systems
  - Use of FMEA and HACCP for validation planning

Day 2 Design, execution, assessment, and reporting of Equipment Qualification

- Equipment Qualification (The key components expected for effective equipment qualification)
  - User Requirement Specifications
  - Stages of Qualification and GMP requirements for IQ, OQ, PQ
  - The new paradigm for equipment qualification and application of risk management
  - Protocol execution, evaluation, and reporting
  - Managing deficiency
- Maintaining a Validated State
  - Change management to effectively accomplish patient safety and regulatory requirements
  - Validation lifecycle and continuous verification
  - Routine Re-validation Schedules
  - Periodic Review

Participants

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

COURSE OUTLINE

Root Cause Analysis and CAPA (06 - 07 June 2023)

As a pharmaceutical or medical device company, you are required to investigate the cause of quality failures or production problems. However, "failure to thoroughly investigate…" is a common finding from regulatory inspections. In this course, you will learn how to conduct effective failure investigations and perform root cause analysis using real-life scenarios from industry and gain a clear understanding that the more structured your investigation process is, the more effective it will be. Then, you will learn how to use the CAPA system, not just to satisfy regulatory requirements, but to implement a closed-loop system for problem solving that will help to minimize product quality issues and improve compliance.

Content

Day 1: Root Cause Analysis

- General principles of 8D problem analysis methodology
- Comparison of 8D with 6-sigma DMAIC and PDCA
- Concept of variation in a problem-solving process
- Key steps of an 8D problem analysis methodology
- Common methods used for problem solving
- Develop an 8D report for an identified problem

Day 2: CAPA

- Regulatory background of CAPA
- Definition of Corrective Action and Preventive Action (CAPA)
- Integration of CAPA with key quality system elements
- Link the concept of risk with CAPA management
- Understand the SMART principles of CAPA
- Elements of a compliant and effective CAPA System
- Develop a CAPA plan from the outcome of RCA using 8D approach

Participants

This course has been designed for all those who are involved in failure investigations and corrective actions. You will benefit from this program whether you are new to formal problem solving and CAPA or are a more experienced professional. It is expected that you are familiar with regulatory GMP and Quality Management System requirements within the pharmaceutical and/or medical device industries.

Behavioural GMP – Minimising Human Errors (26 June 2023)

Managing your deviations contributes to lost productivity. Investigations consume considerable time and often identify human error as a cause, resulting in more training or more procedures. Frustratingly, this approach rarely works and problems persist.

This course on behavioural GMP (bGMP) examines why people don't comply with procedures, either by error or perhaps deliberately, and what can be done about it. You will learn about THREE specific modes of human error and where "retraining" can actually help; but why it doesn't most of the time.

Content

- What causes defective products?
- Understanding the nature of human error
- Sources of Error
- What influences our behaviour?
- Addressing Error
- Stages of Human Learning and Types of Error
- Possible areas that 'encourage' human error and eventuate to non-compliance

COURSE OUTLINE

- Building a compliant quality culture
  - Role of Supervision / Management
  - Strategies for reducing learning error
  - Reducing Inherent Errors and Potential Errors

Participants

Managers and supervisors responsible for GMP compliance, reducing deviations, conducting failure investigations and continuous improvement will benefit from this program.

Process Validation (10 – 11 July 2023)

This course aims to develop contemporary understanding of process validation (PV) in order to comply with regulatory expectations. In addition, it reviews the objectives and standard practices. and provides practical directions on how to use quality risk management principles to prepare validation plans that meet current regulatory expectations.

Content

Day 1: The Principles of Process Validation

- The GMP reasons for process validation.
- Control of Variation, Process Capability Indices, and Sampling Considerations in process validation
- Regulatory basis for process validation
- Strategies for process validation that complies with GMP
- Essentials of a process validation protocol
- Requirements for re-validation and give examples of situations that would give rise to it
- Examples from the Industry

Day 2: The Practices

- Process understanding and effective process validation
- Understand implications of validation deviations
- Workshops exploring common PV problems and solutions

Participants

This course has been designed for validation professionals as well as those involved in approving process validation plans and projects. It also applies to anyone interested in the latest trends and methodologies in process validation that are rapidly becoming industry standards.

Introduction to Laboratory Controls (24 - 25 July 2023)

International GMP regulators continue to find GMP deficiencies in organisations related to Out-of-Specification (OOS) handling. The citations range across:

- Inadequate management (no SOP or not following the SOP)
- Inadequate investigation (lack of depth or lack of documentation)
- Inadequate outcomes (testing into compliance without (justifiably) invalidating the OOS)

As such, GMP inspectors are looking into how companies manage OOS results and one of the objectives of this course is to help you understand the current best practices for OOS investigations.

Besides OOS Handling, Data Integrity (DI) is another hot topic in the industry, including QC laboratories. While there is a flood of industry guidance on DI since 2016 (from the FDA, WHO, MHRA, PIC/S, ISPE and PDA), demonstrable integrity of data/records has been a long-standing GMP requirement, it is not new.

COURSE OUTLINE

This 2-day course will step you through the key elements and basic principles for sustaining compliance in QC laboratories, with specific focus on OOS Handling and Data Integrity.

Content

Day 1: Overview of Laboratory Controls & OOS/OOT Handling

- Key elements and basic principles that are necessary to establish proper control and sustain compliance in a Quality Control / Analytical Laboratory (ISO 17025)
- Difference(s) between Out-of-Specification (OOS) and Out-of-Trend (OOT)
- Best practices and process for conducting successful OOS investigations, including the use of re-testing and re-sampling
- Regulators' perspectives

Day 2: Data Integrity

- What does data integrity (DI) mean, who can contribute to good DI?
- Why is data integrity and security such a hot topic for regulators?
- Data criticality and data risk
- Integration of DI into your QMS using a risk-based approach
- Protection and security of raw data and original records
- Developing practical audit and remediation strategies for DI

Participants

You will benefit from this training if you are a regulated laboratory analyst or supervisor/manager, or if you have an interest in GxP and laboratory practices.

Cleaning Validation (08 - 09 August 2023)

The FDA's Industry Guidance document "Validation of Cleaning Processes (7/93)" stood alone for virtually 20 years. Since then and particularly in the period 2016-2020, we have seen significantly more guidance being published from key industry bodies including the EMA, PIC/S, PDA, ISPE, and WHO. But what do all these documents mean for you and your company?

This training course will help you understand the current 'cleaning validation landscape' by discussing the recent changes in regulatory expectations and what they mean for manufacturers. You will also gain insights into the modern application of a science- and risk-based approach to cleaning validation and be able to develop GMP-compliant cleaning validation (CV) protocols.

Day 1: The Principles of Cleaning Validation

- Regulatory basis / GMP reasons for cleaning validation.
- Strategies for cleaning validation that complies with GMP
- Practical limits for cleaning residues
- Health-based exposure limits (HBEL)
- Essentials of a cleaning validation protocol
- Examples from the industry

Day 2: The Practices

- how to maintain the validated state
- Know how to present your strategy and data to a regulatory body
- Workshops exploring common CV problems and solutions

Participants

You will benefit from this training if you are in a position of Quality or Validation Management or directly responsible for preparing and executing cleaning validation studies within a GMP facility.

COURSE OUTLINE

Computer Systems for Regulated Environment (21 – 22 August 2023)

Your company cannot operate without a level of reliance on computer systems. New technology and the industry hot topic "data integrity" ("information availability, authenticity, correctness and traceability") are driving greater adoption of computerized information systems. In response, regulators like the TGA, FDA, and Medsafe are increasingly scrutinizing the validation of computer systems. As such, you must apply an appropriate level of risk-focused validation effort for your computer systems and organisation to be compliant. This course will provide you with an understanding of what matters in validation of computerized systems to help your company meet regulatory requirements and mitigate 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

Day 1:

  - 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

Day 2:

  - Use
  - 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

MTP 4.0 – Industry 4.0 for Medical Technology, Biotechnology & Pharmaceuticals (11 – 12 September 2023)

You may have heard of Industry 4.0 (or the Fourth Industrial Revolution), and with a global pandemic and an uncertain future, one thing is certain – the speed of advancement in modern smart technology. You may have also heard of ISPE Pharma 4.0™ and maybe you are thinking that this only applies to the pharmaceutical industry. Industry 4.0 and the overlaying quality and regulatory requirements is far more encompassing than just Pharma. The MTP 4.0 (Medical Technology, Biotechnology and Pharmaceutical) training course provides a comprehensive overview of all aspects of Industry 4.0 for regulated industries.

Content

Through this course you will develop an understanding of:

- The key terms, technologies, and processes
- Maturity models that allow the transition for a short-, medium- and long-term digital strategy
- A Holistic Control Strategy for changes to the Quality Management systems
- Validation 4.0 – for streamlining the validation processes
- The importance of Process Maps and Critical Thinking
- Continuous Process Verification, Process Automation and Data Analytics
- Plug and Produce technologies
- The importance of a Management Communication Strategy
- The enablers for data, storage, and speed
- Cybersecurity

This course intends to bring you up to speed with Industry 4.0 and its application in the healthcare setting to get you thinking about opportunities within your company/industry for innovation and improvement. The course focusses on sharing thought-provoking developments in industry, rather than upskilling.

Participants

Anybody keen on understanding Industry 4.0 and its potential for the Medical Technology, Biotechnology and Pharmaceutical sector will be interested in the content. If you are innovative, a future-thinker and want to be a 'champion for change' within your company to adopt the latest technology, you can benefit most from this training.

Internal Audits – A Key to Your Quality System (09 - 10 October 2023)

Internal audits are a fundamental part of implementing, maintaining, and improving your quality system which is critical to your business' success. Whether you work for a pharmaceutical company complying with "self-inspection" requirements of the PIC/S Guide to GMP or a medical device company complying with "internal audit" requirements of ISO 13485, deploying an internal audit program throughout your organisation will help educate personnel, confirm ownership of various quality system elements, and ultimately drive continuous improvement and cost reductions.

Internal audits deliver value irrespective of how mature your organisation's quality system is. Do you need help optimizing and delivering more value from your self-inspection/internal audit program? This course can help you achieve your KPIs.

COURSE OUTLINE

Content

Day 1: Managing Internal Audits

- Critical role of quality audits in compliance & improvement
- Regulatory standards and guidelines for quality auditing
- GMP and QS requirements for internal audit programs
- Risk Assessment as it applies to quality audit practices
- Documents, records, and data for effective audits
- Audit schedules and the use of risk management in relation to prioritizing audits
- Techniques and tips for auditing - 6 fundamental steps of auditing

Day 2: Corrective and Preventive Action (CAPA) in Internal Audits

- What is Corrective and Preventive Action (CAPA)
- How to apply CAPA to quality audits
- How to apply Risk Management principles to:
  - Audit observations
  - CAPA
  - Audit verification

Participants

This course is designed for operational personnel (key operators, supervisors, and managers) who have a key role in quality systems implementation and will assist them to develop a system of quality audit.

Contamination Control (24 - 25 October 2023)

The necessity for preventing or controlling (cross-) "contamination" in the storage, handling and processing of components, materials and products (non-sterile and sterile) is demonstrated by the clear and consistent messaging in the GMPs:

- 40+ references in PIC/S Guide to GMP for Medicinal Products Part I (PE 009-15)
- 20+ references in FDA 21 CFR Part 211 CGMP for Finished Pharmaceuticals

This course will help you:

- understand why contamination control is critical
- understand the GMP rules that you must comply with regarding contamination control
- identify types and major sources of contamination
- implement procedures to reduce contamination risk in compliance with GMPs

Day 1

- **Introduction to Contamination Control**
  - GMP principles and requirements for contamination control
  - Different types of contamination and the potential sources of contamination
  - Risk assessment methodologies that can be used to analyse and assess the major risks to product
  - Develop strategies for contamination control
- **Cleaning and Sanitation**
  - Suitable cleaning and disinfectants for different manufacturing situations
  - Appropriate techniques for cleaning and sanitation

COURSE OUTLINE

Day 2

- **Operating in a Cleanroom**
  - Cleanroom facilities, HVAC, and filtration principles
  - International cleanroom standards
  - Cleanroom garments, gowning procedure, and qualification
  - Cleanroom conduct and operator qualification
  - Cleanroom operation and control
  - Environmental monitoring
- **HVAC and Controlled Environments**
  - The international nomenclature and classification of cleanrooms
  - Key design requirements for cleanrooms
  - The theory of particle filtration, controlled facilities design and operation for the purpose of product protection
  - Certification of cleanrooms: test methods, test instructions, sampling sites
  - Rules for working within a cleanroom
  - GMP deficiencies
- **Environmental Monitoring (EM)**
  - Key elements of an Environmental Monitoring (EM) Program
  - EM sample sites for qualification and routine monitoring purposes using risk assessment
  - Testing required for demonstration of cleanroom standards
  - Strategies for defining sample sites & frequency
  - Strategies for establishing alert & action levels for EM
  - EM test methods and examples of where and when they will be used

Participants

This course has been designed to provide personnel of all levels (Operator, Officer, Supervisor, Manager) with a good understanding of contamination and how to control it in a GMP environment. People from a range of Departments (Production/Manufacturing/Packing, Quality Control, Quality Assurance, Engineering etc.) will benefit from this training.

Good Distribution Practice for the Regulated Industry (06 - 07 November 2023)

This course aims to introduce the requirements of Good Distribution Practice (GDP) for the regulated industries and provide a better understanding of the concepts of management for the handling, storage, and distribution of medicinal products and medical devices.

Content

Day 1:

- GDP: Relationship and Integration with GMP
  - The definitions of Good Distribution Practice (GDP)
  - The relationship and integration of GDP with GMP along the supply chain
  - Scope of GDP
  - Comparing the requirements between GMP and GDP

- Understanding GDP Requirements
  - Quality Management
  - Personnel
  - Premises and Equipment
  - Documentation
  - Operations

- Complaints/ Returns/ Suspected Falsified Products/ Recalls
- Outsourced Activities
- Self-Inspections
- Transportation

Day 2:

- Applying Risk Management in the Supply Chain
  - Overview of the Quality Risk Management Process
  - Practical approach for the implementation of risk management to GDP compliance programs.
  - Consider FMEA
- Overview of Cold Chain Management
  - Definition and challenges of Cold Chain.
  - Regulations and guidelines on GDP, Cold Chain Management, and Mapping.
  - Essential requirements of temperature-controlled storage areas
  - Cold area qualification (including mapping) activities
  - Justification for re-qualification

Participants

This course is suitable for Warehouse Managers, Supervisors, and operational personnel who are new to the industry, as well as well as for refresher or ongoing training (as required by the PIC/S Guide to GDP) of existing staff. It covers fundamental principles of GDP, as well as current trends and how to minimise human error.

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
(RM2,014.00 inclusive 6% SST)
29 – 14 days before commencement of course RM2,100.00
(RM2,226.00 inclusive 6% SST)

Non-MOPI Member – 2 Days Course
30 days before commencement of course RM2,200.00
(RM2,332.00 inclusive 6% SST)
29 – 14 days before commencement of course RM2,400.00
(RM2,544.00 inclusive 6% SST)

Foreign Participant – 2 Days Course
30 days before commencement of course USD $1,000.00
(USD$ 1,060.00 inclusive 6% SST)
29 – 14 days before commencement of course USD $1,200.00
(USD$ 1,272.00 inclusive 6% SST)

MOPI Member – 1 day Course
30 days before commencement of course RM1,000.00
(RM1,060.00 inclusive 6% SST)
29 – 14 days before commencement of course RM1,200.00
(RM1,272.00 inclusive 6% SST)

Non-MOPI Member – 1 day Course
30 days before commencement of course RM1,300.00
(RM1,378.00 inclusive 6% SST)
29 – 14 days before commencement of course RM1,500.00
(RM1,590.00 inclusive 6% SST)

Foreign Participant – 1 day
30 days before commencement of course USD $500.00
(USD $530.00 inclusive 6% SST)
29 – 14 days before commencement of course USD $700.00
(USD $742.00 inclusive 6% SST)

Physical Training Fee

MOPI Member – 2 Days Course
30 days before commencement of course RM2,300.00
(RM2,438.00 inclusive 6% SST)
29 – 14 days before commencement of course RM2,500.00
(RM2,650.00 inclusive 6% SST)

Non-MOPI Member – 2 Days Course
30 days before commencement of course RM2,600.00
(RM2,756.00 inclusive 6% SST)
29 – 14 days before commencement of course RM2,900.00
(RM3,074.00 inclusive 6% SST)

Foreign Participant – 2 Days Course
30 days before commencement of course USD $1,300.00
(USD$ 1,378.00 inclusive 6% SST)
29 – 14 days before commencement of course USD $1,500.00
(USD$ 1,590.00 inclusive 6% 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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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 _____

2 Name_____

Designation_____

Email address _____

Contact Number _____

NRIC Number _____

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

List of 2-Day Courses (please tick accordingly)	
☐ **GMP – What You Need to Know** **16 – 17 January 2023 (Mon – Tue)** Virtual Training	☐ **Introduction to Laboratory Controls** **24 - 25 July 2023 (Mon – Tue)** Physical Training
☐ **Changes to Annex 1 – Manufacture of Sterile Medicinal Products** [NEW] **20 – 21 February 2023 (Mon – Tue)** Virtual Training	☐ **Cleaning Validation** **08 -09 August 2023 (Mon - Tue)** Virtual Training
☐ **Risk Management – Compliance and Process** **13 - 14 March 2023 (Mon - Tue)** Virtual Training	☐ **Computer Systems for Regulated Environment** **21 - 22 August 2023 (Mon – Tue)** Virtual Training
☐ **Good Writing Practice for efficiency and error proofing** [NEW] **08 May 2023 (Mon)** Virtual Training	☐ **MTP 4.0 - Industry 4.0 for Medical Technology, Biotechnology & Pharmaceuticals** **11 – 12 September 2023 (Mon - Tue)** Virtual Training
☐ **Qualification and Validation - getting the essentials for implementation** **22 - 23 May 2023 (Mon – Tue)** Virtual Training	☐ **Internal Audit - a key to effective Quality System** **09 - 10 October 2023 (Mon – Tue)** Virtual Training
☐ **Root Cause Analysis and CAPA** **06 - 07 June 2023 (Tue - Wed)** Virtual Training	☐ **Contamination Control** **24 - 25 October 2023 (Tue - Wed)** Physical Training
☐ **Behavioural GMP - mininising human error** **26 June 2023 (Mon)** Virtual Training	☐ **Good Distribution Practice for the Regulated Industry** **06 - 07 November 2023 (Mon - Tue)** Physical Training
☐ **Process Validation** **10 – 11 July 2023 (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)