Quality Assurance and GMP Training Program

Online, Instructor-Led Training

YEAR 2021

The training program consists of 13 on-line 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.

Training Grant is available under HRDF SBL Scheme

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.

- 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 – What You Need to Know (22 – 23 February 2021)

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:

- An overview of the global regulatory environment
- GMP Basics: Personnel and Training, Premises and Facility Control, Equipment Management, Production and Packaging Control, Validation, Quality Control Functions

Day 2:

- Good Documentation Practices
- A Quality Systems Approach to GMP

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 with current PIC/S GMP, companies that require GMP certification (new/renewal) in PIC/S, or third-party logistics (3PL) providers that repack/reprocess medicinal products.

Risk Management – Quality System and Process (08 – 09 March 2021)

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

COURSE OUTLINE

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.

Validation – A Roadmap to Getting It Right First Time (22 – 23 March 2021)

Charged with the responsibility for validation, 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 validated state. Sometimes you get there by good luck, sometimes you make a few wrong turns. This course looks at the tools you need to navigate the various validation pathways you can take to make sure you get it right first time.

Content

Day 1:

- Introduction to Validation Principles
- Validation Planning

Day 2:

- Equipment Qualification
- Maintaining a Validated State

Participants

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

COURSE OUTLINE

Root Cause Analysis and CAPA (24 – 25 May 2021)

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

- 8D History, and comparison of 8D with 6-sigma DMAIC and PDCA
- Concept of variation in a problem-solving process
- 8D Problem-Solving Approach using a combination of techniques such as 5 WHY's, IS versus IS NOT, 5Ws + 1 H, Ishakawa Analysis, Failure Mode Effect Analysis (FMEA)

Day 2: CAPA

- Regulatory background and definition of Corrective Action and Preventive Action (CAPA)
- Integration of CAPA with key quality system elements, and link the concept of risk with CAPA management
- Understand the SMART principles of CAPA, and elements of a compliant and effective CAPA System

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.

Process Validation (21 – 22 June 2021)

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.
- Statistical process control and 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
- Industrial best practices

Day 2: The Practices

- 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.

COURSE OUTLINE

Computer Systems for Regulated Environment (12 – 13 July 2021)

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
- Principles of Computerized System Validation
- System Life Cycle Approaches
- Development Models
- Data Integrity
- Risk Assessment
- IT Infrastructure Qualification
- IT System Inventory
- Legacy System Validation

Day 2:

- Validation Planning
- User Requirements
- Traceability
- Leveraging of Vendor Documentation
- Testing and Test Documentation
- Release, Use and Decommissioning
- Electronic Records / Electronic Signatures (21 CFR Part 11 and Annex 11)
- Cloud Computing in a Regulated Environment

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.

Behavioural GMP – Minimising Human Errors (02 – 03 August 2021)

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. Secondly, this course aims to explain the significance of good documentation practice and relate the understanding with bGMP in rationalizing what constitutes a sound CAPA, including the reporting.

COURSE OUTLINE

Content

Day 1: bGMP

- What is important to the person doing the work (and therefore how they will behave)
- How people learn and what sort of errors they commit at each stage of learning
- How the culture of the organisation itself influences behaviour
- The importance of systems in influencing and supporting changed behaviour

Day 2: Documentation and CAPA

- Why documentation matters
- Fundamental GMP requirements for documents - content, format, and control
- The importance of documents and records during GMP inspection
- Good documentation tips for SOPs, WI, and Forms, reports
- State the definitions of CAPA elements
- Systematically apply CAPA principles
- Application of CAPA principles to deviation handling
- Understanding CAPA System documentation

Participants

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

Cleaning Validation (16 – 17 August 2021)

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.

Content

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
- Essentials of a cleaning validation protocol
- Current industry practices with examples

Day 2: The Practices

- 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

Introduction to Laboratory Controls (20 – 21 September 2021)

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.

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.

COURSE OUTLINE

Solid Dose Manufacturing (11 - 12 October 2021)

This course aims to develop a practical understanding of the principles, technology and GMP requirements as it applies to the manufacturing and control of Finished Solid Dosage Forms, and introduce the concept and practices of Process Mapping, Risk Analysis, Critical Control points and Validation requirements for the formulation, and optimization controls.

Content

Day 1:

- Quality Assurance in Solid Dose Manufacturing
- Solid dosage form and drug delivery formulation
- Solid oral-modified release dosage forms, for example, tablets/ powders/ granules/ tablets/ capsules/

Day 2:

- Solid dose manufacturing technology and control (granulation/ blending/milling/ compression and coating)
- Quality standards and compendial requirements

Participants

This course is designed for key quality and operational personnel (supervisors and managers) who are involved in solid dosage manufacture, as well as for managers and supervisors responsible for GMP compliance.

Internal Audits – A Key to Your Quality System (25 – 26 October 2021)

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.

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

COURSE OUTLINE

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.

Good Distribution Practice for the Regulated Industry (22 – 23 November 2021)

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 the Manufacturer's Requirements, i.e., 6-Step Plan for Supplier Quality Assurance
    - Planning
    - Selection of Potential Suppliers
    - Supplier Evaluation and Selection
    - Finalization of Controls
    - Delivery, Measurement, and Monitoring
    - Feedback and Communication

- 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

Day 2:

- Understanding the Key GDP Requirements
  - Quality Management
  - Personnel Training
  - Premises and Facility Control
  - Contamination Control/ Cleanliness Pest Control
  - Documentation
  - Qualified Trucks and Transportation Control
  - Complaint Handling
  - Responsible Person
  - Internal Audit
  - Outsourced Activities

- Overview of Cold Chain Management
  - Introduces the key principles of Cold Chain Management.
  - Considers the regulatory perspective and background of Cold Chain Management.

  - Discusses different design considerations for temperature-controlled storage, as well as the qualification activities involved.

COURSE OUTLINE

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.

Bioprocessing (06 – 07 December 2021)

If you are involved in any part of biopharmaceutical manufacturing or are interested in learning how biologics have taken over the global market from traditional small molecules, you should attend this two-day course for a basic introduction to all things involving the biopharma industry. This course will give you an understanding of why the manufacturing process and final drug product are so complex and time-consuming, and ultimately, why the final product is expensive and how biosimilars are hoping to tackle this.

Content

Day 1: Introduction to Biotechnology

- Differences between small (pharma) and large (biologics) molecules
- History of biotechnology
- Different cell lines, their uses and cell culture techniques
- Upstream processing and downstream processing

Day 2: The Practices

- Fill/finish of biologics
- Biological assays
- Singe use technologies compared with traditional stainless steel
- Extractables and leachables with a focus on biologics
- Modular design and room classifications, and regulatory guidelines

Participants

This course has been designed to provide personnel new or with limited exposure to the biotech/biopharma industry with a good understanding of what is a biologics drug, the manufacturing process and associated assays and inherent issues with biologics as different with small molecules. The increased use of single use systems in the manufacturing and fill/finish process will also be discussed including the comparison with traditional stainless-steel production.

COURSE REGISTRATION

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

MOPI Member
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)
13 – 7 days before commencement of course RM2,300,00 (RM2,438.00 inclusive 6% SST)

Non-MOPI Member
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)
13 – 7 days before commencement of course RM2,600.00 (RM2,756.00 inclusive 6% SST)

Foreign Participant
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)
13 – 7 days before commencement of course USD $1,400.00 (USD$ 1,484.00 inclusive 6% SST)

Registration fee is subjected to 6% SST

Payment must be made before the training date

Seats are limited: Only 25 participants per class

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

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

BOOK YOUR SEAT NOW!!!

For further enquiries, please contact:
Mike/Janet,
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E-mail: mike@mopi.org.my and admin@mopi.org.my
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ADMINISTRATION DETAILS:

Important Notice: Payment is required with registration and must be received 2 weeks prior to the start of the relevant module to guarantee your place. Walk-in participants will only be admitted on the basis of space availability at the course and with immediate full payment by banker's cheque in favour of the **"**Malaysian Organisation of Pharmaceutical Industries**"**.

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

CANCELLATIONS & TRANSFERS:

- 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)

1 Name_____

Designation_____

Email address _____

Contact Number _____

2 Name_____

Designation_____

Email address _____

Contact Number _____

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

Enclosed cheque/bank draft No_____ for RM_____ being payment for ____ participant(s) made in favour of the "**Malaysian Organisation of Pharmaceutical Industries**".

List of 2-Day Online Courses (please tick accordingly)	
☐ **GMP – What You Need to Know** **22 – 23 February 2021 (Mon – Tue)**	☐ **Cleaning Validation** **16 – 17 August 2021 (Mon – Tue)**
☐ **Risk Management – Compliance and Process** **08 – 09 March 2021 (Mon – Tue)**	☐ **Introduction to Laboratory Controls (NEW)** **20 – 21 September 2021 (Mon – Tue)**
☐ **Validation – A Roadmap to Getting It Right First Time** **22 – 23 March 2021 (Mon – Tue)**	☐ **Solid Dose Manufacturing** **11 – 12 October 2021 (Mon – Tue)**
☐ **Root Cause Analysis and CAPA** **24 – 25 May 2021 (Mon – Tue)**	☐ **Internal Audits – A Key to Your Quality System** **25 – 26 October 2021 (Mon – Tue)**
☐ **Process Validation** **21 – 22 June 2021 (Mon – Tue)**	☐ **Good Distribution Practice for the Regulated Industry** **22 – 23 November 2021 (Mon – Tue)**
☐ **Computer Systems for Regulated Environment** **12 – 13 July 2021 (Mon - Tue)**	☐ **Bioprocessing (NEW)** **06 – 07 December 2021 (Mon – Tue)**
☐ **bGMP – Minimizing Human Errors** **02 – 03 August 2021 (Mon – Tue)**	* * 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 _____

Company Stamp (with Address, Telephone & Fax Number)

Office Use Only

Registration Accepted on ……

Payment Accepted on ……