INTERNATIONAL GOOD MANUFACTURING PRACTICE TRAINING PROGRAM

Online, Instructor-Led Training

YEAR 2020

Training Grant is available under HRDF SBL Scheme

The training program consists of 10 on-line courses. These courses cover the essential principles of 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.

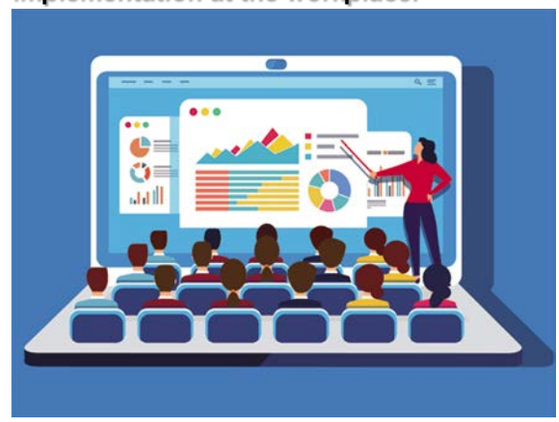
Trainers

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 module 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.

- 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

Validation – A Roadmap to Getting It Right First Time
20 - 23 July 2020 (4 hours per day, 0900 – 1300 hours)

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 and 2:

- Validation Principles and International Regulations
- Validation Master Plans and Validation Documents

Day 3 and 4:

- Equipment Commissioning and Qualification
- Protocol Execution
- Deviation Management
- Final Report Summary
- 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

Good (Quality Control) Laboratory Practices
03 - 06 August 2020 (4 hours per day, 0900 – 1300 hours)

Currently, more and more laboratories are run like businesses, where success is driven by credibility. In order to be credible in the current competitive environment, your laboratory must:

- Produce reliable and accurate results with unambiguous test reports
- Deliver correct information to the correct customer in a timely manner
- Perform economically and efficiently
- Be able to retrieve historical records and data
- Operate independently in quality assessment
- Withstand audits and inspections

Critically, the loss of credibility in a laboratory leads to customer skepticism and a loss in confidence of your capabilities. Without Good (Quality Control) Laboratory Practices – G(QC)LP – you are left focusing on “defending” results, and regulatory or external pressure which distract personnel from value-adding and cost-effective operations. This course will help you and your laboratory perform successfully by providing you with knowledge and the understanding needed to establish and maintain G(QC)LP.

Content

Day 1 and 2:

- Introduction to Good (Quality Control) Laboratory Practices
- Analytical Method Validation

Day 3 and 4:

- Pharmaceutical Sampling Plans
- Stability Program

Participants

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

COURSE OUTLINE

Solid Dosage Manufacture Principles and Practices

24 - 27 August 2020 (4 hours per day, 0900 – 1300 hours)

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 Dose Forms, and introduce the concept and practices of Process Mapping, Risk Analysis, Critical Control points and Validation requirements for the formulation, scale-up and optimization of solid dose forms.

Content

Day 1 and 2:

- Quality Assurance in Solid Dose Manufacturing
- Granulation Technology and Control
- Blending and Milling Technology and Control

Day 3 and 4:

- Encapsulation Technology and Control
- Compression Technology and Control
- Coating Technology and Control

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

07 - 10 September 2020 (4 hours per day, 0900 – 1300 hours)

Internal audits deliver value irrespective of how mature your organization'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.

Content

Day 1 and 2:

- **Good Auditing Practice**
  - Critical role of quality audit in GMP compliance & improvement
  - Regulatory standards and guidelines for quality auditing
  - GxP requirements for internal audit programs
  - Risk assessment as it applies to quality audit practices
  - Documents, records & data for effective audits
  - GxP audit schedules and the use of risk management in relation to prioritizing audits
  - Six fundamental steps of auditing explained in detail (including tips on how to manage & facilitate audits in a constructive manner)

Day 3 and 4:

- **Corrective and Preventive Action (CAPA) and Auditing**
  - Defining Corrective and Preventive Action (CAPA)
  - Overview and systematic application of the CAPA system as it applies to quality audits
  - Relationship between CAPA and risk assessment / management
  - Risk assessment / management as it applies to audit scheduled and observations
  - Application of CAPA to audit observation deficiencies

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.

COURSE OUTLINE

Computer Systems for Regulated Environment

21 - 24 September 2020 (4 hours per day, 0900 – 1300 hours)

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 organization 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 and 2:

- 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 3 and 4:

- 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, Operational Subject Matter Expert (SME), or Manager likely to be involved in using, validating, approving, or purchasing computer systems.

Behavioral Good Manufacturing Practice – minimizing human errors

05 - 08 October 2020 (4 hours per day, 0900 – 1300 hours)

This course examines why people do not comply with procedures, either by error or perhaps deliberately, and what can be done about it. You will learn about the specific modes of human error and where "re-training" can help, but why it does not for 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.

Content

Day 1 and 2:

- 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 organization itself influences behavior
- The importance of systems in influencing and supporting changed behavior

COURSE OUTLINE

- 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

Day 3 and 4:

- 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, failure investigations, and continuous improvement will benefit from this program.

Contamination Control

19 - 22 October 2020 (4 hours per day, 0900 – 1300 hours)

This course aims to introduce you to the necessity for control of contamination in the storage, handling, and processing of components, materials, and products in both non-sterile and sterile forms.

Content

Day 1 and 2:

- Introduction to Contamination Control and why it is critical to product quality
- HVAC and Controlled Environments – control & qualification

Day 3 and 4:

- Environmental Monitoring Programs
- Control of Water Systems

On the completion of this course you will be able to:

- State why contamination control is critical.
- Identify the major sources of physical and chemical contamination
- Implement procedures to reduce the chance of material and product contamination.
- List the regulatory requirements for HVAC systems & environmental monitoring of controlled environments.
- Prepare monitoring procedures with focus on microbiological concepts, sample sites & frequency, and alert & action levels for sterile & non-sterile products.
- Discuss the various environmental monitoring test methods e.g. Air Sampler, Settling Plates, Surface Swabbing & Contact (RODAC) Plate

Participants

This course is designed for personnel who are involved in the handling, storage, and distribution of medicinal products and medical devices, as well as for managers and supervisors responsible for ensuring controls for contamination are in place.

COURSE OUTLINE

Root Cause Analysis and CAPA

02 - 05 November 2020 (4 hours per day, 0900 – 1300 hours)

This course aims to help identifying regulatory requirements and expectations related to failure investigation, root cause analysis (RCA), and CAPA. The CAPA system not only to satisfy regulatory requirements but also to implement a closed-loop problem-solving system to help minimize quality issues and improve compliance.

Content

Day 1 and 2:

- Key steps and activities for an 8D problem analysis
- General principles and approach for 8D problem analysis
- General principles and approach for the use of FMEA in problem analysis
- general principles and approach for the use of Fish Bone Diagram in problem analysis
- Key steps and activities of risk management in problem analysis

Day 3 and 4:

- CAPA elements and principles
- Develop a CAPA form for observations/deficiencies
- DMAIC approach of problem solving
- Understand the SMART principles of CAPA
- Link the concept of risk with CAPA management
- Understand the SMART principles of CAPA
- Link the concept of risk with CAPA management

Participants

Managers and supervisors responsible for GMP compliance, root cause analysis, failure investigations, and CAPA strategies will benefit from this program.

Process Validation and Cleaning Validation

16 - 19 November 2020 (4 hours per day, 0900 – 1300 hours)

This course aims to develop contemporary understanding of both process and cleaning validation 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 and 2:

- The GMP reasons for process validation.
- Strategies for process validation that complies with cGMPs
- Essentials of a process validation protocol
- Requirements for re-validation and give examples of situations that would give rise to it

Day 3 and 4:

- GMP reasons for cleaning validation.
- Strategies for cleaning validation that complies with cGMPs
- Practical limits for cleaning residues
- Essentials of a cleaning validation protocol

Participants

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

COURSE OUTLINE

Good Distribution Practices for the Regulated Industry

30 November - 03 December 2020 (4 hours per day, 0900 – 1300 hours)

This course aims to introduce the requirements of Good Distribution Practices (GDPs) 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 and 2:

- Relationship and Integration with GMP
- Understanding the Manufacturers requirements
- Understanding Risk Management in the Supply Chain

Day 3 and 4:

- Understanding GDP for Therapeutic Products and Medical Devices
- Cold Chain Management

Participants

This course is designed for personnel who are involved in the handling, storage, and distribution of medicinal products and medical devices, as well as for managers and supervisors responsible for GDP compliance.

METHODOLOGY:
Online-line delivery of lectures, workshops, case studies, and group activities.

ASSESSMENT:
A variety of assessment strategies will be used and may include assignments, classroom engagement, projects, and presentations. Participants will be informed of the assessment method, date of assessment and percentage contribution at the start of the module.

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 15 participants per class

TRAINING TIME SCHEDULE:
9.00AM – 1.00PM (in 4 days)

9.00AM – AM TOPIC
11.00AM – BREAK
11.15AM – AM TOPIC
1.00PM – FINISH

BOOK YOUR SEAT NOW!!!

For further enquiries, please contact:
Mike/Janet,
MOPI, 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:

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**".

Select a course accordingly:

Technical Courses	Technical Courses
☐ **GMP – What You Need to Know** **17 – 18 Feb 2020 (Mon – Tue) – 2 Days Course**	☐ **Computer Systems for Regulated Environment and Data Integrity (Online)** **21 - 24 September 2020 (Mon – Thur) – 4 hours per day (0900 – 1300 hours)**
☐ **Risk Management – Quality System and Process** **03 – 04 Mar 2020 (Tue - Wed) – 2 Days Course**	☐ **bGMP – Minimizing Human Errors (Online)** **05 – 08 October 2020 (Mon - Thur) – 4 hours per day (0900 – 1300 hours)**
☐ **Process Validation and Cleaning Validation (Online)** **06 – 09 July 2020 (Mon - Thur) – 4 hours per day (0900 – 1300 hours)**	☐ **Contamination Control (Online)** **19 - 22 October 2020 (Mon - Thur) – 4 hours per day (0900 – 1300 hours)**
☐ **Validation – A Roadmap to Getting It Right First Time (Online)** **20 – 23 July 2020 (Mon - Thur) – 4 hours per day (0900 – 1300 hours)**	☐ **Root Cause Analysis and CAPA (Online)** **02 - 05 November 2020 (Mon - Thur) – 4 hours per day (0900 – 1300 hours)**
☐ **Good (Quality Control) Laboratory Practices (Online)** **03 – 06 August 2020 (Mon - Thur) – 4 hours per day (0900 – 1300 hours)**	☐ **Process Validation and Cleaning Validation (Online)** **16 - 19 November 2020 (Mon - Thur) – 4 hours per day (0900 – 1300 hours)**
☐ **Solid Dosage Manufacture Principles and Practices (Online)** **24– 27 August 2020 (Mon - Thur) – 4 hours per day (0900 – 1300 hours)**	☐ **Good Distribution Practices for the Regulated Industry (Online)** **30 November – 03 December 2020 (2020 (Mon - Thur) – 4 hours per day (0900 – 1300 hours)**
☐ **Internal Quality Audits (Online)** **07 – 10 September 2020 (Mon - Thur) – 4 hours per day (0900 – 1300 hours)**	
	* * 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 ……