INTERNATIONAL GOOD MANUFACTURING PRACTICE TRAINING PROGRAM

YEAR 2020

The training program consists of 13 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 training is delivered in the form of workshop which comes a combination of case studies, class exercises, and group discussion.

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 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

Presenter:

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 (2 days) 17 - 18 February 2020

This course will help by stepping you through the key requirements as per the PIC/S Guide to Good Manufacturing Practice for Medicinal Products 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, Equipment and Facilities, Production and Packaging Controls, Validation, Quality Control, Out-of-Specification, Stability Programs
- Good documentation and record keeping practices

Day 2:

- Quality Management Basics: A Quality-System approach to GMP, Quality Risk Management, Managing Changes and Deviations, Product Quality Reviews

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 for a refresher, or existing companies that require a new GMP licence or GMP certificate from the regulatory bodies, including 3rd party logistics (3PL) providers that repack/reprocess medicines.

Risk Management – Quality System and Process (2 days) 03 – 04 March 2020

Day 1 Risk Management for Quality System

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 nonconforming material 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 management 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:

- The critical importance of quality assurance or Quality Management Systems (QMS)
- The goal of risk management in managing compliance
- The key systems – how they integrate and where risk assessment can be applied to appropriate sub-systems, such as
    - Document Control
    - Change Control
    - Training
    - Customer Complaints
    - Deviation Management
    - Internal Audits
    - CAPA
- The central role of CAPA system in QMS

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 you 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
- GMP requirements for risk assessments
- An overview of the Quality Risk Management Process
- The Quality Risk Management Toolbox: what to use and when
- Conducting Process Risk Assessments:
    - 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 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 manufacturing processes. It does, however, assume a good understanding of Quality Management Systems (QMS).

Process Validation and Cleaning Validation (2 days) 02 - 03 June 2020

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:

- 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 2:

- 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

Contamination Control (2 days) 23 – 24 June 2020

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:

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

Day 2:

- 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.

Validation – A Roadmap to Getting It Right First Time (2 days) 14 - 15 July 2020

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:

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

Day 2:

- 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

COURSE OUTLINE

Good (Quality Control) Laboratory Practices (2 days) 27 - 28 July 2020

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:

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

Day 2:

- 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.

Solid Dosage Manufacture Principles and Practices (2 days) 10 - 11 August 2020

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:

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

Day 2:

- 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.

COURSE OUTLINE

Internal Audits – A Key to Your Quality System (2 days) 25 – 26 August 2020

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:

- **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 2:

- **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.

Computer Systems for Regulated Environment (3 days) 8 – 10 September 2020

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:

- ❖ 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

COURSE OUTLINE

Day 2:

- 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
- Pre-Development Phases
  - Requirements Definition
  - Traceability
  - Audits
  - Design

Day 3:

- Development, Testing, Qualification and Use
  - Coding
  - Testing
  - Qualification
  - 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, 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 (2 days)

22 - 23 September 2020

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 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.

Content

Day 1:

- 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
- 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

COURSE OUTLINE

Day 2:

- 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.

Good Aseptic Practices (2 days) 06 – 07 October 2020

Aseptic processing is a high-risk operation in regulated manufacturing and personnel present the biggest risk to product contamination. You can reduce human error and your level of risk by ensuring that you and your personnel fully understand the purpose and implications of working in a clean room environment and how to handle materials aseptically.

Content

Day 1:

- Introduction to Aseptic Practices and Sterility Assurance
  - PIC/S Guide to GMP, Annex 1 (Manufacture of sterile medicinal products), and what to expect in the new version
- Microbiological Aspects of Sterile Manufacture
- How Cleanroom Design supports sterile pharmaceutical manufacturing
- Operating in a Cleanroom

Day 2:

- Aseptic Gowning Techniques
- Validation of Aseptic Processing
- Cleaning and Sanitation, including Environmental Monitoring
- Sterilization

Participants

Clean room personnel at Operator, Supervisor and Manager levels from pharmaceutical, compounding pharmacy or medical device industries will benefit from this training. Whether you're new in a clean room role or experienced and in need of refresher training, this course will help you gain critical knowledge of current industry expectations for clean room environments and operations as well as Good Aseptic Practices and why they're enforced.

COURSE OUTLINE

Good Distribution Practices for the Regulated Industry (2 Days) 20 – 21 October 2020

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:

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

Day 2:

- 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.

Root Cause Analysis and CAPA (2 days) 17 – 18 November 2020

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:

- 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 2:

- 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

Participants

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

METHODOLOGY:
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 module:
(The fee includes course materials, lunch and refreshments)

MOPI Member – 2 days Course
30 days before commencement of course RM2,300.00
29 – 14 days before commencement of course RM2,500.00
13 – 7 days before commencement of course RM2,700,00

Non-MOPI Member – 2 days Course
30 days before commencement of course RM2,600.00
29 – 14 days before commencement of course RM2,800.00
13 – 7 days before commencement of course RM3,000.00

Foreign Participant – 2 days Course
30 days before commencement of course USD $1,100.00
29 – 14 days before commencement of course USD $1,300.00
13 – 7 days before commencement of course USD $1,500.00

Registration Fee per participant per module:
(The fee includes course materials, lunch and refreshments)

MOPI Member – 3 days Course
30 days before commencement of course RM3,000.00
29 – 14 days before commencement of course RM3,200.00
13 – 7 days before commencement of course RM3,400,00

Non-MOPI Member – 3 days Course
30 days before commencement of course RM3,300.00
29 – 14 days before commencement of course RM3,500.00
13 – 7 days before commencement of course RM3,700.00

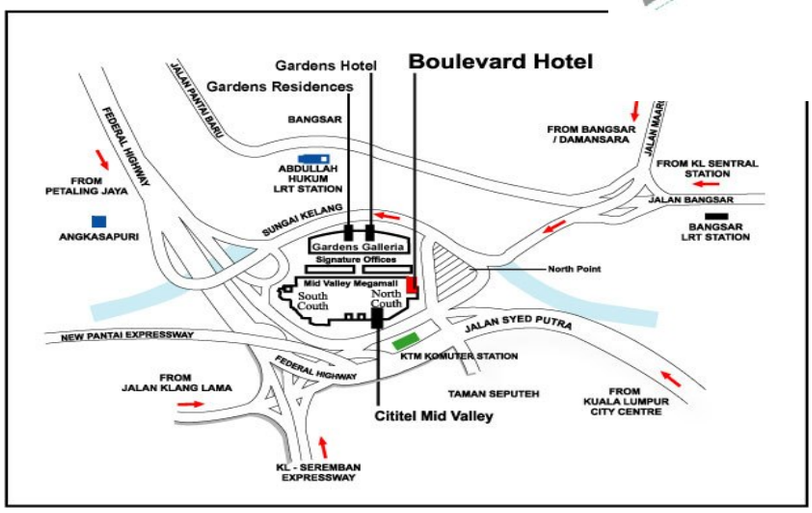
Foreign Participant – 3 days Course
30 days before commencement of course USD $1,500.00
29 – 14 days before commencement of course USD $1,700.00
13 – 7 days before commencement of course USD $1,900.00

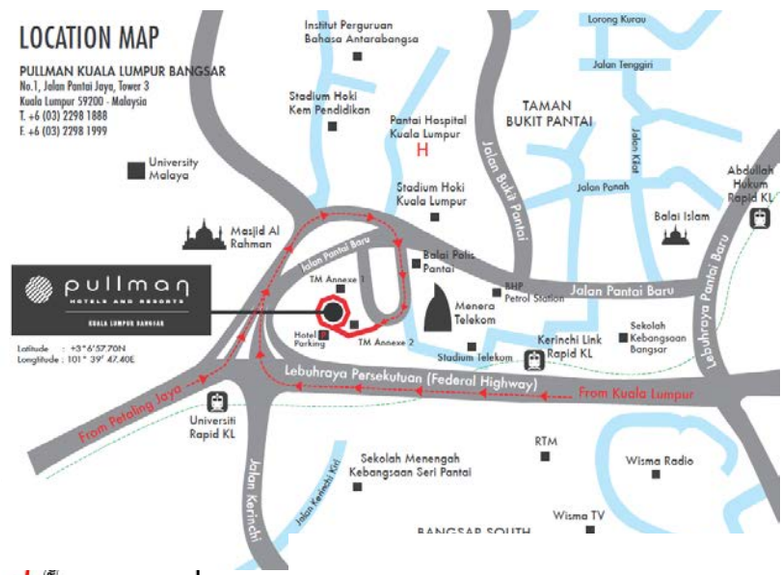
Registration fee is subjected to 6% SST

Training Venue:

THE BOULEVARD
St Giles Premier Hotel

Hotel Address | Mid Valley City | Lingkaran Syed Putra | 59200 | Kuala Lumpur | Malaysia
Tel: +60.3.22958000
Website: www.StGiles-Hotels.com





Training Venue:

Pullman Kuala Lumpur Bangsar

Hotel Address | No. 1, Jalan Pantai Jaya | Tower 3 | 59200 | Kuala Lumpur | Malaysia
Tel: +60.3.22981888
Website: www.pullmanhotels.com/gb/hotel-7962-pullman-kuala-lumpur-bangsar-/index.shtml

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 _____

☐ Vegetarian

2 Name_____

Designation_____

Email address _____

Contact Number _____

☐ Vegetarian

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 (Boulevard Hotel)**	☐ **Computer Systems for Regulated Environment and Data Integrity** **8 – 10 September 20 (Tue – Thu) – 3 Days Course (Pullman Bangsar)**
☐ **Risk Management – Quality System and Process** **03 – 04 Mar 2020 (Tue - Wed) – 2 Days Course (Pullman Bangsar)**	☐ **bGMP – Minimizing Human Errors** **22 - 23 September 2020 (Tue - Wed) – 2 Days Course (Boulevard Hotel)**
☐ **Process Validation and Cleaning Validation** **02 – 03 June 2020 (Tue - Wed) – 2 Days Course (Pullman Bangsar)**	☐ **Good Aseptic Practices** **06 – 07 October 2020 (Tue – Wed) – 2 Days Course (Boulevard Hotel)**
☐ **Contamination Control** **23 – 24 June 2020 (Tue - Wed) – 2 Days Course (Boulevard Hotel)**	☐ **Good Distribution Practices for the Regulated Industry** **20 – 21 October 2020 (Tue – Wed) – 2 Days Course (Pullman Bangsar)**
☐ **Validation – A Roadmap to Getting It Right First Time** **14 – 15 July 2020 (Tue - Wed) – 2 Days Course (Boulevard Hotel)**	☐ **Root Cause Analysis and CAPA** **17 – 18 November 2020 (Tue - Wed) – 2 Days Course (Boulevard Hotel)**
☐ **Good (Quality Control) Laboratory Practices** **27 - 28 July 2020 (Mon - Tue) – 2 Days Course (Boulevard Hotel)**	
☐ **Solid Dosage Manufacture Principles and Practices** **10 - 11 August 2020 (Mon - Tue) – 2 Days Course (Pullman Hotel)**	
☐ **Internal Quality Audits** **25 – 26 August 2020 (Tue - Wed) - 2 Days Course (Boulevard Hotel)**	
	* * 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 ……