INTERNATIONAL GOOD MANUFACTURING PRACTICE TRAINING PROGRAM

YEAR 2018

The course training program consists of 9 principal modules and 6 additional modules. These modules 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 pharmaceutical industry. Each participant will be assessed on their level of participation within classroom discussion, assignments and their level of competence in achieving the course objectives. Assignments will be case studies based on actual events that have occurred in the pharmaceutical industry.

Training Grant is available under HRDF SBL Scheme

Trainers

This course has been developed by SeerPharma and trainers are provided by, SeerPharma (Singapore) Pte Ltd. All SeerPharma trainers hold higher education degrees with a minimum of a Bachelor's degree and have a number of years of industry experience in Quality Management or Production Management roles in major and multinational companies. They have experience in all international regulatory standards including 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 course is to provide an in-depth understanding of International GMP and the knowledge and know-how to be able to implement Good Manufacturing Practices in the work place.

Who Should Attend

Key Personnel in any Aspect of GMP & Quality Management, Managers, Engineers, Executives, Quality Practitioners and any member of a pharmaceutical and related industry, those from Research and Development, Quality and Production will find this program relevant and beneficial to their job function.

- 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

FUNDAMENTAL COURSE OUTLINE

Those who are new to the pharmaceutical manufacturing industry or have recently transferred from other industries such as medical devices, electronics, food, research & development or cosmetics. This series is also recommended to those who have worked in the pharmaceutical industry with less than 3-5 years experience and are not familiar with International GMP standards such as PIC/s, EU or CFRs and wish to expand their current baseline knowledge of international GMP requirements and expectations.

Module 1 – International Good Manufacturing Practices, Quality Management Systems and GMP for Pharmaceutical Operations (23 – 25 January 2018) – 3 day Course

Aim: To provide an introduction to the regulations and Codes of Practice that governs the manufacture of therapeutic goods both nationally and internationally. To develop a broad understanding of the scope of Good Manufacturing Practices and Quality Management Systems applicable to drugs, devices and biologics and to provide a detailed analysis of the GMP requirements for manufacturing pharmaceuticals.

Day 1 AM ►QA Principles & International GMPs, updates of ASEAN Harmonisation focusing on GMP
PM ►Quality Management, Quality Assurance & Quality Control
Day2 AM ►Key Quality Assurance Systems and GMP Responsibilities for Managers & Supervisors
PM ►GMP Principles for Manufacturing Operations
Day 3 AM ►GMP Principles for Packaging Operations includes control of printed packaging materials, line clearance and reconciliation of materials/products
AM ►GMP Principles for Warehousing (related to manufacturing)
PM ►Equipment Management

Recommended for: All Personnel

Module 2 – Validation Principles and Practices (5 - 7 February 2018) – 3 day Course

Aim: This subject aims to introduce students to the validation principles covered in PIC/S, ICH, EU & FDA cGMPs and to extend the principles to practical outcomes.

Day 1 AM ►Validation Principles & International Regulations
PM ►Validation Master Plans and Validation Documents
PM ►Equipment Qualification and Commissioning
Day 2 AM ►Introduction to Process Validation and Cleaning Validation
PM ►Compiling URS against FDS documents
PM ►Preparing DQ, IQ, OQ and PQ protocols
Day 3 AM ►Protocol Execution
AM ►Deviation Management
PM ►Final Summary Report

Recommended for: QA, Engineers Production

Behavourial GMP/Good Documentation Practices/Data Integrity (12 – 14 March 2018) – 3 day Course

Aim: To provide an introduction on the concepts of behavioural GMP and how they relate to human errors and incidents as well as develop methodologies for root cause analysis and failure investigation. This course helps quality managers and supervisors understand and identify personnel's mentality and common behaviours and cultural changes to minimise human errors.

Day 1 **Behavioural GMP**
AM/PM ► Knowledge and Understanding GMP concepts, compliance and improvement
►Discipline Skills – sources of human error and strategies to reduce human error in manufacturing

Day 2 **Good Documentation Practices**
To understand the importance of creating documents and the need to maintain records in the industry to ensure compliance as well as traceability for processes and to prevent error. To understand the need for Good Documentation Practices to be applied throughout the manufacturing and supply chain.
AM/PM ► Reasons and requirements for GMP documents and records
►Importance of document controls
►Current requirements for electronic records and signatories
►Handling of product complaints, recalls and CAPA

Recommended for: All Personnel

With NEW CONTENT

Day 3 **Data Integrity**
Data Integrity has become widely discussed as a global concern for the pharmaceutical industry. This section provides an introduction to develop a broad understanding of the scope of Data Integrity and how key principles may be applied in order to provide strategic elements necessary to ensure reliability and integrity of information and data throughout all aspects of a product's lifecycle.
AM/PM ► The definition of Data Integrity within a Quality Management System
►Regulatory framework for Data Integrity and Document Control Practices
►Behavioural GMP and development of a quality culture to enable Data Integrity compliance

Module 3 – Contamination Control (26 - 28 March 2018) – 3 day Course

Aim: To develop a broad understanding of the types and sources of contamination; and to analyze and assess the major risks to pharmaceuticals and the practical control methods which are used to minimize and correct contamination problems.

Day 1 AM ►Introduction to Contamination Control and why it is critical to product quality
PM ►Microbiological Aspects of Manufacturing including routes of contamination. Identify the key controls within a manufacturing facility
Day 2 AM ►Cleaning and Sanitation
PM ►HVAC and Controlled Environments – control & qualification
Day 3 AM ►Environmental Monitoring Programs
PM ►Control of Water Systems

Recommended for: QA and Production

FUNDAMENTAL COURSE OUTLINE

Module 4 - Good (Quality Control) Laboratory Practices (G(QC)LPs) (23 – 24 April 2018) – 2 day Course

Aim: To facilitate the development of knowledge, and expertise in the regulations, quality standards and guidelines that govern the quality control of pharmaceuticals.

Day 1 AM ► Introduction to Good (Quality Control) Laboratory Practices (GLPs)
PM ► Qualification and Calibration of Laboratory Equipment
PM ► Analytical Method Validation
Day 2 AM ► Biological assays Validation and Control
PM ► Basic Statistics for Quality Control Laboratories
PM ► Pharmaceutical Sampling Plan & Pharmaceutical Stability Programs

Recommended for: QA, QC

Back to back with Practical Stability Study Application to Pharmaceuticals to Pharmaceuticals (25 – 26 April 2018)

Module 5 – Compliance with GMP for the Pharmaceutical Engineer (23 – 25 July 2018) – 3 day Course

Aim: To provide an introduction to the requirements of Good Manufacturing Practices for supporting design of facilities, equipment and processes in the pharmaceutical and related industries, and to develop a broad understanding of the scope of Good Engineering Practices and Good Manufacturing Practices.

Day 1 AM ► Facility Layout and Design Principles
PM ► Design and Construction of Critical Utilities: inc. Water, Gases and Steam
Day 2 AM ► Water Systems: Design, Control & Validation
PM ► HVAC Design, Control & Validation
Day 3 AM ► Qualification of Processing Equipment
PM ► Planned Preventative Maintenance and Calibration

Recommended for: Engineering

Module 6 Good Distribution Practices (GDP) for the Regulated Industry (27 – 29 August 2018) – 3 day Course

Aim: To provide an introduction to the requirements of Good Distribution Practices (GDPs) for the therapeutic and medical device industries, also provide a better understanding of the concepts of validation and management for the handling, storage and distribution of pharmaceutical products.

Day 1 AM ► Relationship and integration with GMP
PM ► Understanding the manufacturer's requirements
Day 2 AM ► Risk Management and continuous improvement in distribution
PM ► Understanding GDPs for therapeutic products and Devices
PM ► Understanding GDPs for medical devices
Day 3 AM ► Cold Chain Management – regulatory updates for the cold chain investigation, current and future, maintenance, handling and packaging of cold chain products
PM ► Validation of the supply chain
PM ► Introduction to the principles of warehouse design for product preservation

Recommended for: QA, Warehousing, Distribution

Module 7 – Good Aseptic Practices & Sterile Products (24 – 26 September 2018) – 3 day Course

Aim: This subject is designed to facilitate the development of knowledge and practical skills in the assessment of special risks associated with the manufacture of sterile pharmaceuticals and to develop and evaluate strategies and plans that will ensure acceptable sterility assurance levels.

Day 1 AM ► Assess the regulatory requirements for aseptic manufacturing processes in order to provide recommendations for their application to ensure compliance
PM ► Evaluate the processing and compliance risks associated with aseptic processing and terminal sterilization
Day 2 AM ► Critically evaluate strategies for bioburden control
PM ► Evaluate the available processes for sterilisation and depyrogenation
Day 3 AM ► Prepare risk based environmental assessments
PM ► Understand the updates to ISO14644-1 and -2:2015

Recommended for: QA and Production

With NEW CONTENT

Module 8 – Solid Dosage Manufacture Principles and Practices (22 – 24 October 2018) – 3 day Course

Aim: To provide an introduction to the GMP requirements for the formulation, scale up and optimization of Finished Solid Dose Forms and to develop a practical understanding of Process Mapping, Risk Analysis and Critical Control points, Validation requirements and Quality Plans as it applies to solid dose formulations.

Day 1 AM ► Granulation Technology and Control
PM ► Blending and Milling Technology and Control
Day 2 AM ► Encapsulation Technology and Control
PM ► Compression Technology and Control
Day 3 AM ► Coating Technology and Control
PM ► Packaging Technology and Control

Changed CONTENT

Recommended for: Production and Engineering

ADVANCED COURSE OUTLINE

Those who have already undergone the Fundamental GMP series or those with a strong GMP background and minimum 5 years of relevant experience. This series is recommended to those with supervisory management positions and wish to consolidate and specialise in areas of advanced GMP knowledge commensurate with their roles and responsibilities within their organisation. In addition, recommended for those whose duties require advanced GMP knowledge of international Quality by Design application as part of their job function, particularly those involved with Research and Development, Validation, Risk Management and site Quality Assurance oversight.

Advanced Process Validation and Cleaning Validation (9 – 11 April 2018) – 3 day Course

Aim: To develop advanced understanding of Sterile and Non Sterile Process and Cleaning Validation in order to comply with contemporary regulatory expectations. Putting into perspective the interpretation of regulatory and industry guidance.

Day 1 AM ► Understanding ASEAN PV Guidance and SUPAC
AM ► PIC/S Annex 15 and FDA Guidance on Process Validation
PM ► Ongoing re-validation

Day 2 AM ► Process Performance Qualification
AM ► Process capability analysis for process validation
PM ► Developing a process validation rationale

Day 3 AM ► The process equipment train and cleanability
AM ► PDE a scientific approach to cleaning validation
PM ► Introduction to CIP principles and validation

Recommended for: QA, QC and Production

With NEW CONTENT

Practical Stability Study Application to Pharmaceuticals (25 – 26 April 2018) – 2 day Course

Aim: This course is designed to provide the quality professional with the key requirements for establishing and implementing a successful stability trial program. It will review the relevant ICH guidance documents and will include workshops to provide practical application of the key requirements for stability. It will develop techniques for planning new and on-going stability trials.

Day 1 AM ► ASEAN stability guidelines
PM ► Preparation of stability protocol
PM ► Bracketing and matrixing designs for new drug substances and products (ICH Q1D)

Day 2 AM ► Evaluation of stability data (ICH Q1E)
PM ► Registration applications in climatic zones III and IV (ICH Q1F)
PM ► FDA guideline on container/closure integrity

Recommended for: QA, QC and Regulatory

Back with High Demand

Back to back with Module 5 - Good (Quality Control) Laboratory Practices (G(QC)LPs) (23 – 24 April 2018)

Pharmaceutical CAPA and Problem Solving (7 – 9 May 2018) – 3 day Course

Aim: To learn about how to use the CAPA system not only to satisfy regulatory requirements but also to implement a closed loop problem solving system to help minimise quality issues and improve compliance. To help identify regulatory requirements and expectations related to failure investigation, root cause analysis (RCA) and CAPA. A brief discussion on controls such as pharmacovigilance for drug products, FSCA and AE reporting for medical devices.

Day 1 AM ► Defining CAPA
PM ► Overview and Systematic application of the CAPA system as it applies to quality audits

Day 2 AM ► Relationships between CAPA and risk assessment/management
PM ► Risk assessment/management as it applies to audit observations

Day 3 AM ► Application of CAPA to audit observation deficiencie
PM ► How to perform Root Cause Analysis for a compliant CAPA

Recommended for: All Personnel

ADVANCED COURSE OUTLINE

Those who have already undergone the Fundamental GMP series or those with a strong GMP background and minimum 5 years of relevant experience. This series is recommended to those with supervisory management positions and wish to consolidate and specialise in areas of advanced GMP knowledge commensurate with their roles and responsibilities within their organisation. In addition, recommended for those whose duties require advanced GMP knowledge of international Quality by Design application as part of their job function, particularly those involved with Research and Development, Validation, Risk Management and site Quality Assurance oversight.

Computer Systems for Regulated Environments/Data Integrity (25 – 27 June 2018) – 3 day Course

Aim: Computer Systems are an established and integral part of management in modern Life Science organisations. All users must ensure that their systems and software have been developed to best engineering practices in a quality assured and secure manner to comply with Regulatory Requirements and to be fit for Business Use.
Data Integrity has become widely discussed as a global concern for the pharmaceutical industry. This section provides an introduction to develop a broad understanding of the scope of Data Integrity and how key principles may be applied in order to provide strategic elements necessary to ensure reliability and integrity of information and data throughout all aspects of a product's lifecycle.

Day 1 AM ► Understand how computer systems are regulated in the local and global regulatory environment
AM ► Understanding the controls necessary to demonstrate data integrity
PM ► Computer Systems Selection and Vendor Qualification
Day 2 AM ► Developing a risk-based approach to CSV
AM ► Best practices for validation test execution, documentation and error handling
PM ► Understanding how the CSV process fits into the company's Software Life Cycle (SLC), understand the types of, and elements of System Development Life Cycles (SDLC) and the use of GAMP 5
Day 3 AM ► Understanding of the key components and principles of a software quality assurance (SQA) program and auditor expectations.
PM ► Hands-on practice creating key validation deliverables, including requirements, test plan, test scripts and test summary
PM ► Data Integrity:

Recommended for: QA, QC and Engineering

With NEW CONTENT

Risk Management in Pharmaceutical Operations (ICHQ9) (8 - 10 October 2018) – 3 day Course

Aim: To provide an introduction to the principles of risk management and its application in the pharmaceutical and related industries. To enable students to identify opportunities and apply risk principles within their GxP related operational areas.

Day 1 AM ► Principles of Risk Management and ICH Q9
PM ► Risk Management Techniques - FMEA, FTA, HACCP
Day 2 AM ► Risk Management to Compliance and Quality Assurance Management
PM ► Applying Risk Management in Compliance
Day 3 AM ► Risk Management Principles in Validation Programs
PM ► Applying Risk Management to Operations

Recommended for: QA

Module 9 – GxP and Quality Auditing Practices (26 – 27 November 2018) – 2 day Course

Aim: To provide an introduction to auditing principles and practices , and to develop a broad understanding of the requirements and techniques for planning, conducting and reporting quality audits applicable to manufacturing systems for drugs, biologics and devices.

Day 1 AM ► GxP audit schedule, managing regulatory audits in an effective manner, what to expect from GMP licensing audits
PM ► The role of supplier audits for actives, excipients and components in Vendor management
PM ► Four fundamental steps of auditing explained in detail, tips on how to manage & facilitate audits in a constructive manner
Day 2 AM ► Utilisation of risk management in relation to prioritizing audits
PM ► Auditing for data integrity

Recommended for: QA

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 – 3 day Course
30 days before commencement of course RM2,900.00
29 – 14 days before commencement of course RM3,100.00
13 – 7 days before commencement of course RM3,300,00

Non-MOPI Member – 3 day Course
30 days before commencement of course RM3,200.00
29 – 14 days before commencement of course RM3,400.00
13 – 7 days before commencement of course RM3,600.00

Foreign Participant – 3 day Course
30 days before commencement of course USD $1,300.00
29 – 14 days before commencement of course USD $1,500.00
13 – 7 days before commencement of course USD $1,700.00

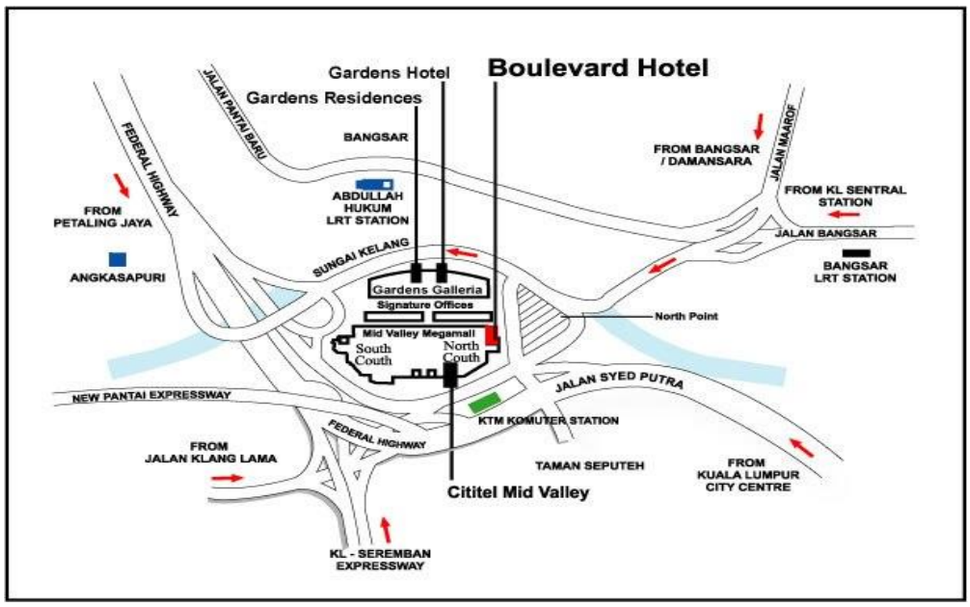
Registration Fee per participant per module:
(The fee includes course materials, lunch and refreshments)

MOPI Member – 2 day Course
30 days before commencement of course RM2,200.00
29 – 14 days before commencement of course RM2,400.00
13 – 7 days before commencement of course RM2,600,00

Non-MOPI Member – 2 day Course
30 days before commencement of course RM2,500.00
29 – 14 days before commencement of course RM2,700.00
13 – 7 days before commencement of course RM2,900.00

Foreign Participant – 2 day Course
30 days before commencement of course USD $900.00
29 – 14 days before commencement of course USD $1,100.00
13 – 7 days before commencement of course USD $1,300.00

Registration fee is subjected to 6% GST



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

TIME SCHEDULE:
9.00 am – 5.00 pm

8.30 am	Registration
9.00 am	AM Topic
10.15 am	Tea Break
10.30 am	AM Topic
12.15 pm	Lunch
1.25 pm	PM Topic
3.00 pm	Tea Break
3.15 pm	PM Topic
5.00 pm	End

Optional Hotel accommodations:
Cititel Mid Valley *Tel: 603-2296 1188*
Website: www.cititelmidvalley.com

Eastin Hotel*, Petaling Jaya Tel: 603-7665 1111*
Website: www.eastin.com

Crystal Crown Hotel, *Petaling Jaya Tel : 603-7958 4422*
Website: www.crystalcrown.com.my

Armada PJ Hotel *Tel: 603-7954 6888*
Website: www.armada.com.my

BOOK YOUR SEAT NOW!!!

For further enquiries, please contact:
Mike/Janet, MOPI
GLOBAL BUSINESS & CONVENTION CENTRE,
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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 reserves 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 occur.

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:

Fundamental GMP Module	Advanced GMP Module
☐ **Module 1 International Good Manufacturing Practices, Quality Management Systems and GMP for Pharmaceutical Operations** 23 – 25 January 2018 (Tues - Thu) – 3 day Course	☐ **Advanced Process Validation and Cleaning Validation** 9 – 11 April 2018 (Mon – Wed) – 3 day Course
☐ **Module 2 Validation Principles and Practices** 5 – 7 February 2018 (Mon – Wed) – 3 day Course	◯ **Practical Stability Study Application to Pharmaceuticals** 25 – 26 April 2018 (Wed – Thu) – 2 day Course
☐ **Behavourial GMP/ Good Documentation Practices/ Data Integrity** 12 – 14 March 2018 (Mon – Wed) – 3 day Course	☐ **Pharmaceutical CAPA and Problem Solving** 7 – 9 May 2018 (Mon – Wed) – 3 day Course
☐ **Module 3 Contamination Control** 26 – 28 March 2018 (Mon – Wed) – 3 day Course	☐ **Computer Systems for Regulated Environments/Data Integrity** 25 – 27 June (Mon – Wed) – 3 day Course
◯ **Module 4 Good Quality Control Laboratory Practices (G(QC)LPs)** 23 – 24 April 2018 (Mon – Tue) – 2 day Course	☐ **Risk Management in Pharmaceutical Operations (ICH Q9)** 8 – 10 October (Mon – Wed) – 3 day Course
☐ **Module 5 Compliance with GMP for the Pharmaceutical Engineer** 23 – 25 July 2018 (Mon – Wed) – 3 day Course	☐ **Module 9 GxP and Quality Auditing Practices** 26 - 27 November 2018 (Mon – Tue) – 2 day Course
☐ **Module 6 Good Distribution Practices (GDP) for the Regulated Industry** 27 – 29 August 2018 (Mon – Wed) – 3 day Course	
☐ **Module 7 Good Aseptic Practices & Sterile Products** 24 – 26 September 2018 (Mon – Wed) – 3 day Course	
☐ **Module 8 Solid Dosage Manufacture Principles and Practices** 22 – 24 October 2018 (Mon – Wed) – 3 day Course	* * 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 _____

Company Stamp (with Address, Telephone & Fax Number)

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

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30 days before commencement of course RM2,900.00
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30 days before commencement of course USD $1,300.00
29 – 14 days before commencement of course USD $1,500.00
13 – 7 days before commencement of course USD $1,700.00

Registration fee is subjected to 6% GST

Office Use Only

Registration Accepted on ……

Payment Accepted on ……