INTERNATIONAL GOOD MANUFACTURING PRACTICE TRAINING PROGRAM

YEAR 2016

The course training program consists of 9 principal modules and 6 additional modules, each of 3 days duration. 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 (under NGO category)

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 factory who is from Research and Development, Quality and Production will find this program relevant and beneficial to their job function.

- Certificates endorsed by the National Pharmaceutical Control Bureau, 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 Control Bureau, MOH

For further details please visit www.mopi.org.my

FUNDALMENTAL 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 (22 - 24 February 2016)

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
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
- GMP Principles for Warehousing (related to manufacturing)

PM ► Equipment Management

Behavourial GMP/Good Documentation Practices (14 – 16 March 2016)

Aim: To provide an introduction on the concepts of behavioural GMP and how they relate to human errors and incidents, as well as to develop methodologies for root causes analysis, failure investigation and cultural change to improve compliance. The course also provides an introduction on managing deviations for regulated industries, including the application of the strategies and steps involved, as well as documentation and reporting processes for continuous improvement.

Day 1 AM ► Practices basis for GMP rules – why a culture of GMP compliance is critical
PM ► Behavioural GMP – What it is, and how does it work in practices
PM ► Sources of human error in manufacturing
Day 2 AM ► Failure investigation and problem solving for continuous improvement
PM ► Identify human behaviours and System errors than can lead to failure
Day 3 AM ► Essential requirements for document control in minimising quality failures
PM ► Handling product complaints, recalls and CAPA

Module 2 – Validation Principles and Practices (28 - 30 March 2016)

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 ► Process 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

Module 3 – Contamination Control (25 - 27 April 2016)

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

FUNDALMENTAL COURSE OUTLINE

Module 5 - Good (Quality Control) Laboratory Practices (G(QC)LPs) (18 - 20 July 2016)

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
Day 2 AM ► Analytical Method Validation
PM ► Biological assays Validation and Control
PM ► Basic Statistics for Quality Control Laboratories
Day 3 AM ► Pharmaceutical Sampling Plan
PM ► Pharmaceutical Stability Programs

Module 6 – Compliance with GMP for the Pharmaceutical Engineer (22 - 24 August 2016)

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 Data Base

Module 7 Good Distribution Practices (GDP) for the Regulated Industry (24 – 26 October 2016)

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
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, handling and packaging of cold chain products and packaging qualification
PM ► Validation of the supply chain

Module 9 - Solid Dose Manufacture Principles and Practices (19 – 21 December 2016)

Aim: To provide an introduction to the GMP requirements for the formulation, scale up and optimization of Finished 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 ► QA/GMPs Over Finished Dose Forms (FDF)
PM ► Granulation Technology & Control
Day 2 AM ► Blending and Milling Technology & Control
PM ► Encapsulation Technology and Control
Day 3 AM ► Compression Technology and Control
PM ► Coating Technology & Control

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 Validation And Cloud Computing (26 – 28 January 2016)

Aim: Computer Systems are established and integral part of management in modern development, validation, manufacturing, logistics, quality and administration for all Life Science organisations such as pharmaceuticals, medical devices, contract laboratories, research organisations (CROs), logistics providers (3 & 4PL) etc. This field of software have been developed to best engineering practices in a quality assured and secure manner to comply with Regulatory and Good Practice (GxP) requirements of the regulators internationally.

Day 1 ► **Understanding of how CSV process fits into your software life cycle (SLC); how computer systems are regulated globally (USFDA Part 11 & Pic/s Annex 11 etc; the types of GxP Systems, validation concepts and implementation (risk based approach); industry and regulatory guidance's on CSV (GAMP-5, FDA etc) and understanding key components and principles of a software quality assurance programs and auditor expectations.**

Day 2 ► **Vendor Qualification; Cloud Computing (models, risks, benefits and challenges); Develop, test, implement and maintain Saas Based Systems in a cloud environment; consideration of legal issues and best practices for validation test execution, documentation and error handling.**

Day 3 ► **Hands-on practice creating key validation deliverables, including Requirements, test plan, test scripts and test summary**

Product Quality Review / QMS Metrics and Practical Statistics (11 – 13 April 2016)

Aim: To introduce the key concepts of Product Quality Review (PQR). To evaluate PQR elements using trend analysis and relevant statistical approach, and to interpret the outcome of PQR evaluation for quality metrics reporting and continuous improvement.

Day 1 **AM ► Regulatory expectations of PQR for API and medicinal products, includes quality assurance for pharmaceutical manufacturing**
PM ► The essential concepts of trend

Day 2 **AM ► Key statistical tools for trend analysis**
PM ► Methodologies of PQR data analysis and statistical tools/ deliverables for PQR reporting – what chart to use and what does it tell

Day 3 **AM ► The role of PQR for quality metrics reporting – what can PQR tell about the current state of compliance**
PM ► PQR commitment tracking

Advanced Process Validation and Cleaning Validation (9 - 11 May 2016)

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 ► PIC/s Annex 1 and FDA Guidance on Process Validation**
AM ► Room classification and ongoing re-validation
PM ► Media fill trial data interpretation
PM ► Ongoing re-validation
PM ► Management Review

Day 2 **AM ► Solid-dose validation (tablets, capsules and powder)**
AM ► Aseptic liquid and powders filling validation (vials and syringes)
PM ► Validating the freeze drying process
PM ► Process capability analysis for process validation

Day 3 **AM ► Worst-case scenarios for cleaning validation studies**
AM ► The process equipment train
PM ► Recovery studies, swabbing and rinse studies
PM ► Selectivity, LOD and LOQ

ADVANCED COURSE OUTLINE

Module 4 – Risk Management in Pharmaceutical Operations (ICHQ9) (23 - 25 May 2016)

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 in Validation

Pharmaceutical CAPA and Problem Solving (26 – 28 September 2016)

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 and overview and systematic application of the CAPA as it applies to quality audits
PM ► Relationship between CAPA and risk assessment/management
Day 2 AM ► Risk assessment/management as it applies to audit observations and schedules
PM ► Application of CAPA to audit observation deficiencies and failure investigations
Day 3 AM ► Pharmacovigilance for drug products, product complaints and recalls
PM ► Field corrective and Safety Actions (FSCA)/Adverse Event (AE) Reporting For medical devices – what, when, why and how?

Module 8 – GxP and Quality Auditing Practices (21 - 23 November 2016)

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 ► Critical role of quality audit in GxP compliance & improvement
PM ► GxP audit schedule, managing regulatory audits in an effective manner, what to expect from GMP licensing audits
Day 2 AM ► The role of supplier audits for actives, excipients and components in Vendor management
PM ► Documents, records & data for effective audits.
Day 3 AM ► Four fundamental steps of auditing explained in detail, tips on how to manage & facilitate audits in a constructive manner
PM ► Utilisation of risk management in relation to prioritising audits

Good Aseptic Practices And Sterile Products (5 - 7 December 2016)

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 risks associated with aseptic processing and terminal sterilization to establish ongoing monitoring and reporting systems that can be used as the basis for changes, updates and continuous improvement.
Day 2 AM ► Critically evaluate strategies for bioburden control
PM ► Design sterilization validation protocols
Day 3 AM ► Utilize mathematical equations to evaluate, interpret and establish sterilization parameters
PM ► Perform simple tasks in an aseptic manner

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
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

Non-MOPI Member
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

Foreign Participant
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

TIME SCHEDULE:
9.00 am – 5.00 pm

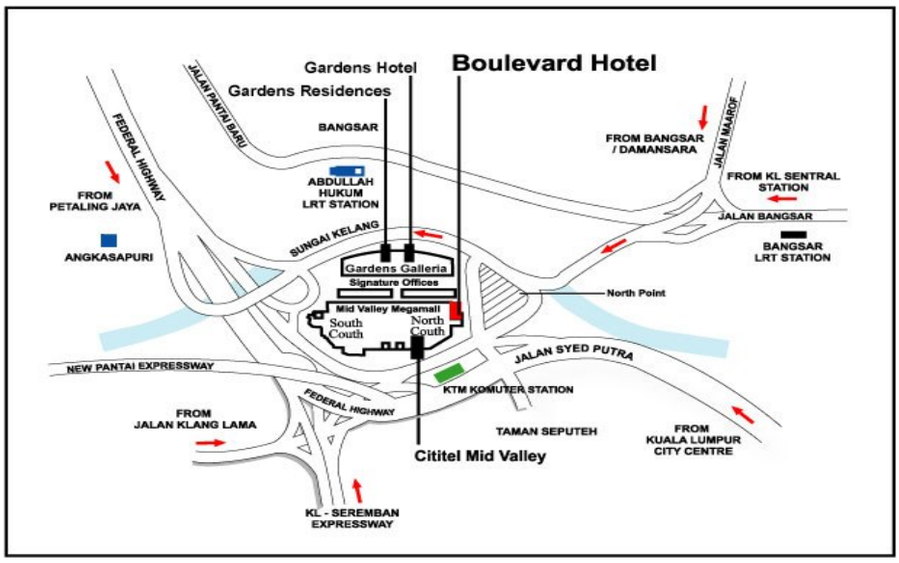
8.30 am	Registration
9.00 am	AM Topic
10.15 am	Tea Break
10.30 am	AM Topic
12.15 pm	Lunch
1.25 pm	PM Topic
3.00 pm	Tea Break
3.15 pm	PM Topic
5.00 pm	End

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



Training Venue:

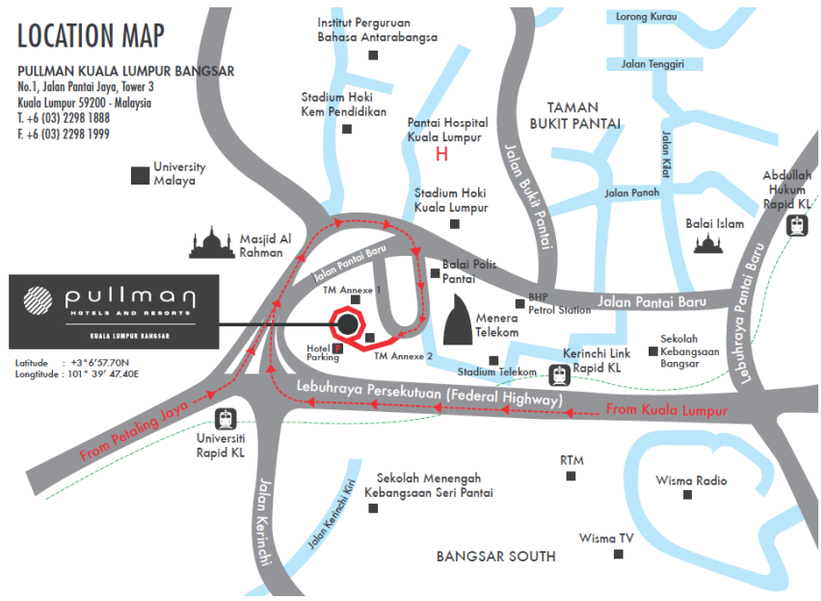
THE BOULEVARD
St Giles Premier Hotel

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, SELANGOR, 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 _____

☐ Vegetarian

2 Name_____

Designation_____

Email address _____

☐ 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 & Advanced QbD Module
☐ Module 1 International Good Manufacturing Practices, Quality Management Systems and GMP for Pharmaceutical Operations 22 - 24 February 2016 (Mon – Wed) @ The Boulevard St Giles Premier Hotel	☐ Computer Systems Validation And Cloud Computing 26 – 28 January 2016 (Mon – Wed) @ The Boulevard St Giles Premier Hotel
☐ Behavourial GMP/Good Documentation Practices 14 – 16 March 2016 (Mon – Wed) @ The Boulevard St Giles Premier Hotel	☐ Product Quality Review / QMS Metrics and Practical Statistics 11 – 13 April 2016 (Mon – Wed) @ The Boulevard St Giles Premier Hotel
☐ Module 2 Validation Principles and Practices 28 - 30 March 2016 (Mon – Wed) @ The Boulevard St Giles Premier Hotel	☐ Advanced Process Validation and Cleaning Validation 9 – 11 May 2016 (Mon - Wed) @ The Boulevard St Giles Premier Hotel
☐ Module 3 Contamination Control 25 - 27 April 2016 (Mon – Wed) @ The Boulevard St Giles Premier Hotel	☐ Module 4 Risk Management in Pharmaceutical Operations (ICH Q9) 23 - 25 May 2016 (Mon – Wed) @ The Boulevard St Giles Premier Hotel
☐ Module 5 Good Quality Control Laboratory Practices (G(QC)LPs) 18 - 20 July 2016 (Tue - Thur) @ Pullman Kuala Lumpur Bangsar	☐ Pharmaceutical CAPA and Problem Solving 26 – 28 September 2016 (Mon – Wed) @ The Boulevard St Giles Premier Hotel
☐ Module 6 Compliance with GMP for the Pharmaceutical Engineer 22 - 24 August 2016 (Mon – Wed) @ Pullman Kuala Lumpur Bangsar	☐ Module 8 GxP and Quality Auditing Practices 21 - 23 November 2016 (Mon – Wed) @ @ The Boulevard St Giles Premier Hotel
☐ Module 7 Good Distribution Practices (GDP) for the Regulated Industry 24 – 26 October 2016 (Tue- Thur) @ The Boulevard St Giles Premier Hotel	☐ Good Aseptic Practices And Sterile Products 5 - 7 December 2016 (Mon – Wed) @ The Boulevard St Giles Premier Hotel
☐ Module 9 Solid Dose Manufacture Principles and Practices 19 – 21 December 2016 (Mon – Wed) @ The Boulevard St Giles Premier 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 _____

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 RM2,600.00
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13 – 7 days before commencement of course RM3,300.00

Foreign Participant
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 ……