# INTERNATIONAL GOOD MANUFACTURING PRACTICE TRAINING PROGRAM

## YEAR 2019

The course training program consists of 9 technical modules and 7 additional trainings. 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.
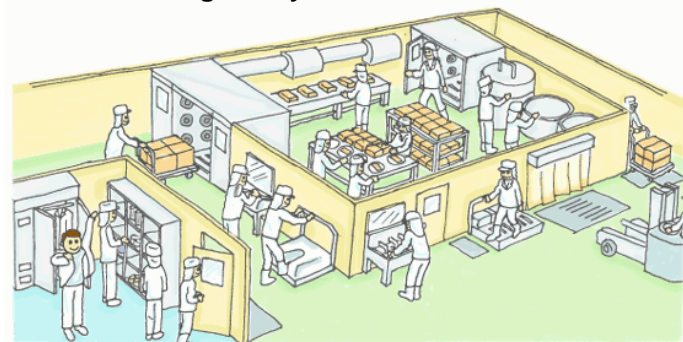
## Aims and Objectives

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:*

**mcpi** 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

# TECHNICAL COURSE

## Behavioral Good Manufacturing Practice and Good Documentation Practices
## 25 – 26 Feb 2019 (Mon – Tue)

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:**
Within the context of a GMP organization, we will examine:
• 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
• 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.

## Risk Assessment – Process, Quality and Compliance
## 25 – 26 March 2019 (Mon –Tue)

**Part 1 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:**
In this course you will learn about:
• Manufacturing considerations: what can go wrong, complex processes and systems
• GMP requirements
• An overview of the Quality Risk Management Process
• The Quality Risk Management Toolbox: what to use and when
• Conducting Process Risk Assessments

**Part 2 Risk Management for Quality and Compliance**
Within a Quality System (QS), the ability to make sound decisions based on facts and good science is key to being compliant with the regulatory requirements as well as being economical to the business. Whether it is tracking customer complaints, identifying 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.

# TECHNICAL COURSE

**Content:**
In this course you will learn about:
• GxP and Quality System principles and key requirements for corrective action and continuous improvement
• An overview of the Quality Risk Management QRM Process
• The QRM Toolbox: what to use and when
• Developing the Risk Registers
• Building risk portfolios on processes and products
• Putting the risk-based approach into practice

**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).

## Validation – A Roadmap to Getting It Right First Time
## 22 – 23 April 2019 (Mon –Tue)

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:**
You will learn about successful validation through:
• Validation Principles and International Regulations
• Validation Master Plans and Validation Documents
• 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.

## Internal Audits (2 Days) + Building A Successful Supplier QA Program (1 Day)

## Internal Audits – A Key to Your Quality System
## 18-19 Jun 2019 (Tue-Wed)

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:**
In this course you will learn about:
• **GxP and Quality Auditing**
o Critical role of quality audit in GMP compliance & improvement
o Regulatory standards and guidelines for quality auditing
o GxP requirements for internal audit programs
o Risk assessment as it applies to quality audit practices
o Documents, records & data for effective audits

o GxP audit schedules and the use of risk management in relation to prioritizing audits
o Six fundamental steps of auditing explained in detail (including tips on how to manage & facilitate audits in a constructive manner)

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

## Building A Successful Supplier QA Program – A Strategic Approach
## 20 Jun 2019 (Thur)

This course will provide you with an overview of the current regulatory requirements and expectations, along with a 6-step plan for managing your supplier quality so you can start reducing your supplier risks and improving your compliance.

**Content:**
You will get an appreciation for:
• Recent changes and enforcement trends in regulatory requirements for supplier management
• SOPs and records needed for compliance and to prove effective supplier qualification.
• 6-step planning for managing supplier quality
• Identifying supplier risk factors
• Establishing supplier risk ratings and evaluation criteria
• Structure and content of the Supplier Quality Agreement
• Reduced testing considerations
• When the supplier is part of your organization – Quality Agreements and the role of QA

**Participants:**
This course is designed for key quality and operational personnel (supervisors and managers) who are involved in supplier assurance implementation.

## Process Validation and Cleaning Validation
## 22 – 23 July 2019 (Mon – Tue)

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:**
In this course you will learn about:
• The GMP reasons for process validation.
• Strategies for process validation that complies with cGMPs
• Essentials of a process validation protocols
• Requirements for re-validation and give examples of situations that would give rise to it
• 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.

## Root Cause Analysis and CAPA
## 19 – 20 August 2019 (Mon – Tue)

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:**
In this course you will learn about:
• 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
• 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.

## Computer Systems for Regulated Environment and Data Integrity
## 23 – 25 Sept 2019 (Mon – Wed)

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:**
In this course you will learn about:
• Regulations and GAMP
o Definition of validation as applied to computerized systems
o Regulatory status and PIC/S
o Introduction to the Principles of CSV
o GAMP
• SDLC, Data Integrity and Risk Assessment
o System Life Cycle Approaches
o Development Models
o More Principles of CSV
o Mapping into Company Procedures
o Data Integrity
o Risk Assessment for Computerized Systems
• IT Infrastructure Qualification and Planning Phases
o IT Infrastructure Qualification / Validation
o Validation Master Planning
o Legacy System Validation
o Generating an Inventory of Systems
o Validation Protocol
o Spreadsheet Validation
o Validation Plan
o Cross Functional Plans

- Pre-Development Phases
o Requirements Definition
o Traceability
o Audits
o Design
- Development, Testing, Qualification and Use
o Coding
o Testing
o Qualification
o Use
o Decommissioning
- Electronic Records / Signatures – Cloud Computing
o Detailed interpretation of Part 11
o Implications for computerized systems in applying Electronic Records and Signatures
o Applying principles to new and existing Systems
o Reviewing Example Scenarios
o 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.

## Solid Dosage Manufacture Principles and Practices
## 07-08 Oct 2019 (Mon – Tue)

This course aims to introduce the GMP requirements for the formulation, scale-up and optimization of Finished Solid Dose Forms and 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.

**Content:**
In this course you will learn about:
- Granulation Technology and Control
- Blending and Milling Technology and Control
- Encapsulation Technology and Control
- Compression Technology and Control
- Coating Technology and Control
- Packaging 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.

# TECHNICAL COURSE

## Good Distribution Practices for the Regulated Industry
## 18-19 Nov 2019 (Mon-Tue)

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:**
In this course you will learn about:
• Relationship and Integration with GMP
• Understanding the Manufacturers requirements
• Understanding Risk Management in the Supply Chain
• 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.

## Supply Chain Management
## 20 Nov 2019 (Wed)

The provision of medicines and medical devices is a global business with active pharmaceutical ingredients, components and products being sourced using increasingly complex supply chains. Recognising the limitations of regulatory oversight by individual countries, the US Government passed the Drug Supply Chain Security Act (DSCSA) as legislation requiring a national track-and-trace system for medicines and electronic tracing of production through the supply chain; enforced by the FDA from 01 May 2015. The EU has also enhanced their GDP requirements, and these have been in place for some time. These actions reinforce the need for all personnel in your organisation's supply chain to understand their role and work to implement and maintain a robust and comprehensive quality system. The application of risk management principles within this system will help your organisation safeguard the quality and supply of product to your customers.

**Content:**
This course will provide you with a detailed understanding of the principles of responsible supply chain management and a framework for implementation and improvements. Specifically, you will learn the principles and practices of Quality and Risk Management Systems that you need to ensure the integrity of your supply chain, including:
• Management responsibility
• Regulatory and customer requirements: current and future
• Maintaining the cold chain
• Process control and validation
• Good documentation and record keeping practices
• Training
• Continual improvement

**Participants:**
This course is for you if you have a level of responsibility for the quality and/or integrity of your organisation's supply chain, specifically in relation to the procurement, distribution and logistics of sourcing and supplying finished pharmaceuticals, pharmaceutical ingredients, and medical devices.

# CAREER DEVELOPMENT COURSE

## Technical Writing
## 11 – 12 March 2019 (Mon – Tue)

This course involves your active participation, so you are encouraged to bring along a laptop or similar device for use during collaborative exercises and workshops. The course is delivered in a small group training environment and provides you with templates and opportunities to practice the tools and techniques being taught. There is also opportunity to discuss specific examples (such as investigation report, CAPA report, validation report) from your own workplace experience and seek advice.

**Content:**
In this course you will learn about good writing practices such as:
• Pruning the 'deadwood'
• Reducing complexity
• Using process mapping to structure documents
• Writing clear instructional documents (e.g. SOPs)
• Preparing data collection forms
• Writing concise reports

**Participants:**
This course is suitable for anyone who writes or reviews workplace documents, whether you are new to this or have been writing for years. It covers fundamental principles of good technical writing as well as current trends in, and tools for, SOP writing. The applicability of this course extends beyond the life sciences industries to any business where documents play a fundamental role.

## Leadership and Learning to Lead
## 08 – 09 April 2019 (Mon – Tue)

Until the late 1940's, most theories of leadership focused on the personal traits of leaders. Based on these theories, leadership depends on leaders' abilities and personality characteristics. Then up to the late 1960's, personal styles of leadership increased in prominence. From the late 1960's to the early 1980's, leadership studies became contingent based on a mix of leaders' and followers' traits and situations. Leadership theories of inspiration and transformation emerged in the late 1980's; they became prominent in the 1990's and developed into a significant concept at the turn of the 21st century. This course brings to you the fundamental nature and meaning of leadership as conceptualized in our contemporary world. Also, in modern organizations, we see that leaders do management tasks, whilst managers are expected to demonstrate leadership. So, what is the different between leadership and management? What are the different types of leadership? Can leadership skills be learnt? These are some of the key aspects that will be considered in this course.

**Content:**
In this course you will learn about:
• The nature and meaning of leadership
• Leading and Managing
• Patterns of leadership
• Full Range Leadership
• Perceived attributes as a leader
• Leadership and Human Values
• Leadership Development
• Learning to lead in specific scenarios

**Participants:**
This course is suitable for those are new to leadership roles or aspiring leaders, as well as for anyone who would like to increase their self-awareness and lead with increasing confidence.

# CAREER DEVELOPMENT COURSE

## Coaching, Counselling, and Mentoring
## 09 - 10 July 2019 (Tue - Wed)

The focus of coaching is usually task and performance; counselling uses listening and questioning to build self-awareness and self-confidence in the client, and the goal is to help the person deal with something difficult; the role of the mentor is to build capability, i.e. to help the learner discover their wisdom by encouraging them to work towards career goals or develop self-reliance. In sum, coaching, counselling, and mentoring are all about helping employees maximise their contribution at work. At the same time, these skills are part of the leader's job as a human developer. Manager or a good leader does not just focus on "getting things done", but also should have a mindset as a human developer. Helping employees to be able to complete their task optimally while helping the person personally to be able to achieve his/her "best self" is currently believed to be the genuine achievement of a leader.

**Content:**
In this course you will learn about:
• Coaching, Counselling, and Mentoring – the differences
• Characteristics and applications of each skill
• When and why to coach, counsel, and mentor
• How do we learn?
• Foundational skills for effective helping
• Coaching
o The GROW model
o Active listening
o Helpful questioning
o Reflection
o Case study
• Counselling
o Types of counselling
o Key features of a counselling relationship
o Effective counselling skills and techniques
o Counselling process
o Case study
• Mentoring
o Role of mentor
o Mentoring process
o Mentoring relationship - concerns and considerations
o Mentoring versus peer relationship
o Case study

**Participants:**
Managers, supervisors, team leaders, executives – anyone with an area they would like to develop.

## Effective Communication at the Workplace
## 02 Dec 2019 (Mon)

Effective workplace communication is the foundation of positive and cooperative working relationships. The objective of this course is to introduce trainees the basics of effective workplace communication. At the end of the course, trainees will be able to understand the benefits of effective workplace communication, recognize obstacles to effective communication, enhance communication skills, and communicate more effectively on the job.

**Content:**
In this course you will learn about:
• Define and understand communication
• Your communication style
• Communication process
• List and overcome the filters/barriers in a communication process

• The art of listening
• Verbal and non-verbal communication

**Participants:**
Anyone who wants to communicate more effectively at modern workplace

## Reasoning and Decision Making
## 03 Dec 2019 (Tue)

This course introduces trainees an integrated landscape of human thinking, reasoning, and decision-making process. You will also discover your problem solving and decision-making pattern and how to work more successfully with people who have different approaches with you. Throughout the course you will work on case studies from your workplace where you can immediately put the skills you learn into practice.

**Content:**
In this course you will learn about:
• Ways of Thinking
• Types of Thinking Process
• Types of Reasoning
• Satisficing
• Heuristics, Biases, and Anchoring Effect
• The Pitfalls of Fallacies
• Problem Structure
• Judgment and Decision Making
• Groupthink

**Participants:**
Anyone who wants to understand how to identify problems, generate solutions and implement them successfully.

## Managing Change – assessing the resistance and readiness
## 04 Dec 2019 (Wed)

This course introduces the meaning of change, the type of change, and the relevant models of change. In addition, the various problems associated with change, including resistance to change, as well as the affective, cognitive, and behavioral aspects of human beings during change are evaluated. With the recognized challenges associated of change, this course considers how leadership should intervene to sustain momentum, and how to assess the readiness to change to create buy-in during the change process.

**Content:**
In this course you will learn about:
• Your experiences with change
• Your perceptions to change
• Change Models
• Why does change need to be led?
• Types of human behaviors during change
• Resistance to change
• Readiness to change
• Factors for successful change

**Participants:**
Individuals who need to lead and manage change initiatives at work.

**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 RM2,200.00
29 – 14 days before commencement of course RM2,400.00
13 – 7 days before commencement of course RM2,600,00

**Non-MOPI Member – 2 days 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 days Course**
30 days before commencement of course USD $1,000.00
29 – 14 days before commencement of course USD $1,200.00
13 – 7 days before commencement of course USD $1,400.00

Registration fee is subjected to 6% SST

**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 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 days 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 days Course**
30 days before commencement of course USD $1,400.00
29 – 14 days before commencement of course USD $1,600.00
13 – 7 days before commencement of course USD $1,800.00

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

**MOPI Member – 1 day Course**
30 days before commencement of course RM1,300.00
29 – 14 days before commencement of course RM1,500.00
13 – 7 days before commencement of course RM1,700,00

**Non-MOPI Member – 1 day Course**
30 days before commencement of course RM1,600.00
29 – 14 days before commencement of course RM1,800.00
13 – 7 days before commencement of course RM2,000.00

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

**LOCATION MAP**
PULLMAN KUALA LUMPUR BANGSAR
No.1, Jalan Pantai Jaya, Tower 3
Kuala Lumpur 59200 - Malaysia
T. +6 (03) 2298 1888
F. +6 (03) 2298 1999



**Training Venue:**

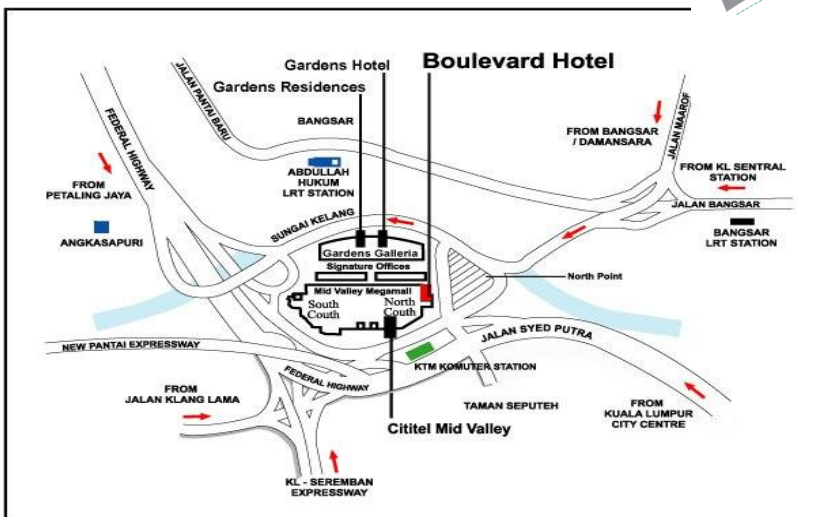**THE BOULEVARD**
**St Giles Premier Hotel**

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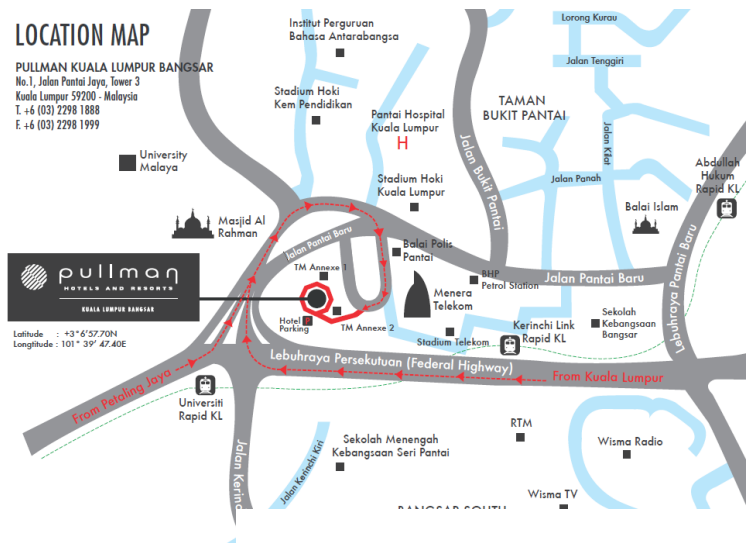


**Training Venue:**

**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!!!

**ADMINISTRATION DETAILS:**

# 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_____  2 Name_____

Designation_____  Designation_____

Email address _____  Email address _____

Contact Number _____  Contact Number _____

☐ Vegetarian  ☐ 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 | Career Development Courses |
|---|---|
| ☐ **Behavioral Good Manufacturing Practice and Good Documentation Practices** <br> 25 – 26 Feb 2019 (Mon – Tue) – 2 Days Course **(Boulevard Hotel)** | ☐ **Technical Writing** <br> 11 – 12 March 2019 (Mon – Tue) – 2 Days Course (Pullman Bangsar) |
| ☐ **Risk Assessment – Process, Quality and Compliance** <br> 25 – 26 March 2019 (Mon – Tue) – 2 Days Course **(Boulevard Hotel)** | ☐ **Leadership and Learning to Lead** <br> 08 – 09 April 2019 (Mon – Tue) - 2 Days Course (Pullman Bangsar) |
| ☐ **Validation – A Roadmap to Getting It Right First Time** <br> 22 – 23 April 2019 (Mon – Tue) – 2 Days Course **(Boulevard Hotel)** | ☐ **Coaching, Counselling, and Mentoring** <br> 09 - 10 July 2019 (Tue - Wed) – 2 Days Course (Pullman Bangsar) |
| ☐ **Internal Audits – A Key to Your Quality System** <br> 18-19 Jun 2019 (Tue-Wed) – 2 Days Course **(Boulevard Hotel)** <br><br> ☐ **Building A Successful Supplier QA Program – A Strategic Approach** <br> 20 Jun 2019 (Thur) – 1 Day Course **(Boulevard Hotel)** | ☐ **Train the Trainer** <br> 21-22 Oct 2019 (Mon-Tue) – 2 Days Course **(Boulevard Hotel)** |
| ☐ **Process Validation and Cleaning Validation** <br> 22 – 23 July 2019 (Mon – Tue) – 2 Days Course **(Boulevard Hotel)** | ☐ **Effective Communication at the Workplace** <br> 02 Dec 2019 (Mon) – 1 Day Course (Pullman Bangsar) |
| ☐ **Root Cause Analysis and CAPA** <br> 19 – 20 August 2019 (Mon – Tue) – 2 Days Course **(Boulevard Hotel)** | ☐ **Reasoning and Decision Making** <br> 03 Dec 2019 (Tue) – 1 Day Course (Pullman Bangsar) |
| ☐ **Computer Systems for Regulated Environment and Data Integrity** <br> 23 – 25 Sept 2019 (Mon – Wed) – 3 Days Course **(Boulevard Hotel)** | ☐ **Managing Change – assessing the resistance and readiness** <br> 04 Dec 2019 (Wed) – 1 Day Course (Pullman Bangsar) |
| ☐ **Solid Dosage Manufacture Principles and Practices** <br> 07-08 Oct 2019 (Mon – Tue) – 2 Days Course (Pullman Bangsar) | |
| ☐ **Good Distribution Practices for the Regulated Industry** <br> 18-19 Nov 2019 (Mon- Tue) – 2 Days Course **(Boulevard Hotel)** <br><br> ☐ **Supply Chain Management** <br> 20 Nov 2019 (Wed) – 1 Day 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 ……………………. |