

# INTERNATIONAL GOOD MANUFACTURING PRACTICE TRAINING PROGRAM



YEAR 2015

The course training program consists of 9 principal modules and 7 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.



Organised by:



Malaysian Organisation of Pharmaceutical Industries

Presenter:



Endorsed by:



National Pharmaceutical Control Bureau, MOH

- ❖ Certificates endorsed by the National Pharmaceutical Control Bureau, Ministry of Health, Malaysia will be awarded to participants upon successful completion of each module.

For further details please visit [www.mopi.org.my](http://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 (9 – 11 February 2015)

**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
- Day 2     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  
            PM ► Equipment Management

## Module 2 – Validation Principles and Practices (16 – 18 March 2015)

**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 (20 – 22 April 2015)

**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  
            PM ► Microbiological Aspects of Manufacturing
- Day 2     AM ► Cleaning and Sanitation  
            PM ► HVAC and Controlled Environments – control & qualification
- Day 3     AM ► Environmental Monitoring Programs  
            PM ► Control of Water Systems

## Module 5 - Good (Quality Control) Laboratory Practices (G(QC)LPs) (8 – 10 June 2015)

**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

# FUNDAMENTAL COURSE OUTLINE

## Module 6 – Compliance with GMP for the Pharmaceutical Engineer (28 – 30 July 2015)

**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 August 2015)

**Aim:** To provide an introduction to the requirements of Good Distribution Practices (GDPs) for the therapeutic and medical device industries.

- 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  
PM ► Validation of the supply chain

## Module 9 - Solid Dose Manufacture Principles and Practices (24 – 26 November 2015)

**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

## Regulatory Focus for Medical Devices Manufacture (14 – 16 December 2015)

**Aim:** To provide the essential concepts of regulations and codes of practice that governs the manufacture of medical devices both nationally and internationally. To develop a broad understanding of scope of the Good Manufacturing Practices and quality system elements applicable to devices.

- Day 1 AM ► Understanding the application of QSIT, 21CFRpart820 and ISO13485  
PM ► Introduction to Supplier Management and Control
- Day 2 AM ► Manufacturing Controls and SPC  
PM ► Medical Device Validation Practices
- Day 3 AM ► Introduction to Design Controls  
PM ► Application of RCA techniques and CAPA System

# 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.*

**NEW**

## Computer Systems Validation And Cloud Computing (6 – 8 April 2015)

**Aim:** Computer Systems are an established and integral part of management in modern Development, Validation, Manufacturing, Logistics, Quality and Administration for all Life Sciences organisations, e.g. pharmaceutical, medical device, contract laboratories, research organisations (CROs), logistics providers (3PL and 4PL), etc. This field of computer technology continues to develop at a considerable speed. Each user must ensure that their software and systems have been developed to best engineering practices in a quality assured manner to comply with Regulatory and Good Practice (GxP) requirements of the regulators from around the globe.

- Day 1**
- AM ► Understand the types of, and elements of System Development Life Cycles
  - AM ► Understand how Computer systems are regulated in the TGA / PIC/s and FDA regulatory environments
  - PM ► Understand what is Medical Device Software and how to classify it
- Day 2**
- AM ► Recognize the compliance, risk, and regulatory compliance consequences of Creating Mobile Medical devices and Medical Device Software
  - PM ► Understand how standards are used in the Validation and Verification for Medical Device Software
    - IEC 62304
    - ISO 13485
    - ISO 14971
    - Application of industry guidance's, e.g. GAMP5 or TIR 36
  - PM ► Industry guidance – GAMP5 and the cloud computing model
- Day 3**
- AM ► • How to do vendor qualification of cloud computing suppliers?
  - PM ► • How do you develop, test and implement in a cloud environment?
  - PM ► • Consideration of the legal issues, specifically those around any data you might collect, store and process on the cloud.

## Advanced Process Validation and Cleaning Validation (11 – 13 May 2015)

**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

## Module 4 – Risk Management in Pharmaceutical Operations (ICHQ9) (25 – 27 May 2015)

**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

# ADVANCED COURSE OUTLINE

## Product Quality Review / QMS Metrics and Practical Statistics (11 – 13 August 2015)

**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  
          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

## Good Aseptic Practices And Sterile Products (7 – 9 September 2015)

**NEW**

**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

## Roles and Responsibilities of the Qualified/Authorised Person (21 – 23 September 2015)

**NEW**

**Aim:** This subject is designed to provide the qualified (or authorised) person with key requirements for being able to release finished product (and APIs) for supply. It will include workshops to provide practical application of the key requirements. There will also be a number of tools provided to assist in the release for supply process. It will focus on Annex 16 of the EU GMP Guide, the EMA Template for the Qualified Person and the Guidance on Release for Supply by the TGA.

- Day 1    Examination and interpretation of EU and PIC/S GMP Regulations and Requirements
- Day 2    Release for Supply – theory, tools and workshops, including use of risk management
- Day 3    Authorised/Qualified Person and the Supply Chain

## Practical Stability Study Application to Pharmaceuticals (5 – 7 October 2015)

**NEW**

**Aim:** This subject is designed to provide the quality professional with the key requirements for 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 ongoing stability trials.

- Day 1    AM ► Stability testing of new drug substances and products (ICH Q1A)  
          PM ► Stability testing of new dosage forms (ICH Q1B)
- Day 2    AM ► Bracketing and matrixing designs for new drug substances and products (ICH Q1D)  
          PM ► Evaluation of stability data (ICH Q1E)
- Day 3    AM ► Registration applications in climatic zones III and IV (ICH Q1F)  
          PM ► FDA guideline on container/closure integrity

## Module 8 – GxP and Quality Auditing Practices (19 – 21 October 2015)

**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

## 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.

## Fee per participant per module:

*(The fee includes course materials, lunch and refreshments)*

### MOPI Member

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

### Non-MOPI Member

30 days before commencement of course RM2,800.00

29 – 14 days before commencement of course RM3,000.00

13 – 7 days before commencement of course RM3,200.00

### Foreign Participant

30 days before commencement of course USD \$1,200.00

29 – 14 days before commencement of course USD \$1,400.00

13 – 7 days before commencement of course USD \$1,600.00

## 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](http://www.cititelmidvalley.com)

**Eastin Hotel, Petaling Jaya** Tel: 603-7665 1111

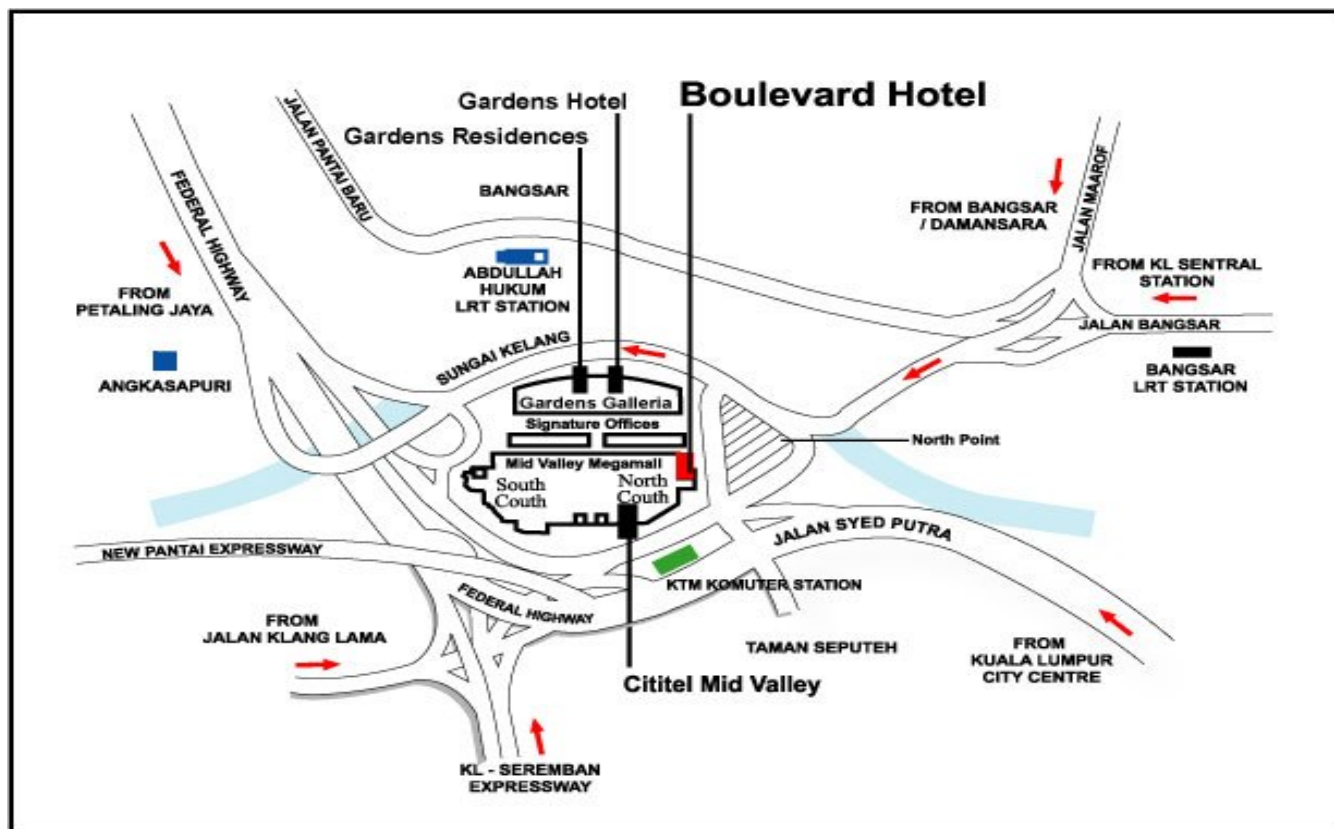
Website: [www.eastin.com](http://www.eastin.com)

**Crystal Crown Hotel, Petaling Jaya** Tel : 603-7958 4422

Website: [www.crystalcrown.com.my](http://www.crystalcrown.com.my)

**Armada PJ Hotel** Tel: 603-7954 6888

Website: [www.armada.com.my](http://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](http://www.StGiles-Hotels.com)

## BOOK YOUR SEAT NOW!!!

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

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[www.mopi.org.my](http://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

2 Name

Designation

Designation

Email address

Email address

☐ Vegetarian

☐ Vegetarian

Enclosed cheque/bank draft No. for RM being payment for participant(s) made in favour of the "Malaysian Organisation of Pharmaceutical Industries".

Registration Submitted by:

Name

Designation

E-mail

Company Stamp (with Address, Telephone & Fax Number)

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

MOPI Member

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

Non-MOPI Member

30 days before commencement of course RM2,800.00  
29 – 14 days before commencement of course RM3,000.00  
13 – 7 days before commencement of course RM3,200.00

Foreign Participant

30 days before commencement of course USD \$1,200.00  
29 – 14 days before commencement of course USD \$1,400.00  
13 – 7 days before commencement of course USD \$1,600.00

Office Use Only

Registration Accepted on

Payment Accepted on