

INTERNATIONAL GOOD MANUFACTURING PRACTICE TRAINING PROGRAM



YEAR 2012

Training Grant is available under HRDF SBL Scheme

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.

Trainers

This course has been developed by SeerPharma Pty Ltd and trainers are provided by SeerPharma Pty Ltd, Australia and 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.

Jointly Organised by:



Malaysian Organisation of Pharmaceutical Industries

Presenter:



SeerPharma®
CONFIDENCE IN COMPLIANCE



National Pharmaceutical Control Bureau, MOH

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

COURSE OUTLINE

Module 1 – International Good Manufacturing Practices, Quality Management Systems and GMP for Pharmaceutical Operations (13 – 15 February 2012)

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** ▶ *QA Principles & International GMPs*
 - ▶ *Quality Management, Quality Assurance & Quality Control*
- Day 2** ▶ *Key Quality Assurance Systems and GMP Responsibilities for Managers & Supervisors*
 - ▶ *GMP Principles for Manufacturing Operations*
- Day 3** ▶ *GMP Principles for Packaging Operations*
 - ▶ *Equipment Management*

Module 2 – Validation Principles and Practices (19 – 21 March 2012)

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** ▶ *Validation Principles & International Regulations*
 - ▶ *Validation Master Plans and Validation Documents*
 - ▶ *Equipment Qualification and Commissioning*
- Day 2** ▶ *Process Validation*
 - ▶ *Compiling URS against FDS documents*
 - ▶ *Preparing DQ, IQ, OQ and PQ protocols*
- Day 3** ▶ *Protocol Execution*
 - ▶ *Deviation Management*
 - ▶ *Final Summary Report*

Module 3 – Contamination Control (23 – 25 April 2012)

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

- Day 1** ▶ *Introduction to Contamination Control*
 - ▶ *Microbiological Aspects of Manufacturing*
- Day 2** ▶ *Cleaning and Sanitation*
 - ▶ *HVAC and Controlled Environments – control & qualification*
- Day 3** ▶ *Environmental Monitoring Programs*
 - ▶ *Control of Water Systems*

Module 4 – Risk Management in Pharmaceutical Operations (ICHQ9) (22 – 24 May 2012)

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** ▶ *Principles of Risk Management and ICH Q9*
 - ▶ *Risk Management Techniques - FMEA, FTA, HACCP*
- Day 2** ▶ *Risk Management to Compliance and Quality Assurance Management*
 - ▶ *Applying Risk Management in Compliance*
- Day 3** ▶ *Risk Management Principles in Validation Programs*
 - ▶ *Applying Risk Management in Validation*

Module 5 - Good (Quality Control) Laboratory Practices (G(QC)LPs) (11 – 13 June 2012)

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** ▶ *Introduction to Good (Quality Control) Laboratory Practices (GLPs)*
 - ▶ *Qualification and Calibration of Laboratory Equipment*
- Day 2** ▶ *Analytical Method Validation*
 - ▶ *Biological assays Validation and Control*
 - ▶ *Basic Statistics for Quality Control Laboratories*
- Day 3** ▶ *Pharmaceutical Sampling Plan*
 - ▶ *Pharmaceutical Stability Programs*

COURSE OUTLINE

Module 6 – Compliance with GMP for the Pharmaceutical Engineer (16 – 18 July 2012)

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** ▶ *Facility Layout and Design Principles*
 - ▶ *Design and Construction of Critical Utilities: inc. Water, Gases and Steam*
- Day 2** ▶ *Water Systems: Design, Control & Validation*
 - ▶ *HVAC: Design, Control & Validation*
- Day 3** ▶ *Qualification of Processing Equipment*
 - ▶ *Planned Preventative Maintenance and Calibration Data Base*

Module 7 - Solid Dose Manufacture Principles and Practices (18 – 20 September 2012)

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** ▶ *QA/GMPs Over Finished Dose Forms (FDF)*
 - ▶ *Granulation Technology & Control*
- Day 2** ▶ *Blending and Milling Technology & Control*
 - ▶ *Encapsulation Technology and Control*
- Day 3** ▶ *Compression Technology and Control*
 - ▶ *Coating Technology & Control*

Module 8 – Liquid and Cream Manufacture Principles and Practices (22 – 24 October 2012)

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 liquids and creams formulations.

- Day 1** ▶ *QA/GMPs Over Liquid and Cream Finished Dose Forms (FDF)*
 - ▶ *Introduction to Oral Liquid Preparation Formulation*
- Day 2** ▶ *Introduction to Topical Preparation Formulation*
 - ▶ *Manufacture and Packaging of Cream and Ointments*
- Day 3** ▶ *Labelling and Packaging Liquids, Creams and Ointments*
 - ▶ *Case Study – Validation Plans for a new Topical Products*

Module 9 – GxP and Quality Auditing Practices (19 – 21 November 2012)

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

COURSE OUTLINE

Behavioural GMP: Minimizing Human Error (5 – 7 March 2012)

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 and failure investigation. The course also provides an introduction on managing deviations for regulated industries. This includes the application of strategies and steps involved, as well as documentation and reporting, all focused towards continuous improvement.

- Day 1** ▶ *Practices basis for GMP rules – why compliance to GMP is critical*
 - ▶ *Behavioural GMP – What it is, and how does it work in practices*
 - ▶ *Sources of human error in manufacturing*
- Day 2** ▶ *Role of the QA, Compliance and Production in problem solving and continuous improvement*
 - ▶ *Identify and apply tools used to assist with failure investigation and root cause analysis (RCA)*
 - ▶ *Classify deviations based on risk to compliance and product integrity*
- Day 3** ▶ *Essential steps and investigation strategies in managing deviations*
 - ▶ *Assess whether a deviation merits correction or escalation to CAPA*
 - ▶ *Documentation and reporting*



NEW

Deviations, CAPAs and Commitment Tracking for the Regulated International Therapeutic Markets (2 – 4 July 2012)

Aim: To provide advanced learning on the principles of incidents, deviations and CAPAs and understanding of international regulators expectations for management and control in accordance to the regulations and Codes of Practice that govern the manufacture of therapeutic goods both nationally and internationally.

To incorporate the principles of ICH Q9 and Q10 into the management of deviations and CAPAs and to identify practical approaches to incorporate these principles into a compliant QMS.

- Day 1** ▶ *Definition of incidents, deviations, correction, corrective action and preventive action*
 - ▶ *Integration of CAPA with risk management and key quality system elements*
 - ▶ *Appropriate and compliant escalation to management*
- Day 2** ▶ *Effective investigations*
- Day 3** ▶ *Documentation of CAPAs*
 - ▶ *Commitment tracking and CAPA closure*
 - ▶ *Trending and reviewing deviations and CAPAs*

Good Distribution Practices (GDP) for the Regulated Industry (8 – 10 May 2012)

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

- Day 1** ▶ *Relationship and integration with GMP*
 - ▶ *Understanding the manufacturer's requirements*
- Day 2** ▶ *Risk management and continuous improvement*
 - ▶ *Understanding GDPs for therapeutic products and Devices*
 - ▶ *Understanding GDPs for medical devices*
- Day 3** ▶ *Cold Chain Management*
 - ▶ *Validation of the supply chain*

COURSE OUTLINE



NEW

Advanced Process Validation and Cleaning Validation (3 – 5 September 2012)

Aim: To provide advanced learning on the principles of incidents, deviations and CAPAs and understanding of international regulators expectations for management and control in accordance to the regulations and Codes of Practice that govern the manufacture of therapeutic goods both nationally and internationally.

To incorporate the principles of ICH Q9 and Q10 into the management of deviations and CAPAs and to identify practical approaches to incorporate these principles into a compliant QMS.

Day 1 ► PIC/s Annex 1 and FDA Guidance on Process Validation

- Room classification and ongoing re-validation
- Media fill trial data interpretation
- Ongoing re-validation
- Management Review

Day 2 ► Solid-dose validation (tablets, capsules and powder)

- Aseptic liquid and powders filling validation (vials and syringes)
- Validating the freeze drying process
- Process capability analysis for process validation

Day 3 ► Worst-case scenarios for cleaning validation studies

- The process equipment train
- Recovery studies, swabbing and rinse studies
- Selectivity, LOD and LOQ

Introduction to Computer Validation: Principles and Practice (8 – 10 October 2012)

Aim: To provide an introduction to the data management systems with product and GMP impact (MES, LIMS, EDMS, ERP, MRP), and to develop a broad understanding of the scope of Good Automated Manufacturing Practices and Quality Management Systems applicable to drugs, devices and biologics.

Day 1 ► Regulations and GAMP

- System Development Life Cycle and Risk Assessment

Day 2 ► Network Qualification and Planning Phases

- Pre Development Phases

Day 3 ► Development, Testing, Qualification and Use

- 21 CFR Part 11

Compliance for the Biopharmaceutical Industry (3 – 5 December 2012)

Aim: To provide an introduction to the basic requirements of aseptic biopharmaceutical manufacture.

Day 1 ► Understanding basic concepts of “fill and finish”

- Regulatory requirements for QA/QC for biopharmaceuticals

Day 2 ► HVAC and critical facility design requirements

- Lyophilization for biopharmaceuticals
- Validation considerations for product analysis

Day 3 ► QA/QC for biopharmaceutical product release

- Quality Management requirements for biopharmaceuticals

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 course:

(The fee includes course materials, lunch and refreshments)

MOPI Member

30 days before commencement of course RM2,450.00
29 – 14 days before commencement of course RM2,650.00
13 – 7 days before commencement of course RM2,850.00

Non-MOPI Member

30 days before commencement of course RM2,750.00
29 – 14 days before commencement of course RM2,950.00
13 – 7 days before commencement of course RM3,150.00

Foreign Participant

30 days before commencement of course USD \$1,100.00
29 – 14 days before commencement of course USD \$1,300.00
13 – 7 days before commencement of course USD \$1,500.00

Time:

9.00 am – 5.00 pm

Venue:

Boulevard Hotel
Mid Valley City, Lingkaran Syed Putra,
59200 Kuala Lumpur, Malaysia
Tel: 603-22958000
Website: www.blvhotel.com

Boulevard Hotel Room Rates:

Single with breakfast RM275++
Twin Sharing with breakfast RM295++
Extra bed with breakfast RM70++

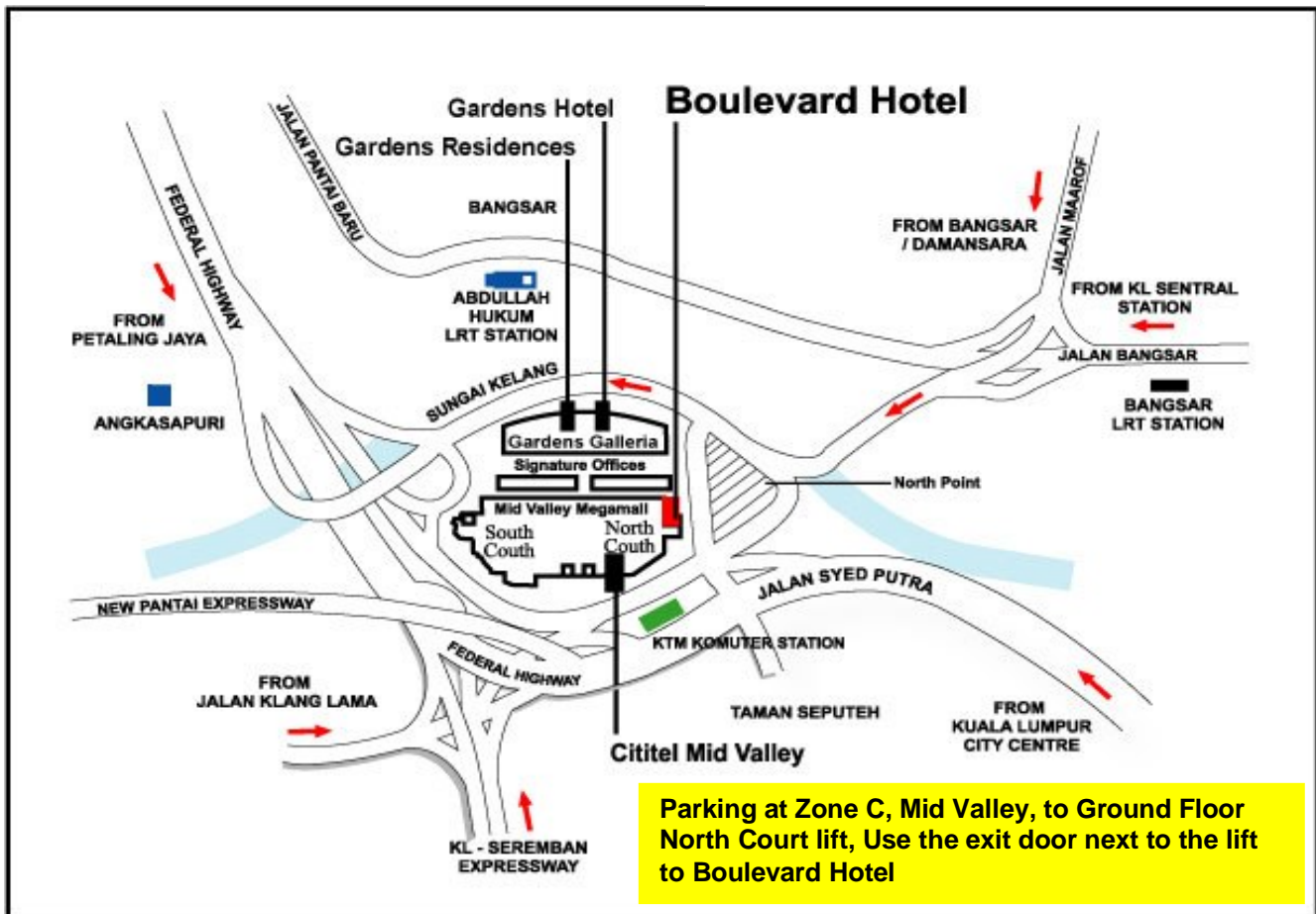
Alternative Hotel :

Cititel Mid Valley
Tel : 603-2296 1188
E-mail: resvn@cititelmidvalley.com

Crystal Crown Hotel, Petaling Jaya

Tel : 603-7958 4422
E-mail: cchpj@crystalcrown.com.my

**Module 1 will be held at
Eastin Hotel, Petaling Jaya,
Tel: 603-7665 1111
E-mail: info.pj@eastin.com
Website: www.eastin.com*



BOOK YOUR SEAT NOW!!!

For further enquiries, please contact:

Mike/Janet, MOPI

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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 company 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

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 _____

MOPI Member Non-Member Foreign

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:	
<input type="checkbox"/> Module 1 International Good Manufacturing Practices Quality Management Systems and GMP for Pharmaceutical Operations 13 – 15 February 2012 (Mon – Weds) at Eastin Hotel*	<input type="checkbox"/> Module 9 GxP and Quality Auditing Practices 19 – 21 November 2012 (Mon – Weds) at Boulevard Hotel
<input type="checkbox"/> Module 2 Validation Principles and Practices 19 – 21 March 2012 (Mon – Weds) at Boulevard Hotel	<input type="checkbox"/> Behavioural GMP: Minimizing Human Error 5 – 7 March 2012 (Mon – Weds) at Boulevard Hotel
<input type="checkbox"/> Module 3 Contamination Control 23 – 25 April 2012 (Mon – Weds) at Boulevard Hotel	<input type="checkbox"/> Deviations, CAPAs and Commitment Tracking for the Regulated International Therapeutic Markets 2 – 4 July 2012 (Mon – Weds) at Boulevard Hotel
<input type="checkbox"/> Module 4 Risk Management in Pharmaceutical Operations (ICHQ9) 22 – 24 May 2012 (Tue - Thu) at Boulevard Hotel	<input type="checkbox"/> Good Distribution Practices (GDP) for the Regulated Industry 8 – 10 May 2012 (Tue -Thu) at Boulevard Hotel
<input type="checkbox"/> Module 5 Good Quality Control Laboratory Practices (G(QC)LPs) 11 – 13 June 2012 (Mon – Weds) at Boulevard Hotel	<input type="checkbox"/> Advanced Process Validation and Cleaning Validation 3 – 5 September 2012 (Mon – Weds) at Boulevard Hotel
<input type="checkbox"/> Module 6 Compliance with GMP for the Pharmaceutical Engineer 16 – 18 July 2012 (Mon – Weds) at Boulevard Hotel	<input type="checkbox"/> Introduction to Computer System Validation: Principles and Practices 8 – 10 October 2012 (Mon – Weds) at Boulevard Hotel
<input type="checkbox"/> Module 7 Solid Dose Manufacture Principles and Practices 18 – 20 September (Tue - Thu) at Boulevard Hotel	<input type="checkbox"/> Compliance for the Biopharmaceutical Industry 3 – 5 December 2012 (Mon – Weds) at Boulevard Hotel
<input type="checkbox"/> Module 8 Liquid and Cream Manufacture Principles and Practices 22 – 24 October 2012 (Mon – Weds) at 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 _____

Company Stamp (with Address, Telephone & Fax Number)



Office Use Only

Registration Accepted on

Payment Accepted on