Quality Assurance and GMP Training Program

Online, Instructor-Led Training And Physical Training

YEAR 2024

The training program consists of 8 on-line courses and 8 physical courses. These courses cover the essential principles of Quality Assurance (QA), Good Manufacturing Practice (GMP), Validations, Supply chain Management, Medical Devices etc. Participants are expected to gain an understanding of current requirements and future international trends within the regulated industry. The courses consist of a lively combination of case study workshops and group presentation. The training has been adapted for delivery in an online, virtual

Trainers

The courses are both developed and delivered by SeerPharma. All SeerPharma trainers have academic qualification with at least a bachelor's degree, as well as a number of years of industry experience in Quality Management or Production Management in major and multinational companies. They have worked with various regulatory standards including the FDA, EU, PIC/S, TGA and ISO. The trainer for each course will have specific expertise in that subject matter.

SeerPharma is Asia-Pacific's leading premier training & consulting group for Quality and GMP compliance. Offering integrated consulting, training and software from MasterControl to pharmaceutical and medical device companies in the Asia Pacific region to help meet

Aims and Objectives

The aim of the training program is to provide conceptual understanding of GMP, as well as to introduce the various current practices for implementation at the workplace.

Who Should Attend?

Key personnel in GMP & Quality Management, Managers, Engineers, Executives, Quality Practitioners, and any member of the pharmaceutical and related industry. Those from Research and Development, Quality and Production will find this program relevant and beneficial to their job function as well.

- E-Certificates endorsed by the National Pharmaceutical Regulatory Agency, Ministry of Health, Malaysia will be awarded to participants upon successful completion of each module.

Organised by:

MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES

Presented by:

SeerPharma® CONFIDENCE IN COMPLIANCE

Endorsed by:

National Pharmaceutical Regulatory Agency, MOH

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

Course Outline

GMP – Essentials to Know (23 – 24 January 2024)

If you hold responsibilities related to pharmaceutical product quality or GMP compliance, it is crucial to grasp both your legal and ethical obligations. Achieving a thorough understanding of these obligations necessitates familiarity with the regulatory environment, the Pharmaceutical Quality System's intent and requirements, and the current Good Manufacturing Practice as outlined by PIC/S. This course is designed to assist individuals in GMP-regulated organizations by guiding them through the various stipulations of the current PIC/S Guide GMP Part I. Through the utilization of case studies and examples derived from industry and consulting experiences, participants will gain insights into these requirements and how to implement them in their manufacturing environments. The emphasis will be on ensuring product quality and preventing adulteration and misbranding.

Content

Day 1:

- Overview of the Global Regulatory Environment
  - Drug product lifecycle - development, manufacturing, and distribution
  - Types of Quality System versus applicable GMP Standard(s)
  - The meaning of GMP
  - Compliance Focus and Product Identity-Safety-Purity-Efficacy
  - Fundamental Requirements for GMP

- GMP Basics:
  - Personnel and Training
  - Premises/Facility Control
  - Production Areas
  - Storage Areas
  - Quality Control Areas
  - Ancillary Areas and supporting systems
  - Equipment Management
  - Production and Packaging Control
  - Validation
  - Quality Control Functions

Day 2:

- Good Documentation Practices
  - GMP requirements on ‘Documentation’
  - What is Good Documentation Practice (GDocP)?
  - The significance of GDocP in ensuring data integrity
  - Common do’s and dont’s of GDocP
  - Tips on designing SOPs, WIs, and Forms
- A Quality Systems Approach to GMP
  - What is a Pharmaceutical Quality System?
  - Quality Risk Management
  - Key Quality System Elements for Continual Improvement
  - Deviation Handling
  - Complaints and Recalls
  - Corrective and Preventive Action
  - Change Management
  - Product Quality Review

<u>Participants</u>

This course has been designed to provide personnel new to the pharmaceutical industry with a good understanding of PIC/S GMP and Pharmaceutical Quality System requirements. It also applies to experienced GMP staff looking to update for compliance in the current PIC/S GMP, companies that require GMP certification (new/renewal) in PIC/S, or manufacturers who do secondary packaging of medicinal products.

Course Outline

Quality Risk Management Training (6 - 7 February 2024)

Principles of Quality Risk Management (QRM) mandate the assessment of risks to patient safety and product quality grounded in scientific knowledge, data, and experience. Regulatory expectations dictate that QRM is intricately integrated into the core of the Quality Management System (QMS), employing a lifecycle approach to implement both formal and informal risk tools. These tools align with the elements outlined in ICH Q9, encompassing risk assessment, risk control, risk review, communication of identified risks, and acceptance of residual risks.

This advanced and interactive training utilizes case studies to offer practical tools and techniques, enabling participants to address current challenges through the application of QRM principles. The program also provides hands-on experience in preparing for and facilitating risk assessments.

Contents:

Day 1 Risk Management for 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 non-conforming materials 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 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.

- Quality Risk Management Framework
- The goal of risk management in managing GMP compliance
- The key systems – how they integrate and where risk assessment can be applied to appropriate sub systems, such as
  - Auditing
  - Change Control
  - Product Complaints and ADEs
  - Deviation Investigation
  - CAPA

Day 2 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 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.

- Manufacturing considerations: what can go wrong, complex processes and systems
- Overview of the Quality Risk Management Process
- GMP requirements for risk assessments
- The Quality Risk Management Toolbox: what to use and when
- Conducting Process Risk Assessments, considering:
  - Preliminary Hazard Analysis (PHA)
  - Hazard Analysis and Critical Control Points (HACCP)
  - Failure Mode and Effects Analysis (FMEA)

<u>Participants:</u>

This course is designed for both personnel new to process 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 quality compliance and/or manufacturing processes.

Course Outline

Qualification and Validation – Getting the essentials for implementation
(5 - 6 March 2024)

This training course has been crafted to enhance your comprehension of the present criteria governing the design, execution, assessment, and reporting of equipment qualification and validation studies. Explore how adopting a science and risk-based approach to validation can not only drive business efficiency but also elevate reliability, fortify processes, and ensure product quality robustly. Embracing this methodology can significantly contribute tangible value to your business, simultaneously enhancing safeguards for patients. Gain insights into the latest industry standards and best practices to stay at the forefront of ensuring the efficacy and integrity of your processes.

Content

Day 1: Introduction to Validation Principles and Application of Quality Risk Management (QRM)

- Fundamental Principles of Validation and Qualification
  - Explore regulatory requirements and the scope of Validation and Qualification (Q&V).
  - Understand the sequence and stages involved in Q&V processes.
  - Validation Planning
  - Regulatory requirements of Q&V
  - Scope of Q&V
  - Sequence and stages of Q&V
- Validation Planning
  - What is in a validation program?- Delve into the components of a validation program.
  - Validation master plans (VMP), project plans (VPP) and other documents
  - Apply Quality Risk Management (QRM) principles to validation, emphasizing a science and risk-based approach.
  - Critical and non-critical systems Distinguish between critical and non-critical systems
  - Utilize Failure Mode and Effects Analysis (FMEA) and Hazard Analysis and Critical Control Points (HACCP) for validation planning.

Day 2 Design, execution, assessment, and reporting of Equipment Qualification

- Equipment Qualification (The key components expected for effective equipment qualification)
  - Identify key components crucial for effective equipment qualification.
  - Discuss User Requirement Specifications (URS) and the stages of Qualification, addressing GMP requirements for Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).
  - Explore the new paradigm for equipment qualification and the application of risk management.
  - Cover protocol execution, evaluation, and reporting, along with managing deficiencies.
- Maintaining a Validated State
  - Understand change management strategies to effectively ensure patient safety and meet regulatory requirements.
  - Explore the validation lifecycle and continuous verification processes.
  - Discuss routine re-validation schedules and periodic review for sustained compliance and performance optimization.

Participants

This course has been designed to provide personnel new to the Q&V principles and practices. It also applies to . It also applies to experienced GMP staff looking to update for compliance in the current Q&V requirements or practices.

Course Outline

Deviations and Investigation Management- How to ensure CAPA Efficiency
(23 - 24 April 2024)

As a pharmaceutical or biotech or medical device company, the obligation to investigate the causes of quality failures or production issues is paramount. Yet, regulatory inspections often reveal a common finding: "failure to thoroughly investigate." This course is designed to equip you with the skills to conduct meticulous failure investigations and proficiently perform root cause analyses. Real-life scenarios from the industry will be employed to provide practical insights. The course emphasizes that the more structured your investigation process, the more effective it will be.

Additionally, the program delves into the strategic utilization of the Corrective and Preventive Action (CAPA) system. Beyond meeting regulatory requirements, this system is explored as a tool to establish a closed-loop mechanism for problem-solving. By integrating CAPA effectively, you can not only address immediate concerns but also institute a proactive approach to minimize product quality issues and enhance overall compliance. Practical examples and case studies will be employed to illustrate the tangible benefits of implementing a robust CAPA system.

Content

Day 1: Root Cause Analysis

- General principles of 8D problem analysis methodology
- Comparison of 8D with 6-sigma DMAIC and PDCA
- Concept of variation in a problem-solving process
- Key steps of an 8D problem analysis methodology
- Common methods used for problem solving
- Develop an 8D report for an identified problem

Day 2: CAPA

- Regulatory background of CAPA
- Definition of Corrective Action and Preventive Action (CAPA)
- Integration of CAPA with key quality system elements
- Link the concept of risk with CAPA management
- Understand the SMART principles of CAPA
- Elements of a compliant and effective CAPA System
- Develop a CAPA plan from the outcome of RCA using 8D approach

Participants

This course has been designed for all those who are involved in failure investigations and corrective actions. You will benefit from this program whether you are new to formal problem solving and CAPA or are a more experienced professional. It is expected that you are familiar with regulatory GMP and Quality Management System requirements within the pharmaceutical and/or medical device industries.

Course Outline

Good Writing Practice – How to improve your SOP writing, investigation reports, CAPA Reports, Summary Reports (7 - 8 May 2024)

Revised

Well writtenSummary reports, investigation reports, documents, technical SOPs help employees understand information the first time they read or hear it. Who doesn't want to improve compliance, shorten induction time and reduce deviations caused by confusing procedures? If you are asked to write SOPs as part of your job role, would you like some straightforward guidance on where to start and how to write?

Are your documents caught in a cycle of endless revisions, taking months to gain approval after the review date? Do you find yourself slogging through convoluted language to extract the information you need? Are issues of Data Integrity causing challenges? Are you grappling with writer's block? This training course has been meticulously crafted to address these concerns and enhance your skills in crafting clear and effective Standard Operating Procedures (SOPs), data collection forms, and various other documents.

By the end of the course, participants will have the ability to:

- Draft SOPs that offer unequivocal instructions.
- Develop data collection forms that prioritize Data Integrity.
- Create documents that are submission-ready upon the first review.
- Produce reports containing the precise and pertinent information needed.

Ultimately, the course aims to instill confidence in writing SOPs, data collection forms, and other documentation that is not only easily comprehensible but also readily applicable.

Content

Day 1

- 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

Day 2:

- Writing Effective Documents
- Identify the proper sequence of actions
- Employ consistency from document to document
- Construct an SOP in the appropriate format
- Hands-on Writing Sessions
  - Using skills attained, create and/or edit SOP documents
  - Write Investigation Reports (Deviations, CAPA, OOS reports)
  - Design a SMART data Collection Form
  - Effective writing of Summary Reports (Validation, Technical 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.

Course Outline

Computer Systems for Regulated Environment (11 - 12 June 2024)

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 organisation 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

Day 1:

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

Day 2:

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

<u>Participants</u>

You will benefit from this course if you are a key Quality, IT or Operational Subject Matter Expert (SME) or Manager likely to be involved in using, validating, approving, or purchasing computer systems.

Course Outline

Process Validation and application of Statistics in Validation
(25 - 26 June 2024)

This course is designed to foster a contemporary comprehension of process validation (PV), ensuring alignment with stringent regulatory expectations. Beyond a review of the objectives and standard practices, the program offers practical guidance on harnessing quality risk management principles. Attendees will learn how to strategically utilize these principles to formulate comprehensive validation plans that not only align with current regulatory standards but also establish a proactive approach to quality assurance. The course aims to empower participants with practical tools and insights to enhance their PV processes, promoting compliance and elevating the overall quality management framework.

Content

Day 1: The Principles of Process Validation

- The GMP reasons for process validation.
- Control of Variation, Process Capability Indices, and Sampling Considerations in process validation
- The validation life cycle
- Regulator's current thinking
- Ongoing changes in the Quality Management philosophy
- Real-life examples

Process Design

- Quality by Design, ICH Q8 and Q11
- Quality Target Product Profile
- Critical Quality Attribute
- Critical Process Parameter
- Design Space
- Control Strategy
- Continual Improvement
- Link between QbD the Control Strategy and Process Design

Day 2: How to Manage the Data in Process Validation

- Process understanding and effective process validation
- Understand implications of validation deviations
- Statistical Tools
- Process Capability and Performance
- Workshops exploring common PV problems and solutions

Participants

This course has been designed for validation professionals as well as those involved in approving process validation plans and projects. It also applies to anyone interested in the latest trends and methodologies in process validation that are rapidly becoming industry standards.

Course Outline

Introduction to Laboratory Controls and analytical Method validation – managing OOS/ OOT/ OOE, Basics about Analytical Method Validation (10 - 11 July 2024)

International GMP regulators continue to find GMP deficiencies in organisations related to Out-of-Specification (OOS) handling. The citations range across:

- Inadequate management (no SOP or not following the SOP)
- Inadequate investigation (lack of depth or lack of documentation)
- Inadequate outcomes (testing into compliance without (justifiably) invalidating the OOS)

GMP inspectors are scrutinizing how companies manage Out-of-Specification (OOS) results, and one of the primary objectives of this course is to facilitate your understanding of the current best practices for conducting OOS investigations.

Beyond OOS handling, Data Integrity (DI) stands out as another prominent topic in the industry, particularly within QC laboratories. Despite the surge in industry guidance on DI since 2016 from regulatory bodies like the FDA, WHO, MHRA, PIC/S, ISPE, and PDA, it's important to note that the demonstrable integrity of data and records has been a long-standing GMP requirement.

This two-day course will guide you through the essential elements and fundamental principles for maintaining compliance in QC laboratories, placing specific emphasis on OOS handling and Data Integrity. A critical factor for QC laboratories and regulators alike is the successful validation of methods. It is imperative to ensure that the test methods and the data generated by the laboratory are reliable. Consequently, this course will concentrate on the key elements integral to the successful validation of test methods.

Content

Day 1:

Overview of Laboratory Controls & OOS/OOT Handling

- Key elements and basic principles that are necessary to establish proper control and sustain compliance in a Quality Control / Analytical Laboratory (ISO 17025)
- Difference(s) between Out-of-Specification (OOS) and Out-of-Trend (OOT), Out of Expectation (OOE)
- Best practices and process for conducting successful OOS investigations, including the use of re-testing and re-sampling
- Statistical approach when considering the trend data
- Regulators' perspectives

Day 2:

Analytical Method Validation

- Overview of analytical method validation
- Basic statistical tools for method validation
- Key performance characteristics of analytical methods
- Analytical Method- Fit for purpose
- Design an analytical method validation

Participants

You will benefit from this training if you are a regulated laboratory analyst or supervisor/manager, or if you have an interest in GxP and laboratory practices.

Course Outline

Behavioural GMP and Data Integrity – essentials to know about minimising human error (23 - 24 July 2024)

Addressing and managing deviations is crucial for preventing lost productivity. Typically, investigations into deviations consume significant time and frequently pinpoint human error as a causal factor, leading to the common but often ineffective response of implementing more training or additional procedures. Unfortunately, this approach tends to yield limited success, and issues persist.

This course, focusing on behavioral Good Manufacturing Practices (bGMP), delves into the reasons behind non-compliance with procedures—whether due to error or intentional actions—and explores effective strategies for improvement. Participants will gain insights into three specific modes of human error and understand where "retraining" can be beneficial, but also recognize its limitations in most cases.
Day 2 of the course extends its focus to Data Integrity (DI), a critical aspect in the pharmaceutical industry. Understanding and ensuring the integrity of data is paramount for regulatory compliance and the overall quality management framework. The session will cover key principles, industry guidelines, and practical approaches for maintaining data integrity in various stages of pharmaceutical operations, Quality Control (QC), and all other departments. Practical case studies and real-world examples will be incorporated to illustrate effective strategies for upholding Data Integrity standards. Participants will leave with a comprehensive understanding of how to navigate the complexities of managing data integrity within their organizations.

Content

Day 1

- What causes defective products?
- Understanding the nature of human error
- Sources of Error
- What influences our behaviour?
- Addressing Error
- Stages of Human Learning and Types of Error
- Possible areas that ‘encourage’ human error and eventuate to non-compliance
- Managing Non-Compliant Behaviours
- Building a compliant quality culture
    - Role of Supervision / Management
    - Strategies for reducing learning error
    - Reducing Inherent Errors and Potential Errors

Day 2: Data Integrity

- What does data integrity (DI) mean, who can contribute to good DI?
- Why is data integrity and security such a hot topic for regulators?
- Data criticality and data risk
- Integration of DI into your QMS using a risk-based approach
- Protection and security of raw data and original records
- Developing practical audit and remediation strategies for DI

Participants

Executives, Managers, specialists and supervisors responsible for GMP compliance, reducing deviations, conducting failure investigations and continuous improvement will benefit from this program.

Course Outline

Cleaning Validation (13 - 14 August 2024)

For nearly two decades, the FDA's Industry Guidance document "Validation of Cleaning Processes (7/93)" stood as the primary reference. However, in the period between 2016 and 2020, there has been a notable surge in guidance publications from major industry bodies, including the EMA, PIC/S, PDA, ISPE, and WHO. The question then arises: What implications do these myriad documents have for you and your company?

This training course is designed to provide clarity on the current 'cleaning validation landscape' by delving into recent changes in regulatory expectations and elucidating their significance for manufacturers. Participants will not only gain insights into the contemporary application of a science- and risk-based approach to cleaning validation but also acquire the skills to craft GMP-compliant cleaning validation (CV) protocols.

- **Regulatory Evolution:** Understand the evolution of cleaning validation regulations over the years and the key updates introduced by various regulatory bodies.
- **Practical Application:** Explore real-world applications of a science- and risk-based approach to cleaning validation, drawing on industry best practices.
- **Interactive Discussions:** Engage in interactive discussions and case studies to reinforce the understanding of how to navigate the complexities of the updated cleaning validation landscape.
- **GMP Compliance:** Learn strategies and techniques to ensure that your cleaning validation protocols align seamlessly with Good Manufacturing Practices (GMP) standards.
- **Industry Perspectives:** Gain insights into industry perspectives on the evolving cleaning validation landscape and how different companies are adapting to these changes.

Day 1: The Principles of Cleaning Validation

- Regulatory basis / GMP reasons for cleaning validation.
- Strategies for cleaning validation that complies with GMP
- Practical limits for cleaning residues
- Health-based exposure limits (HBEL)
- Essentials of a cleaning validation protocol
- Examples from the industry
- Sampling, inspection and testing

Day 2: The Practices

- Current global regulations and requirements for Cleaning Validation
- Cleaning process and method design, equipment design and qualification
- Residue determination, analytical methods and limit calculations
- The documentation used to support an effective cleaning program.
- Common issues and how to deal with failures during the cleaning program.
- How to maintain the validated state
- Know how to present your strategy and data to a regulatory body
- Workshops exploring common CV problems and solutions

<u>Participants</u>

You will benefit from this training if you are in a position of Quality or Validation Management or directly responsible for preparing and executing cleaning validation studies within a GMP facility. Participants can be any one from Quality Assurance personnel, Quality Control personnel, Operations and Manufacturing personnel, Qualification & Validation personnel, Engineering and Automation personnel, R&D personnel, or anyone within the GMP industry interested in learning about or improving their knowledge of cleaning validation.

Course Outline

Internal Audit – a key to effective Quality System (27 - 28 August 2024)

Conducting internal audits is an integral component of instituting, sustaining, and enhancing your quality system, a pivotal element for the success of your business. Whether you are part of a pharmaceutical company aligning with the "self-inspection" prerequisites outlined in the PIC/S Guide to Good Manufacturing Practice (GMP) or a medical device company adhering to the "internal audit" specifications of ISO 13485, implementing an internal audit program across your organization serves multiple purposes. It not only imparts knowledge to personnel but also reinforces accountability for various elements within the quality system, fostering a culture of continuous improvement and driving cost reductions.

The value derived from internal audits remains consistent regardless of the maturity level of your organization's quality system. If you find yourself seeking ways to optimize and extract more value from your self-inspection/internal audit program, this course is tailored to assist you in achieving your Key Performance Indicators (KPIs).

Content

Day 1: Managing Internal Audits

- Critical role of quality audits in compliance & improvement
- Regulatory standards and guidelines for quality auditing
- GMP and QS requirements for internal audit programs
- Risk Assessment as it applies to quality audit practices
- Documents, records, and data for effective audits
- Audit schedules and the use of risk management in relation to prioritizing audits
- Techniques and tips for auditing - 6 fundamental steps of auditing

Day 2: Corrective and Preventive Action (CAPA) in Internal Audits

- What is Corrective and Preventive Action (CAPA)
- How to apply CAPA to quality audits
- How to apply Risk Management principles to:
    - Audit observations
    - CAPA
    - Audit verification

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.

Course Outline

Supply chain management and Supplier QA program-Application of QRM principles (10 - 11 September 2024)

The pharmaceutical industry operates on a global scale, where active pharmaceutical ingredients, components, and products are procured through increasingly intricate supply chains. Recognizing the challenges posed by the limitations of individual countries' regulatory oversight, the US Government enacted the Drug Supply Chain Security Act (DSCSA) as legislation mandating a national track-and-trace system for medicines, including electronic tracing throughout the supply chain. This measure, enforced by the FDA since 2015, emphasizes the importance of ensuring the integrity of the pharmaceutical supply chain. Simultaneously, the European Union (EU) has bolstered its Good Distribution Practice (GDP) requirements, which have been in effect for an extended period. These regulatory developments underscore the imperative for all personnel involved in your organization's supply chain to comprehend their roles and actively contribute to the implementation and maintenance of a robust and comprehensive quality system. This training will aim to focus an below;

- **Global Regulatory Landscape:** Understand the evolving regulatory landscape, particularly the DSCSA in the United States and enhanced GDP requirements in the European Union, and how they impact the pharmaceutical supply chain.
- **Compliance Enforcement:** Explore how these regulations are actively enforced by regulatory agencies such as the FDA, emphasizing the significance of compliance to ensure the safety and integrity of pharmaceutical products.
- **Educating Personnel:** Highlight the importance of educating all personnel in the supply chain about their roles and responsibilities, ensuring a collective effort towards maintaining compliance and quality standards.
- **Risk Management Principles:** Emphasize the integration of risk management principles within the quality system, illustrating how this approach can be instrumental in safeguarding product quality and ensuring a consistent and reliable supply to customers.
- **Continuous Improvement:** Discuss the role of a comprehensive quality system in fostering continuous improvement within the supply chain, enabling organizations to adapt to regulatory changes and enhance overall operational efficiency.

Day 1 Content

You will develop 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
- Building A Successful Supplier QA Program – A Strategic Approach

You will be provided 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.

Course Outline

Day 2 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 organisation – Quality Agreements and the role of QA

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, supplier quality assurance, distribution and logistics of sourcing and supplying finished pharmaceuticals, pharmaceutical ingredients, and medical devices.

Course Outline

Contamination Control - How to Develop an Effective Contamination Control Strategy (25 - 26 September 2024)
(Incorporation of Virtual Reality (VR) for Classroom Exercises).

The imperative to prevent or manage (cross-) "contamination" during the storage, handling, and processing of components, materials, and products—both non-sterile and sterile—is underscored by the explicit and consistent directives outlined in Good Manufacturing Practices (GMPs). This is evident in the extensive references within key regulatory documents, such as the PIC/S Guide to GMP for Medicinal Products Part I (PE 009-17) with over 40 references and FDA 21 CFR Part 211 CGMP for Finished Pharmaceuticals with over 20 references.

This comprehensive course aims to equip participants with essential knowledge and practical skills to address contamination control effectively. Key objectives include:

- **Critical Understanding:** Gain insight into the critical importance of contamination control and its impact on product quality, safety, and regulatory compliance.
- **GMP Compliance:** Understand the GMP regulations that mandate compliance with contamination control measures, referencing both the PIC/S Guide and FDA 21 CFR Part 211.
- **Identification of Contamination Types and Sources:** Learn to identify various types of contamination and recognize major sources within the manufacturing environment.
- **Procedural Implementation:** Acquire skills to implement robust procedures aimed at reducing contamination risks, ensuring alignment with GMP standards.
- **Real-world Application:** Explore practical case studies and examples to illustrate effective contamination control strategies in real-world manufacturing scenarios.
- **Continuous Improvement:** Emphasize the role of contamination control as an integral part of continuous improvement efforts, promoting sustained compliance and operational excellence.
- **Regulatory Updates:** Stay informed about the latest updates and changes in contamination control regulations, ensuring the ability to adapt to evolving industry standards.
- **Interactive Learning:** Engage in interactive learning experiences, including discussions and exercises, to reinforce understanding and facilitate the application of contamination control principles.

By the end of the course, participants will not only have a theoretical understanding of contamination control but will also possess practical tools and knowledge to implement and enhance contamination control measures in their respective manufacturing environments.

Day 1

- **Introduction to Contamination Control**
  - GMP principles and requirements for contamination control
  - Different types of contamination and the potential sources of contamination
  - Risk assessment methodologies that can be used to analyse and assess the major risks to product
  - Develop strategies for contamination control
- **Cleaning and Sanitation**
  - Suitable cleaning and disinfectants for different manufacturing situations
  - Appropriate techniques for cleaning and sanitation

Course Outline

Day 2

- **Operating in a Cleanroom**
  - Cleanroom facilities, HVAC, and filtration principles
  - International cleanroom standards
  - Cleanroom garments, gowning procedure, and qualification
  - Cleanroom conduct and operator qualification
  - Cleanroom operation and control
  - Environmental monitoring
- **HVAC and Controlled Environments**
  - The international nomenclature and classification of cleanrooms
  - Key design requirements for cleanrooms
  - The theory of particle filtration, controlled facilities design and operation for the purpose of product protection
  - Certification of cleanrooms: test methods, test instructions, sampling sites
  - Rules for working within a cleanroom
  - GMP deficiencies
- **Environmental Monitoring (EM)**
  - Key elements of an Environmental Monitoring (EM) Program
  - EM sample sites for qualification and routine monitoring purposes using risk assessment
  - Testing required for demonstration of cleanroom standards
  - Strategies for defining sample sites & frequency
  - Strategies for establishing alert & action levels for EM
  - EM test methods and examples of where and when they will be used

Participants

This course has been designed to provide personnel of all levels (Operator, Officer, Supervisor, Manager) with a good understanding of contamination and how to control it in a GMP environment. People from a range of Departments (Production/Manufacturing/Packing, Quality Control, Quality Assurance, Engineering etc.) will benefit from this training.

Course Outline

A practical approach to ISO 13485 QMS for medical devices (15 - 16 October 2024)
Your organisation may be involved in one or more medical device life-cycle stages such as design and development, production, storage and distribution, installation, servicing or associated activities (e.g. technical support). ISO 13485 can also be used by suppliers that provide products and/or services to organisations working in these stages. Participants will gain knowledge and learn process steps to facilitate the implementation of an effective QMS aligned with or certified to ISO 13485:2016. Applying ISO 13485 helps ensure that businesses deliver consistent good-quality products and services, ultimately improving customer satisfaction and contributing to commercial success.

The course will provide a short introduction to the regulatory landscape of Quality for medical device companies followed by practical advice to help you implement a QMS across the four (4) key areas of ISO 13485. It will cover:

- The Regulatory Environment
- The ISO model for an effective process-based QMS
- The application and integration of a Quality Risk Management (QRM) framework
- Key areas of ISO 13485 (including changes in the 2016 standard)
    - Management responsibility
    - Resource management
    - Product realisation
    - Measurement, analysis and improvement

Content

Day 1:

- ISO 13485 Overview
    - A Process-Based Quality Management System
- How to implement a Quality Management System in a manufacturing organisation
    - Management Responsibility
    - Resource Management
    - Application of RISK Management Principles
    - Product Realization
    - Measurement and Analysis
- How can we prove equipment and processes are fit for purpose?
- The Regulatory Environment and expectations
- Integrated QMS system- What does this mean?

Course Outline

Day2

- Know your legal obligations
- Understand the success factors for an effective QMS and the benefits it delivers
- Develop risk management strategies for products and processes
- Determine if your organisation is ISO 13485 audit-ready
- Develop plans to streamline your QMS and maintain practical compliance
- ISO Requirements for a Process Based QMS
- Cleanliness of product and contamination control
- Production and Process Control
    - Elements of design control
    - Quality system requirements for design control SOPs and records
    - Role of risk assessment and mitigation of risk through design
    - Relationship between design input, out put and reviews
    - Importance of design transfer, verification and validation
    - Role of change control in the design life cycle
    - Importance of the design history file
- Validation Principles
    - State the reasons for validation.
    - Describe the development of validation and regulatory control.
    - List the scope of validation.
    - Describe the V model approach to validation documentation.
    - State the difference between IQ/OQ and Engineering commissioning.
    - Describe the difference between critical and non-critical items.
    - State the definitions of some important validation terms.
    - List the important regulatory and GMP validation guidance documents
- Industry Case studies

<u>Participants</u>

This course is open to anyone interested in learning more about the application of ISO 13485:2016 requirements and benefits of a quality management system for medical devices. You may be a subject matter expert, researcher, start-up, supplier or a graduate with interest.

Course Outline

Good Distribution Practice for the Regulated Industry (12 - 13 November 2024)

This course is designed to acquaint participants with the essential principles of Good Distribution Practice (GDP) within regulated industries. Its primary objective is to enhance comprehension of management concepts related to the handling, storage, and distribution of medicinal products and medical devices.

Key Components and Objectives:

- **GDP Requirements Introduction:** Delve into the foundational requirements outlined in Good Distribution Practice, offering a comprehensive overview of the regulatory landscape.
- **Industry Relevance:** Explore the specific applicability of GDP principles to regulated industries, emphasizing the importance of compliance for pharmaceuticals and medical devices.
- **Regulatory Compliance:** Understand how adherence to GDP requirements is integral to maintaining regulatory compliance and ensuring the quality and safety of distributed healthcare products.
- **Risk Management:** Explore the incorporation of risk management principles within GDP, focusing on strategies to identify, assess, and mitigate risks in the distribution process.
- **Practical Implementation:** Acquire practical insights into implementing GDP requirements within day-to-day operations, with a focus on real-world applications and case studies.
- **Role of Technology:** Recognize the role of technology in enhancing GDP, including the use of tracking systems, temperature monitoring, and other advancements that contribute to the integrity of the distribution process.

Content

Day 1:

- GDP: Relationship and Integration with GMP
  - The definitions of Good Distribution Practice (GDP)
  - The relationship and integration of GDP with GMP along the supply chain
  - Scope of GDP
  - Comparing the requirements between GMP and GDP
- Understanding GDP Requirements
  - Quality Management
  - Personnel
  - Premises and Equipment
  - Documentation
  - Operations
  - Complaints/ Returns/ Suspected Falsified Products/ Recalls
  - Outsourced Activities
  - Self-Inspections
  - Transportation

Day 2:

- Applying Risk Management in the Supply Chain
- Overview of the Quality Risk Management Process
- Practical approach for the implementation of risk management to GDP compliance programs.
- Consider FMEA
- Overview of Cold Chain Management
- Definition and challenges of Cold Chain.
- Regulations and guidelines on GDP, Cold Chain Management, and Mapping.
- Essential requirements of temperature-controlled storage areas
- Cold area qualification (including mapping) activities
- Justification for re-qualification

Participants

This course is suitable for Warehouse Managers, Supervisors, and operational personnel who are new to the industry, as well as well as for refresher or ongoing training (as required by the PIC/S Guide to GDP) of existing staff. It covers fundamental principles of GDP, as well as current trends and how to minimise human error

COURSE REGISTRATION

Registration Fee per participant per course:
(The fee includes complete set of course materials)

Virtual Training Fee
MOPI Member – 2 Days Course
30 days before commencement of course RM1,900.00
(RM2,052.00 inclusive 8% SST)
29 – 14 days before commencement of course RM2,100.00
(RM2,268.00 inclusive 8% SST)

Non-MOPI Member – 2 Days Course
30 days before commencement of course RM2,200.00
(RM2,376.00 inclusive 8% SST)
29 – 14 days before commencement of course RM2,400.00
(RM2,592.00 inclusive 8% SST)

Foreign Participant – 2 Days Course
30 days before commencement of course USD $1,000.00
(USD$ 1,080.00 inclusive 8% SST)
29 – 14 days before commencement of course USD $1,200.00
(USD$ 1,296.00 inclusive 8% SST)

Physical Training Fee
MOPI Member – 2 Days Course
30 days before commencement of course RM2,400.00
(RM2,592.00 inclusive 8% SST)
29 – 14 days before commencement of course RM2,600.00
(RM2,808.00 inclusive 8% SST)

Non-MOPI Member – 2 Days Course
30 days before commencement of course RM2,700.00
(RM2,916.00 inclusive 8% SST)
29 – 14 days before commencement of course RM2,900.00
(RM3,132.00 inclusive 8% SST)

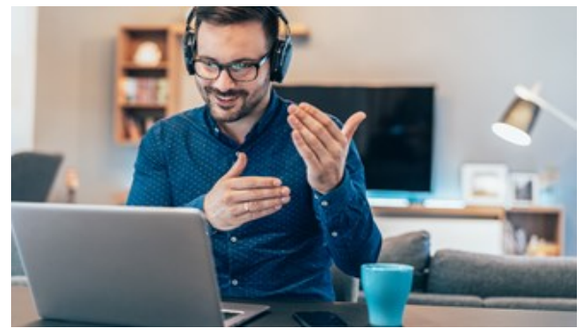
Foreign Participant – 2 Days Course
30 days before commencement of course USD $1,300.00
(USD$ 1,404.00 inclusive 8% SST)
29 – 14 days before commencement of course USD $1,500.00
(USD$ 1,620.00 inclusive 8% SST)

Seats are limited: Only 25 participants per class

Payment must be made before the training

TRAINING TIME SCHEDULE:
9.00AM – 5.00PM (in 2 days)

9.00AM – AM TOPIC
11.00AM – BREAK
11.15AM – AM TOPIC
1.00PM – LUNCH BREAK
2.00PM – PM TOPIC
3.00PM – BREAK
3.15PM – PM TOPIC
5.00PM – FINISH



BOOK YOUR SEAT NOW!!!

For further enquiries, please contact:
Mike,
Malaysian Organisation of Pharmaceutical Industries,
Global Business & Convention Centre,
Mezzanine Floor, Block A, No. 8, Jalan 19/1, Section 19,
46300 Petaling Jaya, Selangoer, West Malaysia
Tel: 03-7931 9003 Fax: 03-7932 2730
E-mail: mike@mopi.org.my and admin@mopi.org.my
www.mopi.org.my

ADMINISTRATION DETAILS:

Registration will be treated as confirmed only upon receipt of payment in full.

CANCELLATIONS & TRANSFERS:

- If you are a HRDF-registered employer, you may apply to HRDF for SBL-Khas training grant for the training.
- If you are not claiming or unable/unsuccessful to claim HRDF, full payment should be made in advance within 14 days of invoice issuance prior to the training event.
- All cheques should be crossed and made payable to **MALAYSIAN ORGANISATION OF PHARMACEUTICAL INDUSTRIES**
  Banker Name : Malayan Banking Berhad Account Number : 5122 3139 2242
- 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 reserve 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 occurs.

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)

HRDF Registered Employer [ ] Yes [ ] No Apply for HRD Claimable Course [ ] Yes [ ] No

HRDF Registered Number [ ]

1 Name_____

Designation_____

Email address _____

Contact Number _____

NRIC Number _____

☐ Vegetarian

2 Name_____

Designation_____

Email address _____

Contact Number _____

NRIC Number _____

☐ Vegetarian

Participant's Email Address must be in complete for online training

List of 2-Day Courses (please tick accordingly)	
☐ **GMP – Essentials to know** **23 - 24 Jan 2024 (Tue - Wed) Physical Training**	☐ **Behavioural GMP and Data Integrity – essentials to know about minimising human error** **23 - 24 July 2024 (Tue - Wed) Virtual Training**
☐ **Quality Risk Management Training** **6 - 7 Feb 2024 (Tue - Wed) Virtual Training**	☐ **Cleaning Validation** **13 - 14 Aug 2024 (Tue - Wed) Virtual Training**
☐ **Qualification and Validation – getting the essentials for implementation** **5 - 6 March 2024 (Tue - Wed) Physical Training**	☐ **Internal Audit – a key to effective Quality System** **27 - 28 Aug 2024 (Tue - Wed) Physical Training**
☐ **Deviations and Investigation Management- How to ensure CAPA Efficiency** **23 - 24 Apr 2024 (Tue - Wed) Physical Training**	☐ **Supply chain management and Supplier QA program- Application of QRM principles** **10 - 11 Sep 2024 (Tue - Wed) Virtual Training**
☐ **Good Writing Practice – How to improve your SOP writing, investigation reports, CAPA Reports, Summary Reports** **7 - 8 May 2024 (Tue - Wed) Virtual Training**	☐ **Contamination Control - How to Develop an Effective Contamination Control Strategy** **25 - 26 Sep 2024 (Wed - Thu) Physical Training**
☐ **Computer Systems for Regulated Environments** **11 - 12 June 2024 (Tue - Wed) Virtual Training**	☐ **A practical approach to ISO 13485 QMS for medical devices** **15 - 16 Oct 2024 (Tue - Wed) Virtual Training**
☐ **Process Validation and application of Statistics in Validation** **25 - 26 June 2024 (Tue - Wed) Physical Training**	☐ **Good Distribution Practice for the Regulated Industry** **12 - 13 November 2023 (Tue - Wed) Physical Training**
☐ **Introduction to Laboratory Controls – Managing OOS/ OOT/ OOE. Basics about Analytical Method Validation** **10 – 11 July 2024 (Wed - Thu) Physical Training**	*** * 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 / Mobile No _____

Company Stamp (with Address, Telephone & Fax Number)