

# Advanced Pharmacovigilance Auditing and Inspections



## TRAINING OVERVIEW

PV Audit Strategy Planning course will provide an overview of the European Medicines Agency's (EMA) Guideline on good pharmacovigilance practices (GVP), Module IV requires that risk-based audits of the quality system be performed at regular intervals to assure that it complies with the established quality requirements and to determine its effectiveness.

It includes audit of the pharmacovigilance system which is covered by the quality system. The GVP Modules are applicable to EU-based companies and any company marketing medicinal products on a global basis. The legally required risk based audit strategy shall cover all PV processes and tasks undertaken by or delegated to other departments, MAH affiliates, and third parties such as distributors, external service providers, partners (the PV Universe). The PV Audit Strategy Plan is used to prepare the PV audit program, i.e. annual PV Audit Schedule.

## LEARNING OBJECTIVES

**Upon completing of this course, participants should be able to:**

- Understand the legal requirements and health authority expectations for a risk based audit program and current interpretation. Plan, develop and implement the PV Audit Strategy Plan, which includes the following processes:
- Develop a high-level PV audit strategy
- Identify the PV activities and processes subject to PV audit
- Develop risk assessment criteria
- Identify the PV audit universe – entities subject to PV audit
- Categorize the entities subject to PV audit
- Perform risk assessments
- Prioritize entities for audit according to relative risk
- Prepare a 3-5 year PV audit plan
- Identify procedures/tools to monitor PV quality of third parties

## FACULTY MICHAEL RAMCHARAN

**Quality Assurance Expert  
( 30 + yrs Exp. )**

Our trainer has 30 years of experience in Quality Assurance having worked with multinational Pharmaceutical and Clinical Research Organisations (CRO) mainly in the GCP and GPV areas. He has conducted a wide variety of audits (both On-site and Remote) globally, and managed various risk-based audit programmes. He has also hosted and supported many European Regulatory Authority Inspections (eg; MHRA, EMA, Local EU country Inspectorates).

# AGENDA DAY 01

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## Introductions

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### Regulations

ICH- Guidance US/EU/Japan

### ICH Q10 – Pharmaceutical Quality System

- Life time of a Product
- Resources to monitor the QS

### ICH Q9 – Quality Risk Management

- Risk Management Methods and Tools

ICH E2- Clinical Safety Data Management

21 CFR Part 314.80/81

### EU GVP Module IV (R1) – PV audits (12AUG2015)

- Risk Based approach
- Strategic Level (2-5 years)
- Tactical level
- Operational level

### Pharmacovigilance System Master File

- GVP Module II – PSMF (31MAR2017)
- Main body covers the PV QMS including QA

Annex G – Quality System.....

### Background & Design of QA Programme

#### Strategic Level– Plan to cover:

- All pharmacovigilance activities
- The Quality Management System (QMS) for pharmacovigilance activities
- Interactions with other company departments, as appropriate (GMP, Regulatory Affairs)
- Pharmacovigilance activities conducted by affiliated organisations
- Pharmacovigilance activities conducted by third parties

#### Strategic Level

- Service Level Agreements – outlines
- SDEA
- Key Performance Indicators (KPI)

#### Tactical Level Planning

#### Tactical Aspects

#### Operational Level

#### Pre-Audit Questionnaires

**BREAK)**

#### Case study/Exercise with Q&A

#### Implementation of a PVQA Audit Programme

- Exercise – Design a QA Audit Programme for Company A
- Some questions to consider

#### End of Day 1

# AGENDA DAY 02

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## Q&A session from Day 1

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### PV Inspections

- EU GVP Module III – PV Inspections (16SEP2014)
- EMA Remote PV Inspections – During crisis situations(SEP2020)
- MHRA guidance on Remote Inspections
- Routine Inspections
- Pre-Authorisation Inspections
- For Cause' Inspection
- Preparing for a PV Inspection
- Tools
- ·Inspection Checklist (Plan) should cover
- Document Request form
- Metrics from MHRA 2020 Symposium, London
- SMART Responses when drafting CAPAs

### BREAK

### Audit & Inspection findings

- Questions to consider
- Case Study 1
- Case Study 2
- Case Study 3

### Q&A session

**Certificate of Completion for 2 Days Virtual Training Online on Advanced Pharmacovigilance Auditing & Inspections**

## WHO WILL BENEFIT

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This course is designed for people with some PV experience and tasked with developing, maintaining, updating and/or reviewing the PV quality system audit strategy plan, risk assessment and/or the annual PV audit schedules. It is also beneficial for staff responsible for the quality oversight of third parties conducting PV activities.

**The following personnel will benefit from the course:**

- PV Quality Assurance Staff
- PV Compliance professionals
- Quality auditors
- Pharmacovigilance Auditors
- Relevant Pharmacovigilance Staff
- PV Service Provider Relationship Managers
- MAH Affiliates responsible for Pharmacovigilance