Advanced Pharmacovigilance Auditing and Inspections

15-16 December , 2021
12:30 PM - 04:00 PM EDT(US)
06:30 - 10:00 PM CET(EU)

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

Michael Ramcharan 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

Introductions (12:30 – 12:45 EDT)

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 (12:45 – 02:00 PM EDT)

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 (02:00 PM – 02:15 PM EDT)

Case study/Exercise with Q&A (02:15 PM – 03:45 PM EDT)

Implementation of a PVQA Audit Programme

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

End of Day 1 (03:45 PM EDT)

AGENDA DAY 02

Q&A session from Day 1 (12:30 PM – 01:00 PM EDT)

PV Inspections (01:00 PM – 02:30 PM EDT)

- 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 (02:00 PM – 02:15 PM EDT)

Audit & Inspection findings (02:45–03:45 PM EDT)

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

Q&A session (03:45 PM – 04:00 PM EDT)

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

WHO WILL BENEFIT

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

REGISTRATION

Advanced Pharmacovigilance Auditing and Inspections
15-16 December , 2021

REGISTRATION FEES

Registration fee includes full admission to virtual course and electronic access to training course material.

Name **Email**

Organization **Department** **Position**

Phone **Mobile**

One Dial-in One Attendee - Live	Live Group-Max. 5 Attendees + 12 month Access
$1295	**$3995**

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Testimonial

"Michael is a pleasure to work with, his professionalism and subject matter knowledge is exemplary. Thanks to his ability to grasp the client's needs and expectations all work is produced in a timely manner with no compromise on quality "

Head of PV Services, CRO

"I have worked with Michael in different situations and periods, first as auditee and later, as a client. I'd emphasize his skills for creating real relationships of trust, his flexibility, his capacity to focus on the important details and his easy-going way of working. He has a great understanding of the quality management processes, the clinical and pharmacovigilance areas, as well as a very insightful view of the requirements in a changing environment - increasingly regulated - which makes him a great asset and advisor you can rely on....."

QA Manager, Pharma

"I originally became acquainted with Michael when he hosted a pharmacovigilance partner audit performed by myself and another auditor from our company. I was thoroughly impressed by his interactive abilities - treating us as equals and as respected partners in the audit. As host he supplied the documentation and interviewees that we needed in order to successfully conclude the audit and he congratulated us on identifying relevant improvements/issues during that PV audit. It was a pleasure to work with him then and I was happy to work together again when he took up a new position in another company, and where I was their client in the role of QA Director for a major Pharma company. Michael is knowledgeable and personable while remaining results-oriented."

Director QA, Large Global Pharma