DIA Learning

The Pharmacovigilance Quality Management System

14-15 October 2019
Hotel Bildungszentrum 21, Basel, Switzerland

OVERVIEW

This training course will describe contemporary principles, practical approaches, and regulatory expectations for the Pharmacovigilance Quality Management System. The topics will cover organizational structure, responsibilities, processes and resources required for the pharmacovigilance (PV) system and its quality system.

The course is designed for the intermediate level professional and employs a mixture of informative instructional sessions, real-world case studies, and hands-on interactive exercises where attendees can apply what they learn. Learners will leave the course with an understanding of how elements of the Pharmacovigilance and Quality Management Systems fit together to achieve regulatory compliance.

LEARNING OBJECTIVES

At the conclusion of this course, participants will be able to:

- Describe how to design, develop, and manage a quality system related to your pharmacovigilance system
- Explain the components of the Pharmacovigilance Quality Manual
- Describe the process for the development and maintenance of the Pharmacovigilance System Master File
- Analyze how the pharmacovigilance quality system integrates with the pharmacovigilance system
- Discuss the development, maintenance, and quality oversight of pharmacovigilance SOPs and pharmacovigilance related documents, including Safety Management Plans and Pharmacovigilance Agreements across clinical study programs and post-marketing
- Assess the effectiveness of the Quality Management System
- Explain Quality Risk Management Planning for risk-based audits of the Pharmacovigilance System and Quality System
- Define the scope of pharmacovigilance audits, including process audits, drug specific pharmacovigilance audits, and business partner pharmacovigilance audits
- Describe how to prepare for audits and inspections
- Practice preparing responses to a pharmacovigilance audit and inspection findings

Participants will complete a knowledge check at the end of the course to ensure learning objectives are attained.

WHO WILL ATTEND

This program is designed for professionals involved in:

- Quality assurance and compliance of the pharmacovigilance system
- Pharmacovigilance auditors
- Drug safety and pharmacovigilance personnel responsible for compliance, training, pharmacovigilance agreements, and/or pharmacovigilance quality documents
- Pharmacovigilance activities at a pharmaceutical company or service provider
- Pharmacovigilance personnel who are considering the Pharmacovigilance Quality Management System field as a future career path

A working knowledge of safety and pharmacovigilance principles is necessary in order to gain maximum benefit from the course.

FACULTY

Brian Edwards
Principal Consultant, Pharmacovigilance and Drug Safety, Vice-President ACRES NDA Group, United Kingdom

KEY TOPICS

- Structures and processes of a quality system and a pharmacovigilance system
- Pharmacovigilance System Master File (PSMF) and Pharmacovigilance Quality Manual requirements, content, and maintenance
- Safety Data Exchange Agreements across clinical study programs and post-marketing, including the development, regulatory requirements, and quality oversight
- Recommendations for Pharmacovigilance System Inspection Readiness
- Design of strategy and methodologies for Risk Based Audits
- Corrective and Preventative Action (CAPA) Plan preparation and effectiveness checks

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION

08:45 SESSION 1

QUALITY AND THE QUALITY SYSTEM

- What a Quality System is, its purpose, and what it typically includes

09:30 SESSION 2: QUALITY MANAGEMENT SYSTEM OVERVIEW

- Overview of the regulatory framework
- First steps in setting up a Quality Management System (QMS), core principles applicable to all quality management standards, and the Quality Cycle

10:15 COFFEE BREAK

10:45 SESSION 3

THE PHARMACOVIGILANCE SYSTEM

- Objectives, structures, and processes for the Pharmacovigilance System and how these interact
- Key pharmacovigilance activities/processes required per legal requirements and Pharmacovigilance System Element Ownership

11:30 SESSION 4

SYSTEMS, PROCESSES, QUALITY DOCUMENTS

- Quality System SOPs versus Pharmacovigilance System SOPs
- Interactions of the Pharmacovigilance System with the Quality System and identifying potential gaps

12:15 LUNCH BREAK

13:15 SESSION 5

PHARMACOVIGILANCE SYSTEM MASTER FILE AND PHARMACOVIGILANCE QUALITY MANUAL

- Overview and description of the Pharmacovigilance System Master File (PSMF) and the Pharmacovigilance Quality Manual
- Review requirements, content, and maintenance for these documents

14:00 SESSION 6

RISK ASSESSMENT OF IDENTIFIED GAPS

- Identifying potential risks and determining if they are critical based on impact
- Review common pharmacovigilance inspection findings from FDA and MHRA

14:45 COFFEE BREAK

15:15 SESSION 7

PROCEDURES AND STANDARDS

- Overview of a Quality Management Policy and its elements
- Quality document hierarchy
- SOP hierarchy
- SOP components, regulatory requirements, and writing hints

16:15 SESSION 8

PHARMACOVIGILANCE IN THE STUDY AND CLINICAL TRIAL ENVIRONMENT

- Review of study classification, causality assessments, expedited reporting, reference safety information and other areas subject to pharmacovigilance audits and inspections
- Pharmacovigilance-related clinical processes and cross-functional SOPs
- Safety Management Plans, when they are required, and key elements to include

17:15 QUESTIONS AND ANSWERS AND DAILY WRAP-UP

17:30 END OF DAY 1

DAY 2

08:30 SESSION 9

PHARMACOVIGILANCE AGREEMENTS (PVAS) AND PV PROVISIONS

- Various relationships requiring a PVA (also known as Safety Data Exchange Agreement) or PV provisions and the types of contracts
- Development of PVAs across clinical study programs and post-marketing, including regulatory requirements, updating, quality oversight, operational aspects and best practices

09:15 SESSION 10

COMMERCIAL ACTIVITIES AND PV OBLIGATIONS

- New and innovative ways that commercial gathers information on drugs and diseases to help guide future strategies such as patient support programs, mobile healthcare apps, and customer engagement/marketing programs
- Recommendations to ensure pharmacovigilance regulatory compliance due to the increased interaction with healthcare providers and patients

10:00 COFFEE BREAK

10:30 SESSION 11

COMPLIANCE MANAGEMENT AND MONITORING

- Specific quality system procedures and processes that should be in place to ensure compliance with the various required pharmacovigilance activities
- Processes to monitor the performance and effectiveness of a Pharmacovigilance System and its Quality System

11:15 SESSION 12

RISK-BASED AUDITING AND THE PHARMACOVIGILANCE AUDIT UNIVERSE

- FDA and EMA requirements regarding Risk-Based Audits of the Pharmacovigilance System and Quality System
- Recommendations on the design of the pharmacovigilance audit strategy
- Identification of the pharmacovigilance processes and entities subject to pharmacovigilance audits (define the pharmacovigilance audit universe)
- Development of risk assessment methodology
- Implementation of the pharmacovigilance audit strategy plan
- Methods of quality oversight and management of third parties performing pharmacovigilance activities

12:15 LUNCH BREAK

13:15 SESSION 13

RECORD MANAGEMENT AND DOCUMENTATION OF QMS

- Requirements for information protection, classification, and management including computerized systems
- Implications of the 2018 reform of the EU data protection rules and the General Data Protection Regulation (GDPR)

14:00 SESSION 14

PHARMACOVIGILANCE INSPECTIONS AND INSPECTION READINESS

- The types and scopes of pharmacovigilance inspections
- The role of the PSMF in ensuring Marketing Authorization Holders and pharmacovigilance units remain inspection ready
- How to prepare for inspections and be inspection ready
- Checklists for planned and unplanned inspections, and tips on being the interviewee

14:45 COFFEE BREAK

15:00 SESSION 15

RESPONDING TO INSPECTION AND AUDIT FINDINGS

- Preparation of responses to inspection and audit findings across commercial and research & development organizations
- Corrective and Preventive Action (CAPA) plans and effectiveness checks
- Responses accepted by regulators

15:45 SESSION 16

CORRECTIVE AND PREVENTIVE ACTION (CAPA) PLAN

- Conducting root cause analysis
- Preparing a CAPA Plan with the aim of correcting areas of noncompliance and determining how to prevent these issues from arising in the future

16:30 SESSION 17

PHARMACOVIGILANCE QMS COURSE SUMMARY AND KEY POINTS

16:45 QUESTIONS AND ANSWERS AND WRAP-UP

17:00 END OF TRAINING COURSE

| Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@diaglobal.org.

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| Training Course Venue

HOTEL BILDUNGSZENTRUM 21

Missionsstrasse 21
4055 Basel
Switzerland

HOW TO GET THERE

Route from the EuroAirport Basel Mulhouse Freiburg .
Please exit the Airport through the Exit to Switzerland. T
ake Bus Nr 50 towards Basel SBB. Change to bus Nr 30
direction Badischer Bahnhof and take off at "Spalentor".

Arrival by Train
From Germany: exit at station Badischer Bahnhof and
take Bus Nr 30 towards Basel SBB, take off at "Spalentor"
From Switzerland: exit at station Basel SBB, change to bus
Nr 30 direction Badischer Bahnhof and take off at "Spalentor".

Arrival from Zurich Airport
There is a direct train service every hour from Zurich Airport to
Basel SBB (travel time approx 1 h 30 min). Take the bus
Nr. 30 direction Badischer Bahnhof and take off at "Spalentor".

| Hotel Accommodation

Participants are kindly requested to make their own hotel

| Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 13 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 13 credits.

SwAPP | Swiss Association of Pharmaceutical Professionals

| Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact Basel@diaglobal.org for a custom group rate.