IRE ISTITUTO NAZIONALE TUMORI REGINA ELENA ISG ISTITUTO DERMATOLOGICO SAN GALLICANO
ISTITUTI DI RICOVERO E CURA A CARATTERE SCIENTIFICO

UOC Sviluppo Organizzativo e del Capitale Umano

Il dirigente della UOC Sviluppo Organizzativo e del Capitale Umano

in virtù della delega conferita con deliberazione N°232/2015

HA ASSUNTO LA PRESENTE DETERMINAZIONE

N. 1027 del 01/12/2020

OGGETTO: IMPEGNO DI SPESA DI EURO 880,00 QUALE SOMMA DESTINATA AL PAGAMENTO DELLA QUOTA DI ISCRIZIONE RELATIVA ALLA PARTECIPAZIONE DEL DIPENDENTE DOTT. FELICE MUSICCO AL CORSO FORMATIVO DAL TITOLO "THE PHARMACOVIGILANCE QUALITY MANAGEMENT SYSTEM TRAINING COURSE" ORGANIZZATO DALLA SOCIETA' DIA DA SVOLGERE IN MODALITA INTERATTIVA/VIRTUALE DAL 26 AL 29/01/2021

Esercizi/o 2021 - conto 502020302 Centri/o di costo 1000100

- Importo presente Atto: € 880,00

- Importo esercizio corrente: € .

Budget

- Assegnato: € .

- Utilizzato: € .

- Residuo: € .

Autorizzazione n°: .

Servizio Risorse Economiche: **Giovanna Evangelista**

UOC Sviluppo Organizzativo e del Capitale Umano Proposta n° DT-1040-2020

L'estensore

Massimo Bisozzi

Il Responsabile del Procedimento

Tiziana Lavalle

Il Dirigente della UOC Sviluppo Organizzativo e del Capitale Umano

Tiziana Lavalle

La presente determinazione si compone di n° 4 pagine e dei seguenti allegati che ne formano parte integrante e sostanziale:
- Programma

Il Dirigente della UOC Sviluppo Organizzativo e del Capitale Umano

VISTO il Decreto Legislativo 30 dicembre 1992, n. 502 e successive modificazioni ed integrazioni;

VISTO il Decreto Legislativo 16 ottobre 2003, n. 288;

VISTA la Legge Regionale 23 gennaio 2006, n. 2;

VISTA la delibera n. 917 del 18/10/2019 di Attivazione della UOC Sviluppo Organizzativo e del Capitale Umano in attuazione del nuovo Atto Aziendale;

VISTA la delibera n°111 del 24/01/2020 con la quale è stato approvato il Piano Formativo Aziendale 2020 (PFA), ed il budget assegnato per le attività di Formazione interne ed esterne;

PREMESSO che il dipendente dott. Felice Musicco, matricola 2446, ha manifestato interesse circa la partecipazione ad un corso formativo sul sistema di gestione della qualità della farmacovigilanza, dal titolo "The Pharmacovigilance Quality Management System Training Course", organizzato dalla società DIA, al costo di € 880,00 (esente IVA) quale quota di iscrizione individuale, da svolgere in modalità interattiva/virtuale nelle giornate dal 26 al 29/01/2021;

CONSIDERATO che i corsi formativi proposti dalla DIA sono di altissima qualità, e che il dott. Felice Musicco, vista la sperimentazione di Fase1, deve obbligatoriamente svolgere almeno un corso l'anno sulla Farmacovigilanza;

CONSIDERATO che il dott. Felice Musicco ha ottenuto l'autorizzazione necessaria alla partecipazione al sopracitato corso, che lo stesso afferisce alla UOC Farmacia e

all'Area Funzionale Farmacovigilanza, pertanto l'importo complessivo di € 880,00 rientrerà nel budget che verrà assegnato alle Direzioni operative e strutture di Staff per l'anno 2021;

RITENUTO pertanto opportuno di:

- assumere l'impegno di spesa complessivo di € 880,00 (esente IVA) quale somma destinata al pagamento della quota di iscrizione del dipendente dott. Felice Musicco al corso formativo dal titolo "The Pharmacovigilance Quality Management System Training Course", organizzato dalla società DIA, da svolgere in modalità interattiva/virtuale nelle giornate dal 26 al 29/01/2021;
- far gravare la relativa spesa di € 880,00 (esente IVA) sul conto n.502020302 bilancio 2021;

ATTESTATO che il presente provvedimento, a seguito dell'istruttoria effettuata, nella forma e nella sostanza è totalmente legittimo e utile per il servizio pubblico, ai sensi dell'art. 1 della legge 14 gennaio 1994, n. 20 e successive modifiche, nonché alla stregua dei criteri di economicità e di efficacia di cui all'art. 1, primo comma, della legge 7 agosto 1990, n. 241, come modificata dalla legge 11 febbraio 2005, n. 15;

ATTESTATO altresì che il presente provvedimento è predisposto nel pieno rispetto delle indicazioni e dei vincoli stabiliti dai decreti del Commissario ad acta per la realizzazione del Piano di Rientro dal disavanzo del settore sanitario della Regione Lazio;

DETERMINA

Per i motivi esposti in narrativa di:

- assumere l'impegno di spesa complessivo di € 880,00 (esente IVA) quale somma destinata al pagamento della quota di iscrizione del dipendente dott. Felice Musicco al corso formativo dal

titolo “The Pharmacovigilance Quality Management System Training Course”, organizzato dalla società DIA, da svolgere in modalità interattiva/virtuale nelle giornate dal 26 al 29/01/2021;

- far gravare la relativa spesa di € 880,00 (esente IVA) sul conto n.502020302 bilancio 2021;

La U.O.C. Sviluppo Organizzativo e del Capitale Umano curerà gli adempimenti relativi alla liquidazione della somma di cui alla presente determinazione.

La UOC Sviluppo Organizzativo e del Capitale Umano curerà tutti gli adempimenti per l’esecuzione della presente determinazione.

Il Dirigente della UOC Sviluppo Organizzativo e del Capitale Umano

Tiziana Lavalle

Documento firmato digitalmente ai sensi del D.Lgs 82/2005 s.m.i. e norme collegate

DIA Learning

The Pharmacovigilance Quality Management System

Virtual Live Training Course

26-29 January 2021 09:00-13:30 CET

OVERVIEW

This beginner to intermediate level virtual 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 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.

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

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 PV 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

WHO WILL ATTEND

This course is designed for professionals involved in:

- Quality assurance and compliance of the pharmacovigilance system
- Pharmacovigilance auditors
- Drug safety and pharmacovigilance personnel responsible for compliance, pharmacovigilance agreements, and/or pharmacovigilance quality documents
- Pharmacovigilance activities at a pharmaceutical company or external service provider

Pharmacovigilance personnel who are considering the Pharmacovigilance Quality Management System field as a future career path would benefit from this course.

FACULTY

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

Jose Alberto Ayala Ortiz
QPPV
PVpharm, Spain

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 (PV 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

DAY 1

09:00 WELCOME AND INTRODUCTION

09:30 SESSION 1

QUALITY AND THE QUALITY SYSTEM

Brian Edwards

- What a Quality System is, its purpose, and what it typically includes
- Exercise: Each participant to write answers to four questions on the Quality System

10:15 SESSION 2

QUALITY MANAGEMENT SYSTEM (QMS) OVERVIEW

Brian Edwards

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

11:00 BREAK

11:15 SESSION 3

THE PHARMACOVIGILANCE SYSTEM

Jose Ortiz

- 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
- Exercise: List the key/critical PV activities

12:00 SESSION 4

SYSTEMS, PROCESSES, QUALITY DOCUMENTS

Brian Edwards

- Quality System SOPs versus Pharmacovigilance System SOPs
- Interactions of the Pharmacovigilance System with the Quality System and identifying potential gaps
- Gap Analysis of PV Processes Workshop

13:00 QUESTIONS AND ANSWERS AND DAILY WRAP-UP

13:30 END OF DAY 1

DAY 2

09:00 SESSION 5

PHARMACOVIGILANCE SYSTEM MASTER FILE AND PHARMACOVIGILANCE QUALITY MANUAL

Jose Ortiz

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

10:00 SESSION 6

RISK ASSESSMENT OF IDENTIFIED GAPS

Brian Edwards

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

10:45 BREAK

11:00 SESSION 7

PROCEDURES AND STANDARDS

Brian Edwards

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

12:00 SESSION 8

PHARMACOVIGILANCE IN THE STUDY AND CLINICAL TRIAL ENVIRONMENT

Brian Edwards

- 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

13:00 QUESTIONS AND ANSWERS AND DAILY WRAP-UP

13:30 END OF DAY 2

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom has accredited this training course with 12.5 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 12.5 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

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.

DAY 3

09:00 SESSION 9

PHARMACOVIGILANCE AGREEMENTS (PVAS) AND PV PROVISIONS

Brian Edwards

- 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
- Exercise: Who is the functional owner of each agreement?

10:00 SESSION 10

COMMERCIAL ACTIVITIES AND PV OBLIGATIONS

Brian Edwards

- 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

11:00 BREAK

11:15 SESSION 11

COMPLIANCE MANAGEMENT AND MONITORING

Jose Ortiz

- 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
- Exercise: Using list of PV activities you prepared in Sessions 3, 4, & 9, identify where you could use KPIs/metrics

12:00 SESSION 12

RISK-BASED AUDITING AND THE PHARMACOVIGILANCE AUDIT UNIVERSE

Brian Edwards

- 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
- Risk Assessment Workshop

13:00 QUESTIONS AND ANSWERS AND DAILY WRAP-UP

13:30 END OF DAY 3

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

DAY 4

09:00 SESSION 13

RECORD MANAGEMENT AND DOCUMENTATION OF QMS

Brian Edwards

- Requirements for information protection, classification, and management including computerized systems
- Data integrity, good documentation practices, maintenance of documents

10:00 SESSION 14

PHARMACOVIGILANCE INSPECTIONS AND INSPECTION READINESS

Jose Ortiz

- 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

11:00 BREAK

11:15 SESSION 15

RESPONDING TO INSPECTION AND AUDIT FINDINGS

Jose Ortiz

- 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
- MHRA Inspection Findings Response Workshop

12:00 SESSION 16

CORRECTIVE AND PREVENTIVE ACTION (CAPA) PLAN

Brian Edwards

- 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
- Root Cause Analysis Workshop

12:45 SESSION 17

PHARMACOVIGILANCE QMS COURSE SUMMARY AND KEY POINTS

13:00 QUESTIONS AND ANSWERS AND WRAP-UP

13:30 END OF VIRTUAL LIVE TRAINING COURSE

Group Discounts

Register 3 individuals from the same company and receive complimentary registration for a 4th!*

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 via email to basel@diaglobal.org.

*Terms and Conditions apply. Please contact DIA EMEA office for more information.

REGISTRATION FORM Virtual Live Training Course

The Pharmacovigilance Quality Management System # 21543
26-29 January 2021 09:00-13:30 CET

DIA Learning

REGISTRATION FEES

Registration fee includes full admission to virtual course, and electronic access to course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.		

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CET. **Tel.** :+41 61 225 51 51

Email: **Basel@DIAglobal.org** **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: **www.DIAglobal.org**

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy. You agree that your personal data will be transferred to DIA in the US.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

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Exp. Date | | / | |

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #21543 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature