Quality in Pharmacovigilance Summer School 2015

POINTS TO CONSIDER WHILE IMPLEMENTING A QUALITY-ASSURED PHARMACOVIGILANCE SYSTEM

THE LECTURERS Dr. Nadine Epp
Dr. Daniela Marcozzi

420 € Early Bird discount
for enrolment by 30th March 2015

Wednesday 08th, Thursday 09th, Friday 10th
July 2015 Garda – Verona (Italy)

For additional info: (+39)035515684 training@LSacademy.eu www.LSacademy.eu

INTRODUCTION

This training course aims for a deep understanding of quality aspects in pharmacovigilance (PV) in order to tailor a PV quality system to the needs of a company.

TO WHOM IT MAY CONCERN

This training course and workshop is ideally suited for employees of small-, middle- and large-sized companies in the pharmaceutical sector especially concerned with the implementation and/or maintenance of pharmacovigilance (PV) systems, with its critical PV processes and quality system. Participants may come from various departments involved in fulfilling legal PV requirements, which is not limited to MAHs but may also apply to Service Providers, CROs, Distributors or consultants.

TYPE OF TRAINING

Training course including lecture and workshop Program

PARTICIPANT EXPERIENCE

An in depth knowledge or experience is not required.
However, participants should have an overview or basic knowledge about quality management or pharmacovigilance-related tasks.
They do not need to be directly involved or experienced in PV.

AT THE END OF THE TRAINING, YOU WILL BE ABLE TO:

- Know about quality-related GVP requirements
- Create a company-specific pharmacovigilance quality system
- Implement processes according to quality standards

PROGRAM

The Program will include lectures and workshops:

Lectures:

- EU PV Legislation: Overview
- Roles and Responsibilities
- Quality Management System: basic concepts and requirements for PV Systems
- Quality Documentation and relation with the PV requirements
- PV processes and their documentation (PV SOPs): overview about processes required by GVP, their implementation as Standard Operating Procedures (SOPs) and their quality assurance
- Methods for Implementing Signal Management (GVP Module IX) and Continuous benefit-risk assessment: method of continuous benefit-risk assessment as example of implementing a quality-assured process required by GVP
- Safety Data Exchange Agreements (SDEAs) and PV Agreements in compliance with GVP
- The Pharmacovigilance System Master File (PSMF): basic requirements and documentation of a pharmacovigilance-related quality system
- The Pharmacovigilance System Master File (PSMF): Q&A, how to develop, how to maintain
- Contents of a pharmacovigilance-related inspections
- Planning of PV Audits: audits to provide inspection readiness
- Findings, CAPAs and Deviations Management
- Risk Management Systems and Risk Management Plans
- Trainings requirement
- Quality aspects applicable to PSUR, RMP and Signal Detection process
- KPIs
- Computer System and Data Bases for PV: Risk assessment, Implementation, Validation and Maintenance

Workshops:

- PV Duties at Department Interfaces
- Generation and Review of a Quality Document
- Generation of a PSMF
- Risk-based approach for PV Audits Planning

AGENDA

July 08th	10:00 - 10:30	Registration
	10:30	Start of the course
	13:00	Lunch
	16:15	Coffee Break
	18:00	End of course
July 09th	09:00	Start of the course
	11:00	Coffee Break
	13:00	Lunch
	16:15	Coffee Break
	18:00	End of course
July 10th	09:00	Start of the course
	11:00	Coffee Break
	13:00	Lunch
	16:00	Coffee Break
	16:30 - 17:00	Learning and Evaluation questionnaire
	17:00	End of course

LS Academy is organizing a **wine tasting dinner** at the end of the second day of the course.
It will be an informal opportunity for networking between participants and instructors.
The participation fee is € 40,00 including: visit to cellars in one of the most famous wine area of Bardolino / Valpolicella; Wine tasting; transfer by minibus.

THE LECTURERS

Dr. NADINE EPP

Dr. Nadine Epp
Quality Manager Pharmacovigilance
Dr. Ebeling & Assoc GmbH, Hamburg, Germany.

In 2014, Dr. Epp joined the quality department of Dr. Ebeling & Assoc. GmbH, an experienced pharma consultancy for medical science, medical affairs and pharmacovigilance services. Prior to this, she successfully graduated her biology studies which were complemented by her PhD in the field of biochemistry. Combined with numerous training courses relating to quality management and quality assurance in the pharmaceutical industry, this is the basis for her collaborative operations in supporting small-, mid- and large-sized pharmaceutical companies in terms of implementing quality management systems for pharmacovigilance.
At Dr. Ebeling & Assoc. GmbH, Dr. Epp provides her diverse expertise to those requiring comprehensive support and specialists in the fields of pharmacovigilance, regulatory and medical affairs.

Dr. DANIELA MARCOZZI

Daniela Marcozzi
Vice-President, Quality Assurance and Compliance Consultancy,
PM Clinical Limited UK

Daniela Marcozzi has a degree in Biological Sciences, and begins her professional career in 1990 in the Regulatory Affairs Department at SIAPA (a Pesticides Products Manufacturing Company) and then joins the Pharmacovigilance Department at Janssen.
In 1993 she was hired by Sigma-Tau i.f.r. S.p.A. as a Clinical Auditor. In 1999 becomes Head of the Clinical Quality Assurance Department of Sigma Tau, and then in 2008 she takes the position of Head of Corporate QA R&D.
In 2014 Daniela moved to PM Clinical, as Vice – President, Quality Assurance & Compliance Consultancy.
Daniela has a very long and extensive experience in Quality System Management, GxP Quality Assurance and regulatory compliance, including Good Pharmacovigilance Practices. She has conducted and supervised hundreds of GxP audits, as well as audits to CROs, Labs and Suppliers. She is qualified as Responsible Person /Internal Auditor within the ISO 9001 Quality Management Systems. She is also an expert in the field of Compliance for GxP Computerised Systems, such as EDC, ePRO, DBs, PV Systems and Data Bases, participating in several implementing and validation projects, including the preliminary selection and qualification phase of the concerned System Vendors and SW Houses.
She has experienced FDA, EMA, and Local Competent Authorities (e.g.: AIFA, Austrian Health Authorities) GxP Inspections and had the honor of attending meetings with European Inspectors in Rome and in London, as well.
She is an active member of SSFA ("Società di Scienze Farmacologiche Applicate"), the Italian Group for Quality Assurance in Research and member of the British Association of Research Quality Assurance and AFI ("Associazione Farmaceutici Italiani"). She has worked in several projects with the aim of promoting the Quality culture and Compliance in the Pharmaceutical and Academic environment, as well. She has attended as speaker or chairman of a number of Congresses, Conferences and Workshops both nationally and internationally.
She has published several works including, in 2010, the SSFA "Pharmacovigilance Audit Manual".

WHAT IS LS ACADEMY SUMMER SCHOOL?

Ls Academy Summer school offers intensive specialization courses of 3 full time days dedicated to a specific subject.

In 2015 the subjects treated will be about:

- ***Marketing Plan***
- ***Medical Writing***
- ***Quality in Pharmacovigilance***

WHY ATTEND TO LS ACADEMY SUMMER SCHOOL?

The interactive process of teaching, the course architecture and the selected location will permit to achieve to the learning objectives with a balanced mix of study and relax.
The educational programs, of high training, are aimed to the development of specific professional tasks.
The "traditional" teaching is integrated by testimonies, exercises, simulations, illustrations of practical records in a perfect mix of theory and practice.
At the end of the course it will be given to the students a certificate of attendance.
To know more visit: **www.LSacademy.eu**

THE VENUE

Poiano Resort - www.poiano.com
Set in the breathtaking valley of Lake Garda, sheltered by San Vigilio and La Rocca on either side, stands the Poiano Hotel. The central building accommodates the Spa, the reception, hall, TV lounge, bar, restaurant and the hotel's panoramic terrace. A path lined with flowers and shaded by the trees leads to two buildings that accommodate the bedrooms and the Conference Centrefacing Lake Garda. Ample car parking is at the disposal of the guests.

Directions: Poiano Resort - Via Poiano; 37016 Garda (Verona) - Italy
http://www.poiano.com/lakegarda/garda.php

Poiano Resort is available for any information about transfers, accommodation and dinner at special rates.
For info contact: Reservations - reservation@poiano.com +39 045 7200950

The registration is restricted to a limited number of participants.
Registration can be done until Monday, 13th April 2015.

REGISTRATION FEES

Early bird: **€ 2.090,00 by 30/03/2015** Ordinary: **€ 2.510,00**

The fees includes: tuition, teaching materials, lunches and coffee breaks, organizational office assistance, attendance certificate.

METHODS OF REGISTRATION AND PAYMENT

1) You can fill in and send the **registration form** below (for each attendee), via fax +39.035.4501262 or via email training@LSacademy.eu and pay by **bank transfer**. Please attach proof of payment to the registration form.
Bank transfer payable to:

EasyB S.r.l Via Roma, 20 - 24022 Alzano Lombardo (BG) P. IVA **03633040161**
Banca Popolare di Vicenza - Filiale di Nese IBAN: **IT36 B057 2853 2508 2657 0697 999**
SWIFT Code : **BPVIIT21820**

2) You can directly register **online** and pay by **credit card.** Please go to: http://events.lsacademy.it/europe

For additional information:
Secretarial office
LS Academy (+39) 035.515684 (+39) 035.4501262 training@LSacademy.eu

REGISTRATION FORM

Name _____ Surname _____
Company name _____ Job Title _____
Address _____ City _____
Tel. _____ Fax. _____ E-mail _____
Special dietary requests _____

INVOICING DETAILS

Company name _____ Address _____
Mail address (if different) _____ City and Country _____
Post Code _____ VAT number _____

I would like to attend to the wine tasting evening on July 09th 2015, , € 40 ☐ yes ☐ no

Terms of payment The registration fee must be paid at the time of registration. Confirmation of course admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants.
Cancellation Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the course date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities.

The course will proceed with a minimum of 8 participants.
Should this number not be reached the registered participants will be no notified one week prior to the commencement of the course.

Date ..... Signature .....