Compliance Online
The Largest GRC Advisory Network

2-Day In-Person Seminar:

The Risk-Based Approach to Pharmacovigilance Audits - A Practical Approach to Design and Implementation

By: **Natasa Mihajlovic**, Managing Director, NostraPharma Ltd

Location: San Francisco, CA | April 20-21, 2020

SPEAKER

Natasa Mihajlovic, Managing Director, NostraPharma Ltd

Natasa Mihajlovic is an experienced European Qualified Person for Pharmacovigilance, certified trainer and certified lead auditor with over 23 years' experience in the pharmaceutical consultancy and industry coupled with MSc in pharmacovigilance. She has worked at the corporate and affiliate level and has been consultant since 2008. During her consultancy career, Natasa has worked with big pharma as well as, a number of small and medium sized companies with headquarters in the USA, UK, Sweden, France, Spain, Belgium, Italy, Germany, India and Japan. She has been auditing since 2005 and conducted over 230+ audits and have +540 days auditing experience of headquarters, affiliates, licensing partners, PV processes and PV service providers in the EU, US, Middle East, Central and South America, Asia and Australia. Natasa has taken part in the multiple regulatory pre-inspections and inspections (including EMA, FDA, Swedish, French, German, Croatian, Turkey, Hungarian Regulatory Authority and number of MHRA inspections).

In 2008, Natasa has established NostraPharma Ltd. NostraPharma Ltd is a group of the independent Senior Consultants each with 20+ years' experience, knowledge, and potential to provide a variety of PV and quality services. NostraPharma Ltd specializes in GVP/GCP remote and process audits and focuses on setting up and improvements of PV quality systems, QPPV office including PSMF maintenance, inspection readiness and gap analysis.

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:
  - Identify the PV activities and processes subject to PV audit
  - Identify the PV audit universe – entities subject to PV audit
  - Categorize the entities subject to PV audit
  - Develop risk assessment criteria specific to PV areas
  - Perform risk assessments
  - Develop a high-level PV audit strategy
  - 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

COURSE DESCRIPTION

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 has to cover all PV processes and tasks undertaken by or delegated to other departments, Marketing Authorization Holder affiliates, and third parties such as distributors, external service providers, licensing partners. In other words, has to cover all PV Universe. The PV Audit Strategy Plan is used to prepare the PV audit program, i.e. annual PV Audit Schedule. Using risk-based approach to develop an audit strategy, companies can conform to the regulatory requirements and business needs. But the questions remain: How to do it? Where to start? How to improve? What are the best industry practices?

In this two day workshop, we will review the legal GVP requirements (predominantly European, FDA and Arab League) regarding risk-based audits of the PV system and quality system. The course will focus on

- The design of the PV audit strategy and tactical PV audit plan/schedule.
- Identification of the PV processes and entities subject to PV audit (understanding how to define the PV audit universe)
- Development of risk assessment methodology for various aspects of PV world (for instance computerized systems, market research, patient support programmes, vendors, processes etc)
- Development of procedures/tools to monitor PV processes and activities, and implementation of the PV audit strategy plan.

AGENDA

Day 1 (8:30 AM – 4:30 PM)

- **8:30 – 9:00 AM: Registration**
- **9:00 AM: Session Start Time**
- Review legal requirements for risk-based PV audits
- The pharmacovigilance system and the quality system
- Identifying PV audit universe - all entities subject to PV audit, such as
  - Pharmacovigilance (PV) Agreements
  - Computerized systems
  - Market research/ patient support programmes
  - Vendors/ service providers
  - PV activities and critical PV processes
  - MAH affiliates
- Risk assessment criteria
- Strategic level PV audit planning
- Hands on exercise
- Q & A

Day 2 (8:30 AM – 4:30 PM)

- Categorization of the entities (PV Audit Universe)
- Prioritization of entities for audit according to relative risk
- 3-5 year PV audit plan
- Procedural documents supporting PV audits and common gaps
- Identify procedures/tools to monitor PV quality for oversight of third parties
- Hands on exercise
- Q & A

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 Form

Registration Information:

Register Online. Click Here Use your American Express, Visa or MasterCard.
Get your group to attend the seminar at a discounted price call +1-201 871 0474.
Call 201 871 0474 or Fax your PO: 253 663 7224 Pay your check to "PMA Conference Management" and Mail the check to: PMA PO Box 2303, Falls Church VA 22042. Please fill this form with attendee details and payment details and fax it to 253 663 7224

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ 201 871 0474 or email us @ register@pmaconference.com

Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $300 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($300) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: The Risk-Based Approach to Pharmacovigilance Audits - A Practical Approach to Design and Implementation

Date & Location: April 20-21, 2020 DoubleTree by Hilton Hotel San Francisco Airport, 835 Airport Blvd., Burlingame, CA, 94010

Attendee Details: Registration: $1899.00

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization .....

.....

Address .....

.....

City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

Payment Options

☐ Check enclosed,

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

Signature .....
(Signature required on credit card and bill-me orders.)

Print name.....

☐ Bill me/my company $ .....

Purchase order # .....

(Payment is required by the date of the conference.)
Please fill this form with attendee details and payment details and fax it to 201 871 0474