EU GVP: SAFETY PROFILE WITHIN A GOOD PHARMACOVIGILANCE SYSTEM

9-10 April, 2019
Riga, Latvia
Lecturer: Dr. Irene Fermont

Learning Objectives

- **Comply with EU and international regulation**
- **Review all processes focused on safety profile**
- **Understand the Risk Management approach**
- **Coordinate and generate PSUR and RMP**
- **Standard Operating Procedures (SOPs) according to GVPs requirements**

"An amazing experience to participate in training course led by experienced and knowledgeable expert in the field of pharmacovigilance and regulatory affairs, providing so many examples and hints regarding preparation for audit and inspection."

Medical Advisor / Medical Scientifical,
Novartis Consumer Health Services S.A.

Please note that the number of places is strictly limited

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EU GVP: SAFETY PROFILE WITHIN A GOOD PHARMACOVIGILANCE SYSTEM

Two-day Training Course

Performance & Knowledge Objectives

- Expand your global safety knowledge
- Learn to apply the legislation for ensuring compliance
- Comply with EU and international regulation
- Understand the Risk Management approach
- Standard Operating Procedures (SOPs) according to GVPs requirements
- Set up and follow up CAPA – (Corrective Actions, Preventive Actions)
- Use the PV System Master File
- Review all processes focused on safety profile

Who Should Attend?

This course is valuable to professionals in drug safety with at least two years of experience, who wish to update their skills and enhance their knowledge by in-depth analysis of practical challenges and learn to implement solutions within ever changing pharmacovigilance environment:

- Pharmacovigilance Professionals
- Regulatory Affairs Specialists
- Drug & Product Safety Associates
- Clinical Safety Specialists
- Clinical Trials managers
- Medical Directors

Your Distinguished trainer

Dr Irene Fermont

IFC Founder and Director
ISOP ISRAEL Chairman

Founder and coordinator at Israeli Chapter of the International Society of Pharmacovigilance.
A 20 years of experience in the field of Pharmacovigilance and Risk Management, with creation of a large number Pharmacovigilance departments /systems, either in industry or as a service provider.
Long dedication to training and education leading to the creation of the ISOP ISRAEL Chapter (International Society of Pharmacovigilance), coordinator of Advisory Board.
A two fold education, as physician specialised in Immuno -Haematology, and a Master in Bioengineering.

In-House Training

Would you like one of our training courses delivered at a time and location to suit you? Would you like us to develop a course to meet your Team's requirements? Address your Team's specific needs with a tailored training approach!

Our in-house training can provide you with the flexibility you need whilst providing value for money. There are several options available if you wish to access our in-house training:

1. **Off the shelf:** choose from our range of available programs
2. **Tailored:** have one of our current courses tailored to suit your programme's specific needs
3. **Find solutions** to real problems by incorporating your own case studies and examples
4. **Bespoke:** let us develop and deliver the course unique to You, based on the analysis of Your requirements

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For more details or initial consultation, please contact our Training Specialists Team

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Two-day Training Course Agenda

Pharmacovigilance through GVP and EMA's system changes

This course is an intensive two days pharmacovigilance training course. Two modules of one day will address the major aspects of Pharmacovigilance according to the EU Good PharmacoVigilance Practices (GVP) recommendations. The course will review all processes which are directly linked to the continuous assessment of the product safety profile. A key concept is common to all processes: the proactive approach of risk management, from the individual case assessment to the periodic safety update report (PSUR).

The course will elaborate on how these changes will affect the day-to-day pharmacovigilance operations within the pharmaceutical companies with practical examples, which will be based on real life situations regarding electronic transmissions, signal management and organizational aspects affected by new draft GVP modules and the EMA's system changes. The GVP not only give us the main objectives and methods for analysing the safety profile but also provide accurate and practical recommendations on "how" to reach these objectives.

DAY ONE

Analyzing Products Safety Profile through all processes

- The key concept of risk management and risk minimisation
- Detailed review of all GVP related to safety profile and benefit risk analysis:
  - **Risk Management Plan** (main sections review and case studies) - Risk identification and classification; target patients epidemiology; PAESS; Examples of Prevention/minimisation actions and effectiveness
  - **Individual Case Safety Reports – ICSR (Adverse Drug Reactions)** - Hands on:from receipt to submission; case assessment: company comment; organising Literature review for ICSR; main differences between ICSR Post Marketing and Clinical Trials.
  - **PSUR (Periodic Safety Update Report)** - Sections overview; coordination between the different units for data retrieval; link between all aggregate data reports: PSUR/DSUR/RMP; link with signal detection.
  - **Signal detection and management**- Sources of signal; process to set up; signal management.
  - **Misuse and medication errors: identify; prevent**
  - **Wrap up:** Recommendations and practical tips
- The course will include practical aspects and case studies of Adverse Drug Reactions (ICSR) processing, PSUR, and RMP.

DAY TWO

Organising a Pharmacovigilance System with a Quality Plan

- Overview of the Pharmacovigilance system
- The virtuous circle of Quality
- The Pharmacovigilance System Master File: the very tool for inspection
- Audits organisation GVP Module IV (Audit Plan and audit program, CAPA)
  - **Audit Plan and audit program**
  - **Methodology**
  - **CAPA**
  - **Follow up**
- Inspections: Good Pharmacovigilance Practices (GVP) Module III
  - **What triggers inspections in EMA?**
  - **Methodology**
  - **Getting ready for inspection and follow up**
  - **UK MHRA: examples of findings**
- How much does it apply for Clinical Trials?
- The course will include practical examples.

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For more detailed information, please contact our Training Specialists team

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Dates: 9-10 APRIL, 2019
Venue: **Inpharmatis Riga Headquarters**

5 EASY WAYS TO REGISTER

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I would like to participate for:

Tick	Date	Course	Full price	VAT	Total Price
☐	9-10 April, 2019	EU GVP	1495.00 Euro	21%	1808.95 Euro

Information about participant:

First Name	Company Name
Last Name	Company Address
Job Title	
Mobile No.	Tel. number
Email	Billing address (if different)
Any special requirements	Reg. number
	VAT number

☐ I qualify for 100 Euro corporate discount for booking more than one participant per course
☐ I qualify for 100 Euro early bird discount by booking 6 weeks before the course

☐ I would like to receive information about future events and services

Interest Form

Tick the topics that might be of your interest

☐ Parallel Import	☐ Pharmacovigilance Strategy
☐ Advanced GDP & Serialisation	☐ Strategy in Drug Regulatory Affairs
☐ Introduction to RA in EU	☐ Intermediate Sales skills in Pharma
☐ Filing Variations in EU	☐ Advanced Sales skills in Pharma
☐ eSubmissions	☐ Food Supplements
☐ GDP	☐ Pharmalead Nova – mini MBA for pharma executives
☐ GMP	☐ In-house training
	☐ Other…

☐ *I hereby declare that I agree to the terms and conditions and that information supplied by me is correct*

CANCELLATIONS: Confirm your cancellations in writing 3 weeks before the date and receive a 50% refund. Customer may reschedule a booking to another date at a 100% rescheduling fee by advising Inpharmatis of such rescheduling in writing