Learning Objectives

- **Expand** your global safety knowledge
- **Apply** legislation to ensure compliance
- **Submit** compliant ADR data and avoid delays
- **Increase** the accuracy of your causality assessment
- **Prepare** for advanced crisis management control
- **Implement** e-Submission strategies for ADR tracking & reporting

“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 Scientific, Novartis Consumer Health Services S.A.

Please note that the number of places is strictly limited.
Pharmacovigilance Strategy
Two-day Training Course

Performance & Knowledge Objectives
- Expand your global safety knowledge
- Learn to apply the legislation for ensuring compliance
- Confidently submit ADR data to global regulators and avoid delays
- Ensure you build and maintain a quality Pharmacovigilance department ready for any inspection
- Enhance your Company’s capabilities and compliance
- Increase the accuracy of your causality assessment
- Be prepared for advanced crisis management control
- Prepare to meet MedDRA changes and reflect the change in your safety databases
- Implement e-Submission strategies for ADR reporting

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
- Medical Information Officers
- Clinical Safety Specialists
- Medical Affairs Specialists
- Data Management Officer

Your Distinguished trainer
Rina Irene Fermont
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

For more details or initial consultation, please contact our Training Specialists Team
Pharmacovigilance Strategy
Two-day Training Course Agenda

Pharmacovigilance through GVP and EMA’s system changes

This course is an intensive two days pharmacovigilance training course with focus on GVP guidelines. The course will elaborate from current and draft GVP guidelines and system changes from the EMA implemented during 2017.

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.

<table>
<thead>
<tr>
<th>DAY ONE</th>
<th>DAY TWO</th>
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<tbody>
<tr>
<td>Introduction and presentation of participants</td>
<td>Signal management in Pharmacovigilance</td>
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<tr>
<td>Overview of GVP</td>
<td>GVP Module IX</td>
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<td>Current and draft modules, timelines for implementation</td>
<td>Group work on signal management</td>
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<td>Quality Systems in GVP</td>
<td>Risk minimisation</td>
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<td>PSMF</td>
<td>RMP and PASS</td>
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<td>Inspection and audits</td>
<td>Prepare for change I</td>
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<td>Adverse reaction reporting, GVP Module VI</td>
<td>New EMA training</td>
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<td>Accessing Eudravigilance</td>
<td>Organizational considerations within the MAHs</td>
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<td>E2B from R2 to R3, impact in pharmacovigilance</td>
<td>Prepare for change II</td>
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<tr>
<td>Group work on R2 to R3</td>
<td>A global perspective and conclusions</td>
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<td>Periodic reporting</td>
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<td>GVP Module VII</td>
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Pharmacovigilance Strategy Course

Dates: 7-8 November 2018
Venue: Inpharmatis Riga Headquarters

I would like to participate for:

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<tr>
<th>Tick</th>
<th>Date</th>
<th>Course</th>
<th>Full price</th>
<th>VAT</th>
<th>Total Price</th>
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<tr>
<td></td>
<td>7-8.11.2018</td>
<td>PV</td>
<td>1495.00 Euro</td>
<td>21%</td>
<td>1808.95 Euro</td>
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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

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

Interest Form

Tick the topics that might be of your interest

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

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 Rephine Balticum of such rescheduling in writing.