The focus of this two days training will be on providing an update of ongoing activities regarding medicines’ risk and signal management. The first day will be an opportunity to provide the participants practical advice on RMP drafting and preparation as well the accessors point of view in evaluating an RMP. On the second day participants will have the opportunity to get an insight on the current signal detection and management guidelines and tools, as also on the EMA pilot phase using Eudravigilance Data Analysis System (EVDAS).
INTRODUCTION

The focus of this two days training will be on providing an update of ongoing activities regarding medicines’ risk and signal management. The first day will be an opportunity to provide the participants practical advice on RMP drafting and preparation as well the accessors point of view in evaluating an RMP. Moreover, the increasing number of biosimilars and biologicals being authorized highlighted a need to better streamline the safety specification for these products so that only risks that are important for risk management and relevant for the benefit-risk of the product are included in the RMP. Also, a dedicated section on the risk management aspects of the new GVP guidance on special populations such as children and elderly will be provided.

On the second day participants will have the opportunity to get an insight on the current signal detection and management guidelines and tools, as also on the EMA pilot phase using Eudravigilance Data Analysis System (EVDAS). Regarding signal management using EVDAS, a pilot phase including a limited number of active substances selected based on the list of medicinal products subject to additional monitoring is currently ongoing. During the signal management session, pragmatic approaches, lessons learned, as also processes for signal management and eRMR assessment will be discussed. Finally, during this training an outlook of current and future challenges in pharmacovigilance focusing on the impact of the coming into force of the General Data Protection (GDPR) Regulation in May 2018 will be given and discussed.

WHO SHOULD ATTEND?

- Individuals involved in risk management planning, risk minimisation development and post authorisation safety studies at small to medium enterprises (SMEs), MAAs / MAHs for generic products, MAAs / MAHs for innovator products and Contract Research Organisations (CROs)
- Risk communication experts
- Qualified Persons responsible for Pharmacovigilance (QPPVs)
- Individuals involved in pharmacovigilance, safety database, signal management and information management
Dimitris Zampatis, MSc, PhD, is an Associate Director, Signal and Risk Management Process at Merck Biopharma. He holds a BSc in Biology, a MSc in Medicinal Chemistry: Drug Design and Development and a PhD in Cell and Molecular Biology.

In his current role he is responsible for the development of the company’s benefit-risk assessment framework, the signal detection strategy e.g. quantitative and qualitative signal detection methods using internal and external databases (EVDAS, VigiBase, FAERS, VAERS, JADER) as also the Risk Management and risk minimization measures processes and implementation.

Through his career Dimitris gained substantial knowledge and experience in different aspects of Drug Safety and Pharmacovigilance such as Signal Detection, RMPs, PBRERs/PSURs, DSURs, safety communication (e.g. Direct Healthcare Professional Communication/Dear Investigator Letter). He participated in various successful FDA and EMA submission applications either as a team member or as team leader. Dimitris is also a Pharmacovigilance tutor and trainer and participates in various conferences as a speaker.
<table>
<thead>
<tr>
<th>Time</th>
<th>Day 1</th>
<th>Day 2</th>
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<tbody>
<tr>
<td>09:00</td>
<td><strong>EU guidelines on risk management: some background</strong></td>
<td><strong>EU Guidelines on Signal Management-background</strong></td>
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<tr>
<td>10:00</td>
<td><strong>RMP structure and compilation</strong></td>
<td><strong>Authorities expectation on Signal management</strong></td>
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<tr>
<td>11:00</td>
<td><strong>Coffee Break</strong></td>
<td><strong>Coffee Break</strong></td>
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| 11:15 | **Assessing RMPs and RMP quality indicators**  
  • GVP V rev.2– regulators and industry point of view of the implementation of the revised RMP template  
  • Update on new GVP guidelines for special populations (Paediatrics, elderly, Pregnancy and breastfeeding) | **Signal management and inspections**  
  • Good Pharmacovigilance Practice Module IX on Signal Management (MAH perspective) |
| 12:15 | **Effective risk communication (HA, patient and MAH perspectives)**  
  • Risk communication and measures | **Performing Signal Detection (examples and best practices)**  
  • Tools to support signal detection and validation in EudraVigilance |
| 13:00 | **Lunch Break** | **Lunch Break** |
| 14:00 | **Handling of Risk Minimization measures** | **Data mining using regulatory databases**  
  • Communication of signals to the regulatory authorities |
| 14:45 | **RMP for Biosimilars and biologicals**  
  • Identifying and describing the safety concerns for biologicals and biosimilars | **Signal detection in EVDAS (eRMR analysis, generis and innovative products)**  
  • Processes for signal management and eRMR assessment |
| 15:30 | **Coffee Break** | **Coffee Break** |
| 15:45 | **RMP for special populations (pediatrics, elderly and pregnant women)** | **MAH experience in EVDAS (lessons learned)**  
  • MAH involvement in signal detection and management |
| 17:00 | **End of day 1** | **GDPR in Pharmacovigilance-what is new for MAHs?**  
  • How does GDPR impact Drug Safety |
| 17:30 | | **End of day 2** |
## Upcoming Events

### FINANCIAL EVENTS
- Advanced RBA MasterClass
  - September 2020
- IFRS9 MasterClass
  - September 2020
- Initial Margin Regulation 2020 MasterClass
  - October 2020
- Digitalization in Banking
  - October 2020
- PSD2 MasterClass
  - October 2020
- Internal Audit Summit 2021
  - March 2021
- Supply Chain Management Conference
  - May 2021
- 7th Annual Credit Risk Management Forum
  - May 2021
- 9th Annual Retail and Corporate Payments Forum (BizzPay 9.0)
  - May 2020

### PHARMACEUTICAL EVENTS
- LifeScience Micro MBA MasterClass
  - August 2020
- Risk and Pharmacovigilance MasterClass
  - August 2020
- Risk & Pharmacovigilance MasterClass 3.0
  - June/August 2020
- CMC Biopharma 2.0 MasterClass
  - June/August 2020
- Development of generics: From R&D to GMP MasterClass
  - September 2020
- Digitalization in Pharma 2021
  - March 2021

### HEALTH AND SAFETY EVENTS
- Advanced Human Error MasterClass
  - August 2020
- European HSE Management Forum 5.0
  - October 2020
- MBA for HSE Practitioners MasterClass
  - November 2020
- HSE360 Summit 2021
  - February 2021
- European HSE Management Forum 6.0
  - September 2021

### HUMAN RESOURCES EVENTS
- Agility in HR
  - October 2020
- Advanced Organisation Design MasterClass
  - November 2020
- Advanced Compensation and Benefit MasterClass
  - September 2020
- Personal Effectiveness Tools MasterClass
  - September 2020
- 15th HR Minds TalentON Forum – October 2020
  - October 2020
- HR Minds Forum – September 2021
  - September 2021

### CROSS INDUSTRY EVENTS
- Situational Leadership MasterClass
  - October 2020
- Women in Leadership Summit
  - September 2020
- Coaching MasterClass
  - October 2020
- Machine Learning MasterClass
  - September 2020
- Climate Risk Financing MasterClass
  - September 2020
- Oil & Gas Digitalisation MasterClass
  - September 2020
- Audit Summit 2020
  - March 2021
- Agile Workplace Design
  - May 2021
- Supply Chain Management Forum
  - May 2021

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## About GLC

Global Leading Conferences (GLC) is an industry leader in the field of business intelligence. We provide interactive & impactful business platforms and networking opportunities for senior level executives by bringing them together for B2B Conferences, Global Summits, Training & Workshops. Being customer focused and having our client’s priorities at the forefront, are amongst our core values and is of high importance to the way we operate our business.

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- No travel or logistic expenses for the team (we deliver it at your facilities)
- Maximize ROI with a depth tailored content accordingly to your corporate needs
- 360 degrees GLC Learning experience – Individual pre-questionnaire for each participant, several case studies and post training diagnose with participants
- Maturity assessment for the team during the preparation of the course

Contact us for more information and tailored details: booking@glceurope.com