Advanced Regulatory Affairs in EU Course

Dates: 13 – 14 October 2016
Venue: Rephine Balticum Riga Headquarters

5 EASY WAYS TO REGISTER

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Suite 2, 34a Dzirnavu Street
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I would like to participate for:

Tick	Date	Course	Full price	VAT	Total Price
☐	13-14.10.2016.	Advanced RA	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

☐ Advanced EU Regulatory Affairs	☐ 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
☐ Parallel Import	☐ 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 Rephine Balticum of such rescheduling in writing

Advanced Regulatory Affairs in EU Course

13 – 14 October 2016
Riga, Latvia

Learning Objectives

- **Exploring** and assessing current European legislation and identifying common problems
- **Examining** the pros and cons of the globalisation of regulatory affairs
- **Determining** the role of the Regulatory Affairs Manager
- **Successful** strategies to ensure compliance with current regulatory affairs
- **Avoiding** the pitfalls of new European regulations
- **Developing** and maintaining labelling strategies to conform with the regulatory affairs of your target market

"Thank you so much Rephine Balticum team. I really learned how to solve problematic issues that I'm facing in my daily work."

Regulatory Affairs Specialist, Sandoz

Please note that the number of places is stricly limited
Do not miss your opprotunity to register with Early Bird discount till 1 September 2016

Suite 2, 34a Dzirnavu Street, Riga ☎ +371 67 210 500 registration@rephinebalticum.com www.rephinebalticum.com

Advanced Regulatory Affairs

Two-day Training Course

Performance & Knowledge Objectives

- Gain advanced tools necessary to optimise and maintain your regulatory procedures
- Latest changes in legislation
- Facilitate improvement in your review and maintenance procedures
- Improve your day-to-day management of regulatory affairs
- Identify common problems and solutions through open discussions
- Tackle the challenges of type II Variations under the MRP/DCP/CP

Who Should Attend?

Anyone working within the field of regulatory affairs at management level or above:

- Regulatory Affairs Manager
- Strategy Management
- Regulatory Affairs Officer
- Quality Manager
- Regulatory Affairs Specialist
- Regional Coordinator
- Regulatory Affairs Associate
- Development Pharmacist
- Pharmacovigilance Manager
- Regulatory Affairs Attorney
- Regulatory Affairs Executive
- Project Managers

Your Distinguished Trainers

Mr. Remco Munnik – Director of Asphalion S.L., Spain.

As the Regulatory Information Director Mr. Munnik is responsible for all Regulatory Affairs projects at Asphalion S.L., Barcelona. He has over fifteen years of experience in regulatory affairs procedures in EU (CP/MRP/DCP) and FDA (IND/NDA/ANDA/DMF), electronic submission and regulatory data management (xEVMPD and ISO IDMP). In addition Remco is the chairman of an EU Industry working group for eCTD and ISO IDMP implementation and in direct contact with the EU authorities. He has been a member of the TIGes for 7 years and involved in the implementation of: eCTD roadmap, eCTD/NeeS validation criteria, eAF, CESP, EMA Gateway, xEVMPD and ISO IDMP.

Lidia Cánovas, MBA, MPharm.

Lidia has over 30 years experience in Pharmacovigilance and Regulatory Affairs field. After almost 15 years of working in senior role in Menarini Group, Lidia has joined one of the largest and most successful in the world regulatory and pharmacovigilance consultancies as the General Manager of Operations. Lidia's extensive experience in European pharmacovigilance affairs is unquestionable. Besides her daily hands-on experience in solving complex pharmacovigilance issues for Asphalion clients in EU, America and MENA region, Lidia has been involved in teaching for more than two decades and is known to be a highly interactive and efficient trainer, delivering practical and implementable work strategy solutions in her intensive training classes.

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 Rephine Balticum Training Specialists Team

Advanced Regulatory Affairs

Two-day Training Course Agenda

DAY ONE

Review European Regulatory Affairs legislation

- Managing new strategies based on the changes to European regulatory affairs
- Understanding the new regulatory procedures

What's new in Regulatory Affairs?

- Understanding the impact of new regulatory affairs for new products
- What is the impact for Generics?
- Interpretation of new guidelines
- Developing a compliance strategy for the new regulatory affairs
- What is the impact of new regulation on globalisation
- How to ensure compliance with Paediatrics regulatory affairs

Role of Regulatory Affairs Management

- Management of all European procedures
- Managing the development and regulations of:
- Current products
- New products
- Ensuring effective and efficient system maintenance
- Understanding the needs and benefits of a robust staff training system

Review procedure for CTD & eCTD !

- Review of CTD for global regulations
- Review of module sections
- Review writing patient/physician's information
- The importance of harmonisation
- Summary of modules 3 to 5
- The impact of eCTD on CTD
- An efficient transfer of regulatory information

Review procedure for CTD & eCTD (continued)

- Review of the five modules
- Administrative information and prescribing information
- Common Technical Document summaries
- Optimising the effectiveness of your quality systems
- Non clinical study reports
- Clinical study reports
- Review of the eCTD specifications

DAY TWO

Pharmacovigilance

- Pharmacovigilance regulations
- Risk assessments to ensure compliance with pharmacovigilance regulations
- Successful strategies for monitoring risk
- Meeting the challenges of due diligence
- Benefits vs. risk
- Proven therapeutic value of a product
- Probability of harm being caused by the product
- The impact of drug efficacy in pharmacovigilance
- Risk management reviews
- The impact of a poor pharmacovigilance system

Ensuring compliance with current labelling regulation

- What's new in European labelling regulations
- Medical and pharmaceutical labelling
- Braille – compliance with current regulatory affairs
- Traceability

Interaction of regulatory affairs and manufacturing

- The principles and guidelines for GMP
- Harmonisation and co-ordination of GMP
- GMP implementation for dossier
- The role of regulatory agencies
- Control of quality standards
- Consequence of change to European and non-European regulations

Advanced product lifecycle management

- Compliance management
- Life-cycle management
- Product Data Management (PDM)
- Product and portfolio management
- Strategic analyses of product life cycle management

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