Essentials of EU Regulatory Intelligence
Virtual Live Training Course

27-28 April 2021 09:00-12:30 CEST

OVERVIEW

This virtual live training course intends to provide an overview of key aspects of regulatory intelligence. Participants will have a hands-on experience in identifying the most reliable and valuable sources of information, monitoring selected sources, assessing the impact of new requirements on the company's business and adapting the way of communicating key intelligence to the needs of internal stakeholders.

Regulatory Intelligence has been defined by DIA as "the act of gathering and analyzing publicly available regulatory information (…) including communicating the implications of the information, and monitoring the current regulatory environment for opportunities to shape future regulations, guidance, policy, and legislation." These aspects are more important than ever to keep track of the global regulatory environment that is constantly changing with new science, new unmet needs new technical advances (e.g. Artificial Intelligence). Mastering intelligence skills is critical for any full-rounded regulatory professional and is part of needed skills that make an R&D professional proficient.

This course intends to provide a comprehensive and focused teaching experience to professionals that are interested in developing regulatory intelligence skills and possibly even specializing in that field. It will focus on the EU environment and its key stakeholders such as the EMA and the European Commission and will explore the sources and types of available information that can support regulatory strategies and wider R&D discussions. It will be hosted by the EU Regulatory Intelligence Network Group (EU RING), an informal group of industry regulatory intelligence professionals based in Europe with a wealth of experience.

LEARNING OBJECTIVES

At the conclusion of this course, participants will be able to:
- Correctly identify current key aspects related to the monitoring, impact assessment and internal communication of EU regulatory intelligence
- Successfully navigate relevant sources of information and refine their regulatory intelligence skills
- Better understand the strategic value of regulatory intelligence

WHO WILL ATTEND

Any regulatory professionals interested in updating their knowledge on public information and EU sources to help their regulatory strategies.

New entrants in the regulatory profession or in regulatory intelligence are also welcomed.

FACULTY

Bertrand Fournier
Director
Regulatory Policy & Intelligence
Shionogi, The Netherlands

Denis Burkhalter
Regulatory Intelligence Manager
Novartis Pharma AG, Switzerland

Bettina Doepner
Global Lead Regulatory Intelligence/Policy
CSL Behring GmbH, Germany

João Duarte
Associate Director
Chief of Staff and Regulatory Science
Alexion Pharmaceuticals, France

KEY TOPICS

- Regulatory Intelligence
- Regulatory Affairs
- Impact Assessment
- Compliance
- Knowledge Management

DAY 1

09:00 SESSION 1

INTRODUCTION TO REGULATORY INTELLIGENCE
Mission, organisation and value of the Regulatory Intelligence function in a pharmaceutical company

10:00 SESSION 2

MONITORING/COLLECTION OF INFORMATION
- Overview of the various sources/types of information and different ways to collect it (Push vs. Pull models)
- Collaboration between corporate RI function and local stakeholders

11:00 BREAK

11:15 SESSION 3

CURATION OF INFORMATION/IMPACT ASSESSMENT
- Assessment of the relevance
- Time-sensitivity and impact of information on the company's processes and business

11:45 SESSION 4

CASE STUDIES 1
Interactive session on practical case studies (point of view of several RI professionals on key topics)

12:30 END OF DAY 1

DAY 2

09:00 SESSION 5

COMMUNICATION/DISSEMINATION
Analysis of the strengths and weaknesses of the different media available for dissemination of the information (Newsletters, Intranets, Social media…)

09:45 SESSION 6

CASE STUDIES 2
Interactive session on practical case studies (point of view of several RI professionals on key topics)

10:30 BREAK

10:45 SESSION 7

KNOWLEDGE MANAGEMENT
Discussion on how to store curated information and how to integrate Hard Intelligence and in-house Soft Intelligence

11:30 SESSION 8

REGULATORY DATA ANALYTICS: CAN TECHNOLOGY TAKE IT ONE STEP FORWARD?

12:15 QUESTIONS AND ANSWERS

12:30 END OF THE VIRTUAL TRAINING COURSE

| Group Discounts

Register 3 individuals from the same company and receive complimentary registration for a 4th!

- All 4 individuals must register and prepay at the same time – no exceptions
- DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership
- You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and does not apply to the already discounted fees for government or charitable nonprofit/academia.

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

| Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

Operating Systems

- Windows: XP 32-bit (SP3), 2003, Vista 32-bit/64-bit, Windows 7 32-bit/64-bit
- Mac OS X: 10.5, 10.6, 10.7
- Linux: 32-bit Ubuntu 10.x,11.x 32-bit Fedora 15/16, 32-bit Red Hat 5/6, 32-bit OpenSuSE 11.4

Minimum System Requirements

- Windows: Processor – Requires Sun Java 5 or higher, Recommend ActiveX be enabled for Internet Explorer
- Mac OS X: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access
- Linux: Processor – JavaScript and cookies enabled, Requires Apple Java 5 or higher, No support for Remote Access

Browsers

- Windows: Internet Explorer 6, 7, 8, 9, (Win7 Only), Firefox latest (32-bit), Chrome latest
- Mac OS X: Safari 4-Mar; Firefox 2/3/3.5
- Linux: Mozilla 1.7, Firefox 2/3/3.5

Internet Connection Speed

- Windows: Intel or AMD processor (1GHz or faster), At least 512 MB RAM (at least 2 GB RAM for Vista)
- Mac OS X: Intel processor, At least 512 MB RAM
- Linux: At least 512 MB RAM

Display

- 800x600 pixel resolution or greater (1024x768 pixels recommended).

| Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@DIAglobal.org.

| Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 5 credits.

SwAPP | Swiss Association of Pharmaceutical Professionals

| About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

REGISTRATION FEES

Registration fee includes full admission to virtal live course and electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER EARLY- BIRD valid until 2 March 2021	MEMBER valid from 3 March 2021	NON-MEMBER
INDUSTRY (OR REPRESENTATIVE)	€ 720.00 ❑	€ 800.00 ❑	€ 985.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 400.00 ❑	€ 585.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.			

All registration fees will be subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership**.

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CET. Tel. :+41 61 225 51 51

Email: Basel@DIAglobal.org Mail: DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

TERMS AND CONDITIONS

Cancellation Policy
All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording
If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click here.

Privacy Policy
DIA respects the privacy of all of its members and customers. To view our privacy policy, click here. You agree that your personal data will be transferred to DIA in the US.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name
_____

First Name
_____

Job Title
_____

Company
_____

Address
_____

Postal Code
_____

City
_____

Country
_____

Telephone Number
_____

Attendee email required for course material access
_____

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ Please charge my ❑ VISA ❑ MC ❑ AMEX

Card N° ⬜⬜⬜⬜⬜⬜⬜⬜⬜⬜⬜⬜⬜⬜⬜⬜

Exp. Date ⬜⬜ / ⬜⬜

Cardholder's Name _____

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID #21541 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. If you have not received your confirmation within five working days, please contact DIA.

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature