DIA LEARNING

EU Regulatory Intelligence

1-2 October 2024 | 13:00-17:00 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 virtual live training 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

Doerte Braumann
Senior Manager, Regulatory Policy & Science
Bayer Consumer Care AG, Pharmaceuticals, Switzerland

Bertrand Fournier
Senior Director, Regulatory Policy and Intelligence
Shionogi, Netherlands

Kasia Nowok
Regulatory Intelligence Lead EU
UCB, United Kingdom

Iain Todd
Regulatory Policy & Intelligence Executive
GSK, United Kingdom

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

DAY 1

13:00 WELCOME AND INTRODUCTION OF FACULTY AND PARTICIPANTS

13:30 SESSION 1

INTRODUCTION TO REGULATORY INTELLIGENCE

Bertrand Fournier

Mission, organisation and value of the Regulatory Intelligence function in a pharmaceutical company.

14:30 SESSION 2

MONITORING AND COLLECTION OF INFORMATION

Doerte Braumann and Kasia Nowok

- Overview of the various sources/types of information and different ways to collect it (Push vs. Pull models)
- Deep Dive: Product / disease area related regulatory intelligence

15:30 BREAK

15:45 SESSION 3

CURATION OF INFORMATION AND IMPACT ASSESSMENT

Doerte Braumann

- Assessment of the relevance
- Time-sensitivity and impact of information on the company's processes and business

16:15 SESSION 4

CASE STUDY 1

Iain Todd and Kasia Nowok

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

17:00 END OF DAY 1

DAY 2

13:00 SESSION 5

EFFECTIVE COMMUNICATION STRATEGIES FOR REGULATORY INTELLIGENCE

Iain Todd

Analysis of the strengths and weaknesses of the different media available for dissemination of the information (Newsletters, Intranets, Social media...).

14:00 SESSION 6

CASE STUDY 2

Bertrand Fournier and Doerte Braumann

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

15:00 BREAK

15:15 SESSION 7

REGULATORY INTELLIGENCE SYSTEMS: CURRENT AND FUTURE STATES

Iain Todd

This session will cover the future of regulatory intelligence, including the use of smart systems, artificial intelligence and data analytics to enhance the work of the RI professional.

16:15 QUESTIONS AND ANSWERS

17:00 END OF THE TRAINING COURSE

Group Discounts

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

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.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

Customized Professional Development for Your Team

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

Or explore eLearning to allow self-paced learning.

For more information please contact tereza.krucka@diaglobal.org

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

Technical Requirements

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

For further information on system requirements, please visit the website:
https://www.diaglobal.org/General/System-Requirements

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 6 credits.

SwAPP

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

REGISTRATION FORM

EU Regulatory Intelligence Virtual Live Training Course # 24540
1-2 October 2024 | 13:00-17:00 CEST

REGISTRATION FEES

Registration fee includes full admission to virtual course, 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 6 Aug 2024	MEMBER valid from 7 Aug 2024	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 900.00 ❑	€ 1'000.00 ❑	€ 1'260.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 500.00 ❑	€ 760.00 ❑
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 are 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 CE(S)T. **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 https://www.diaglobal.org/general/photography-policy.

Privacy Policy
DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

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 METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

Payments will be net of all charges and bank charges will be borne by the payer.

If you have not received your confirmation within five working days, please contact basel@diaglobal.org.

By signing below, I confirm that I read and agree with DIA's Terms and Conditions of booking.

These are available from the office or online by clicking:

http://www.diaglobal.org/EUterms

Date	Signature