

Essentials of EU Regulatory Intelligence

Face-to-Face Training Course

28 March 2022, 09:30-18:00 CEST

Square Brussels Convention Centre, Belgium



OVERVIEW

This face-to-face 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

Doerte Braumann

Senior Manager, Regulatory Policy & Intelligence EU
Bayer Consumer Care AG, Pharmaceuticals
Switzerland

Bertrand Fournier

Director, Regulatory Policy & Intelligence
Shionogi BV
Netherlands

Benedetta Polsinelli

EU Regulatory Intelligence Lead
F. Hoffmann-La Roche Ltd
Switzerland

Iain Todd

Regulatory Policy & Intelligence Executive
Glaxosmithkline
United Kingdom

KEY TOPICS

- Regulatory Intelligence
- Regulatory Affairs
- Impact Assessment
- Compliance

09:30 REGISTRATION

10:00 SESSION 1

INTRODUCTION TO REGULATORY INTELLIGENCE

Bertrand Fournier

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

11:00 SESSION 2

MONITORING AND COLLECTION OF INFORMATION

Doerte Braumann and Benedetta Polsinelli

- 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

12:00 BREAK

13:00 SESSION 3

CURATION OF INFORMATION AND IMPACT ASSESSMENT

Doerte Braumann and Benedetta Polsinelli

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

13:30 SESSION 4

CASE STUDIES 1

Doerte Braumann, Benedetta Polsinelli, Bertrand Fournier and Iain Todd

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

14:15 SESSION 5

COMMUNICATION AND DISSEMINATION OF INFORMATION

Iain Todd

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

15:00 SESSION 6

CASE STUDIES 2

Doerte Braumann, Benedetta Polsinelli, Bertrand Fournier and Iain Todd

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

15:45 COFFEE BREAK

16:15 SESSION 7

REGULATORY DATA ANALYTICS

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.

17:15 QUESTIONS AND ANSWERS

18:00 END OF THE TRAINING COURSE

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

Group Discounts

Register 3 individuals from the same company for the same course 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.

| Course Venue

Square Brussels Convention Centre

Glass Entrance

Mont des Arts/Kunstberg

B-1000 Brussels

Tel: +32 2 515 13 00

Email: info@square-brussels.com

How to get there

Brussels Airport is a speedy 17 minutes by train from the Central Station, stopping at the European Institutions on the way. At peak times, 6 trains run every hour and from the Central Station, which is only three minutes walk to Square.

Hotel Information

Book directly, <https://secure.hotel.visitbrussels.be/event/dia-europe-2022/congress/search>, at one of the hotels within walking distance. Discounted room rates have been negotiated for you, availability secured.

For assistance, DIA partnered up with the Brussels Booking Desk, a local support of the Brussels' Hotel Community and visit.brussels.

Tel: +32 478 68 65 00

Email: w.nicolai@brusselsbookingdesk.be

Flight Information

DIA partnered with the Lufthansa Group to secure discounted flights! Do not miss out on this opportunity book your flight today!

The Lufthansa Group airlines bring people together - every day, all around the world. The global route network of Austrian Airlines, Lufthansa, SWISS, Brussels Airlines and Eurowings offers optimal connection and combination options, so you will benefit from quick and direct flights to the event.

You will reach the booking platform via link <https://www.lufthansa.com/de/en/meetings-and-events-delegates> and with the event code **CHZLDFH**. The reduced fares are automatically displayed.

Note: Please enable pop-ups permanently in your browser while booking, otherwise the window in the booking platform will not open.

Of course, you can also book through your IATA travel agency. The travel agency can request the ticketing instructions by sending an email to lufthansa.mobility@dlh.de, stating the

| Event Safety Code of Conduct

DIA is dedicated to providing a safe event experience for all participants and others involved, including attendees, sponsors, vendors, staff, exhibitors, employees, and contractors.

Given that the responsibility of a safe in-person event is shared among event organizers, event attendees, and all others involved, DIA has developed the following **Event Safety Code of Conduct*** for all participants to abide by. This document outlines rules and regulations for acceptable and expected behavior. If we all collectively respect these rules and promote the health and safety of everyone participating, we are advocating for the well-being of our fellow global citizens.

This Event Safety Code of Conduct is not intended to be a complete list of all rule and regulations applicable to a DIA meeting or event. DIA reserves the right to remove, or deny attendance to, any person who either: (i) violates, or is likely to violate, this Code of Conduct, or general health, safety, and well-being of other persons; or (ii) is disruptive and/or interferes, or is likely to disrupt or interfere, with the safe conduct of the meeting or event. All decisions shall be made in DIA's sole and absolute discretion, and shall be final.

* <https://www.diaglobal.org/General/Terms-and-Conditions?productIDs=9623835>

| Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 9.5 credits.



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REGISTRATION FORM

Essentials of EU Regulatory Intelligence #22541

28 March 2022, 10:00-18:00 CEST, Square Brussels Convention Centre, Belgium



REGISTRATION FEES

Registration fee includes full admission to course, breaks 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 31 Jan 2022	MEMBER valid from 1 Feb 2022	NON-MEMBER
INDUSTRY (OR REPRESENTATIVE)	€ 720.00 <input type="checkbox"/>	€ 800.00 <input type="checkbox"/>	€ 985.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 400.00 <input type="checkbox"/>	€ 585.00 <input type="checkbox"/>

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, Kuchengasse 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 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 #22541 as well as the invoice number to ensure correct allocation of your payment.

Please note: if you register 7 days or less before the start of the course, it is not possible to settle the registration fee by bank transfer, but only by credit card. Thank you for your understanding and cooperation.

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