DIA Learning

Global Regulatory Strategy: Regulatory Pathways to Drug Approval in Different Regions

13-14 June 2018
Mercure Paris La Défense Grande Arche Hotel, Nanterre/Paris, France

OVERVIEW

This intermediate course will provide participants practical real-world, actionable information on the nature and development of global regulatory strategies and drug development.

Descriptions of local regulatory environments and requirements for drug development will be enhanced by case examples from the greater European region, US, China, and Japan along with overviews of the ever changing regulatory environment in selected countries in Asia Pacific, Latin America, and Africa.

LEARNING OBJECTIVES

At the conclusion of this course, participants will be able to:

- Discuss building global drug regulatory strategies including how to develop one in the context of global project teams
- Compare the unique and diverse challenges of working within different regulatory environments, regulators, and cultures
- Determine the best ways of communicating effectively with drug regulatory authorities
- List key regulatory requirements for drug development and approval in selected global markets

Participants will engage in learning exercises during the course.

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

KEY TOPICS

- Global regulatory strategy considerations and construction
- Description of local regulatory environments and requirements for drug development in greater Europe, US, China and Japan
- Unique challenges in selected global markets
- Interactions with regulators in different global markets
- Europe, US, China and Japan regulatory strategic considerations
- Overviews of the rapidly changing regulatory environment in selected countries in Asia Pacific, Latin America, Russia and Africa

WHO WILL ATTEND

Pharmaceutical Professionals with an interest in global regulatory requirements in the areas of:

- Regulatory affairs
- Clinical development
- Research and development
- Project management
- Project managers

Level: Intermediate. Participants should have a basic knowledge and understanding of Regulatory processes.

FACULTY

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Senior Expert Drug Regulatory Affairs
Germany

Trine B Moulvad
Vice President, Regulatory & Pharmacovigilance
Zealand Pharma, Denmark

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:30 SESSION 1

CONSIDERATIONS AND REQUIREMENTS FOR GLOBAL REGULATORY STRATEGY DEVELOPMENT

- What is the meaning of global strategy today?
- International regional collaboration agreements incl. the role of WHO and ICH (nonclin, clin, stability/quality, inspections)
- Independent reviews versus reliance on other Agencies' review incl. CPP/ Country of Origin concept
- Target market identification
- How to link the EU/US strategy with the ROW strategy/-ies

09:15 SESSION 2

OVERVIEW OF EU, TURKEY AND MIDDLE EAST

- EU Regulatory Environment
- Approval, maintenance and market access for NCE and Generics
- Interaction with the Agencies (EMA, National Competent Authorities)

10:45 COFFEE BREAK

11:00 SESSION 3

OVERVIEW OF USA

- US Regulatory Environment
- Presence or not in the USA
- Developing new drugs: from IND to NDA
- Interactions with FDA

12:30 LUNCH BREAK

13:30 SESSION 4

OVERVIEW OF CHINA

- The Chinese Regulatory Environment
- Drug approval and maintenance
- Interaction with CDE and CFDA

15:00 COFFEE BREAK

15:15 SESSION 5

OVERVIEW OF JAPAN

- The Japanese Regulatory Environment
- Drug approval and maintenance
- Interaction with PMDA and MHLW

16:45 LEARNING EXERCISE

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

DAY 2

09:00 SESSION 6

OVERVIEW OF NORTH AFRICA, SOUTH AFRICA AND CIS COUNTRIES

- The Regulatory Environment
- Drug approval and maintenance
- Interaction with the national Authorities

10:00 SESSION 7

OVERVIEW OF ASEAN, INDIA, AUSTRALIA AND NEW ZEALAND

- The Regulatory Environment
- Drug approval and maintenance
- Interaction with the national Authorities

11:00 COFFEE BREAK

11:15 SESSION 8

OVERVIEW OF LATIN AMERICA

- The Latin American Regulatory Environment
- Drug approval and maintenance
- Interaction with the national Authorities

12:15 LUNCH BREAK

13:15 SESSION 9

COMMUNICATION WITH REGULATORS

- Optimising Meeting Opportunities
- Anticipating and Managing queries
- Culture and Communication
- Crisis Management and Issues Resolutions

14:00 SESSION 10

COSTRUCTION OF THE GLOBAL REGULATORY STRATEGY

- Strategy components
- Operational components

14:45 COFFEE BREAK

15:00 LEARNING EXERCISE

16:00 WRAP-UP AND CONCLUSION

16:30 END OF THE TRAINING COURSE

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

Plan Your Team's Professional Development

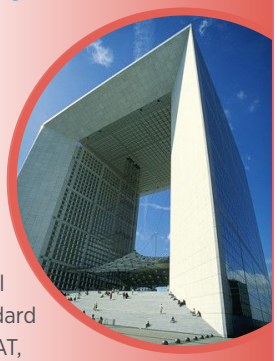
Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@DIAglobal.org.

Follow **@DrugInfoAssn**

Training Course Venue



PARIS LA DÉFENSE GRANDE ARCHE

17/20 Esplanade Ch. de Gaulle -
Rue des Trois Fontanot
92000 Nanterre (Paris region), France

Tel: +33 8 2580 5959
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Email: H1982@accor.com

DIA has blocked a limited number of hotel rooms at the rate of EUR 210.00 per standard room per night including breakfast and VAT, excl. City-Tax. If you would like to make a booking, please fill in the booking form available on DIA website and send it per email to aziza.elkharraze@accor.com with a reference "DIA".
Note: The hotel is located right above the train station, and it is a bit noisy.
The room rate is available until 10 May 2018 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE

From Charles de Gaulle airport take the Blue train line B towards city centre and get off at Chatelet.
Change there to Red train line A towards Cergy/Poissy/St. Germain en-Laye and get off at Nanterre Prefect.
The hotel is located right next to the train station.
Paris train/metro map (the Nanterre Prefect station/hotel is located just outside this map, left from the square A2)

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 13 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted 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 only available for the industry rate.

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 to DIA.

For groups of 5 or more individuals, please contact Basel@DIAglobal.org for a custom group rate.

REGISTRATION FORM

Global Regulatory Strategy # 18542
13-14 June 2018 | Mercure Paris La Défense Grande Arche Hotel | Paris, France

DIA Learning

REGISTRATION FEES

Registration fee includes refreshment breaks, lunches and electronic access to training course material. 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	NON-MEMBER
INDUSTRY	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑

All registration fees are subject to applicable French VAT

Please enter your company's French 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 non-member fees include a one year membership option. If you registered at one of the non-member rates, you have the opportunity to **become a DIA member** at no additional cost.

To explore membership benefits, please click here. If you want a membership, please indicate your preference below.

❑ **I would like to receive a one year complimentary DIA membership at no aditional cost**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. **Tel.** :+41 61 225 51 51 **Fax:** +41 61 225 51 52

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 Fax 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 #18542 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