**OVERVIEW**

Generics are becoming increasingly central in both industrialised countries and in developing countries, making their approval process a matter of utmost importance. This course will detail the overall requirements for generics including problems in relation to generic substitution and falsified medicines.

Participants will get an overview of the development and lifecycle and current landscape of new generic medicines both from a regulatory and development perspective, and learn about the different obligations of a pharmaceutical company versus an active substance manufacturer. European approaches to bioequivalence will be compared to FDA and WHO guidelines.

The course will be taught using a combination of presentations by the faculty and faculty-assisted group work. A significant amount of time will be devoted to working on case studies. Results from the working groups will be presented to the full audience.

**LEARNING OBJECTIVES**

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

- Differentiate the obligations of a pharmaceutical company from those of an active substance manufacturer
- Identify the key elements of the registration dossier for active substances and finished products, including the value of certification schemes
- Compare medicinal product requirements for generics to those of new drug products, and discuss the influence of ICH guidelines Q9 – Q11 on generics documentation
- Recognise the elements and the effects of the current EU guidance on bioequivalence and identify particularities of the EU bioequivalence guidance as compared to current US FDA and WHO recommendations
- Identify the key elements of the variations guideline and discuss the influence of formulation changes on the need for new bioequivalence testing

**WHO WILL ATTEND**

Representatives from governmental institutions, the generic pharmaceutical industry including, but not limited to:

- Regulatory affairs specialists and managers
- Development managers and experts
- Quality assurance managers and experts
- Assessors in regulatory authorities

*Level: Junior to intermediate*
DAY 1

08:30 REGISTRATION

09:00 SESSION 1
INTRODUCTION
- Fundamentals in the CMC area in a world of globalisation
- Status in the three focus areas – active substance, bioequivalence, and finished products/generic medicines
- Survey on the status of knowledge among course participants
- Setting up working groups of participants
- Course process: A mixture of lectures and group work on case studies

10:30 COFFEE BREAK

11:00 SESSION 2
ACTIVE SUBSTANCE MANUFACTURING INCLUDING OUTSOURCING
- Selecting a starting material and its justification
- Supply chain traceability
- Responsibility of the active substance manufacturer
- Responsibility of the pharmaceutical company
- Active substance manufacturer – inspections, supplier audits

Case study/Group work #1

12:30 LUNCH

13:30 SESSION 3
ACTIVE SUBSTANCE REQUIREMENTS
- Basic role of an active substance specification
- Solid phase characteristics
- Impurities

15:00 COFFEE BREAK

15:30 SESSION 3 CONTINUED
- Known and pharmacopoeial versus new substances
- Certification – by EDQM, by WHO

Case study/Group work #2

17:00 DRINKS RECEPTION

18:00 END OF DAY ONE

DAY 2

09:00 SESSION 4
FINISHED PRODUCT REQUIREMENTS
- Pharmaceutical development
- Quality by design and design space
- Basic role of medicinal product specification

10:30 COFFEE BREAK

11:00 SESSION 4 CONTINUED
- Stability testing requirements

Case study/Group work #3

12:30 LUNCH

13:30 SESSION 5
LIFECYCLE-MANAGEMENT
- Variations
- Extensions
- Renewals

Case study/ Group work #4

15:00 COFFEE BREAK

15:30 SESSION 6
BIOEQUIVALENCE, CURRENT EU GUIDANCE
- Basic principles
- Design of studies
- Pharmacokinetic parameters
- Analytical considerations

Case study/Group work #5

17:00 END OF DAY TWO

Continuing Education

SwAPP and SGPM Credits
DIA meetings and training courses are approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine) and are honoured with credits for pharmaceutical medicine. All meeting and training course participants are eligible for applicable credits and certificates are available on request from the DIA registration desk.

This training course been accredited with 16.5 credits.

DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

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.
DAY 3

09:00 SESSION 6 CONTINUED

- Acceptance criteria
- Biopharmaceutical classification system (BCS)
- Bio waivers – how to avoid the need for in-vivo testing

Case study/Group work #6

10:30 COFFEE BREAK

11:00 SESSION 7

OUTSOURCED BIOEQUIVALENCE TESTING

- Relationships and responsibilities CRO/pharmaceutical company
- Supplier audits

Case study/Group work #7

12:30 LUNCH

13:30 SESSION 8

GENERIC MEDICINES IN A GLOBAL CONTEXT

- Role of generic medicines in industrial countries versus developing countries
- Pricing and reimbursement
- Generic substitution
- Falsified medicines

Case study/Group work #8

15:00 END OF TRAINING COURSE

About DIA

DIA is a neutral, non-profit organisation founded in 1964 with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Over the past 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA’s scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: To improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members — regulators, researchers, industry professionals, advocates and patients — join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

Training Course Venue

Hotel NH Collection Berlin Friedrichstrasse
Friedrichstrasse 96
10117 Berlin, Germany
Tel: +49 30 206 26 60

DIA has blocked a limited number of hotel rooms for the course participants from 17 to 20 October 2016 (3 nights) at the rate of EUR 152.90 per superior double room for single use per night including breakfast, taxes and service charges, excluding City Tax.

In order to book a hotel room, please call the hotel directly and quote the booking reference “DIA”.

Tel: +49 30 2238 0233 | +800 0115 0116
E-Mail: reservierunoen@nh-hotels.com

The room rate is available until 12 September 2016 or until the room block is sold-out, whichever comes first.
REGISTRATION FORM
General CMC Regulatory Requirements in the EU and Bioequivalence for Generics # 16538
18-20 October 2016 | Hotel NH Collection Berlin | Berlin, Germany

REGISTRATION FEES
Registration fee includes refreshment breaks and lunches and electronic access to training course material. Please check:

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<thead>
<tr>
<th>FEES</th>
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<th>NON-MEMBER</th>
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<td>INDUSTRY</td>
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All registration fees are subject to the applicable VAT
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.

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All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

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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

email (Required for confirmation)  Attendee email (Required for course material access)

Cancellation Policy
All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa 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.

Photography Policy
By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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

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☑ 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 # 16538 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 Europe, Middle East and Africa.

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 _____________________________

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The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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