DIA Information Day and Interactive Hands-on Workshop on

The New European Medical Device Regulation: Change Management

29-30 November 2016
Austria Trend Hotel Savoyen, Vienna, Austria

OVERVIEW

This event will provide insight to the essential changes of the New Medical Device Regulation, such as the role of notified bodies and requirements in clinical and post-market requirements. Day One of the workshop will be dedicated to key updates to MDR (Information Day), and Day Two will focus on developing skills to apply these regulation updates to attendees' daily work (Interactive Hands-on Workshop).

Day 1: MDR Information Day - Attendees will learn from key experts on the differences and new requirements within the new MDR.

Day 2: Hands-On Application Workshops - Hands-On Application Workshops – Attendees will work through practical application scenarios of the new updates with key subject matter experts.

LEARNING OBJECTIVES

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

- Understand the differences between the previous and the new regulation
- Return to their organisation with practical examples of changes required in key job areas
- Implement the change management in their company

WHO WILL ATTEND

This event is designed for regulatory professionals e.g. medical device – industry and SME:

- QA/RA directors
- QA/RA managers
- Clinical trial managers
- Implementation project leads
- Product managers
- Safety officers

It is also aimed at pharma industry companies who want to enter this market and have to learn about the upcoming changes in the regulatory framework, trade associations, notified bodies, authorities etc., who would like to be updated on the changes and implications of the new EU Medical Device Regulation.

FACULTY

Sabina Hoekstra-van den Bosch
Lead for European Regulation
Philips Healthcare – Global Regulations & Standards, The Netherlands

Gert Bos
Executive Director & Partner
Qserve Group B.V., The Netherlands

Jos Kraus
Consultant on Joint Commission Int.
Academic Medical Centre, The Netherlands

Niels van Tienen
Project Manager
Factory – CRO for Medical Devices
The Netherlands

DIA DEVELOP INNOVATE ADVANCE

PharmaTrain MASTERING MEDICINES DEVELOPMENT

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INNOVATE. ADVANCE.

DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

DIAglobal.org

DAY 1

08:00 REGISTRATION

08:30 INTRODUCTION

09:00 SESSION 1

HIGHLIGHTS OF THE NEW MEDICAL DEVICE REGULATION
Sabina Hoekstra-van den Bosch, Philips Healthcare

10:30 COFFEE BREAK

11:00 SESSION 2

CHANGED ROLE FOR NOTIFIED BODIES UNDER THE NEW MEDICAL DEVICE REGULATION AND IMPLICATIONS FOR MANUFACTURERS
Gert Bos, Qserve Group

12:30 LUNCH

13:30 SESSION 3

CHANGES IN PRE- AND POST-MARKET CLINICAL REQUIREMENTS IN THE NEW MEDICAL DEVICE REGULATION
Niels van Tienen, Factory – CRO for Medical Devices

15:00 COFFEE BREAK

15:30 WORKSHOP 1

GAP ASSESSMENT, PORTFOLIO MANAGEMENT AND PLANNING THE IMPLEMENTATION OF DOSSIER AND QMS CHANGES
Gert Bos, Qserve Group

17:00 Q&A

17:30 NETWORKING RECEPTION

18:30 END OF DAY ONE

DAY 2

08:00 SESSION 4

CHANGES IN VIGILANCE AND POST-MARKET REQUIREMENTS IN THE NEW MEDICAL DEVICE REGULATION
Jos Kraus, Academic Medical Centre

09:30 COFFEE BREAK

10:00 WORKSHOP 2

POST MARKETING CLINICAL FOLLOW-UP AND POST MARKETING MEDICAL DEVICE STUDIES
Niels van Tienen, Factory – CRO for Medical Devices

11:30 SANDWICH LUNCH

12:30 WORKSHOP 3

POST-MARKET – ACTIVITIES AFTER FIRST PLACING THE PRODUCT IN THE MARKET – TRANSFORMING FULFILMENT OF LEGAL REQUIREMENTS INTO BENEFIT FOR ACTORS
Jos Kraus, Academic Medical Centre

14:00 END OF WORKSHOP

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 10.5 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

Training Course Venue

Austria Trend Hotel Savoyen Vienna
Rennweg 16
1030 Vienna, AT
Tel: +43 1 206 33 0
Fax: +43 1 206 33 92 10
Email: savoyen@austria-trend.at
www.austria-trend.at/Hotel-Savoyen-Vienna

DIA has blocked a limited number of hotel bedrooms for the workshop participants from 28 to 30 November 2016 (2 nights) at the rate of EUR 135.00 per single room, including breakfast and taxes. The room rate is available until 28 October 2016, or until the room block is sold-out, whichever comes first.

The booking can be made online at www.austria-trend.at/book/DiaglobalNovember

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.

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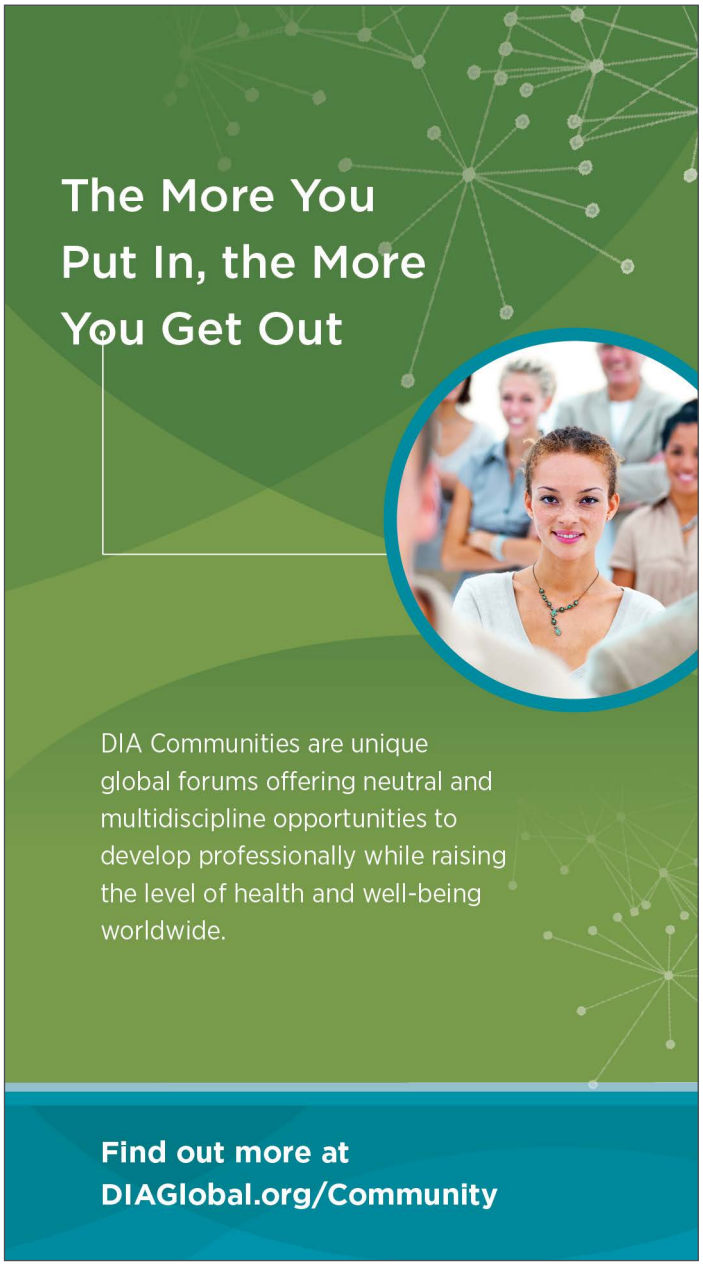

REGISTRATION FORM

The New European Medical Device Regulation: Change Management # 16537
29-30 November 2016 | Austria Trend Hotel Savoyen | Vienna, Austria

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REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course 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 ❑
DAY 1 - MDR INFORMATION DAY REGISTRATION FEES		
INDUSTRY	€ 870.00 ❑	€ 1'205.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 435.00 ❑	€ 590.00 ❑

All registration fees are subject to applicable Austrian VAT

Please enter your company's Austrian 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-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:

❑ I do not want complimentary membership

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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Email: EMEA@DIAglobal.org
Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org

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.

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)

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 # 16537 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