



The New Medical Device Regulation Information Day

Event #15118

22 September 2015

Fleming's Hotel Wien-Westbahnhof, Vienna, Austria

SPEAKERS

Joris Bannenberg

COO / Medical Director
Factory – CRO for Medical
Devices
The Netherlands

Reinhard Berger

Senior Expert Medical Devices
Austrian Agency for Health and
Food Safety (AGES)
Austria

Gert Bos

Head of Regulatory and Clinical
Affairs, Medical Devices
BSI Assurance Ltd.
United Kingdom

Sabina Hoekstra-van den Bosch

Senior Manager Standards &
Regulations
Philips Healthcare - Global
Regulations & Standards
The Netherlands



OVERVIEW

You will get an overview of the EU device legislative system updates. This Information Day provides an insight of the essential changes in various fields, such as the role of notified bodies and all requirements in clinical or post-market requirements.

TARGET AUDIENCE

This Information Day is designed for regulatory professionals (e.g. medical device industry, pharma industry, trade associations, notified bodies, authorities etc.), who would like to be updated on the changes and implications of the new EU Medical Device Regulation.

ADDITIONAL INFORMATION

This Information Day is a part of the DIA Training Course on "Medical Devices: Regulation and lifecycle management". Course participants will attend this event free of charge.

13:00 REGISTRATION

13:30 SESSION 01

Highlights of the New Medical Device Regulation

Sabina Hoekstra-van den Bosch

14:00 SESSION 02

Changed Role for Notified Bodies under the New Medical Device Regulation and Implications for manufacturers

Gert Bos

14:45 COFFEE BREAK

EVENT VENUE

Fleming's Hotel Wien-Westbahnhof

Neubaugürtel 26-28
1070 Vienna, Austria
Tel: +43 1 22 73 70
Email: wien@flemings-hotels.com

HOTEL INFORMATION

DIA has reserved a limited numbers of rooms at the rate of EUR 130.00 per single room per night inclusive of breakfast, VAT and taxes. To make your reservation, please use the booking form available on DIA website. Important: The room rate is available until 20 August 2015 or until the group block is sold-out, whichever comes first. Hotel reservations can be cancelled free of charge until 20 August 2015. In case of a cancellation after this date, no show or early departure, the hotel reserves the right to charge 100% of the confirmed booking.

15:15 SESSION 03

Changes in pre- and post-market clinical requirements in the New Medical Device Regulation

Joris Bannenberg

16:00 SESSION 04

Changes in vigilance and post-market requirements in the New Medical Device Regulation

Reinhard Berger

16:45 QUESTIONS & ANSWERS

17:00 DRINKS RECEPTION

18:00 END OF INFORMATION DAY

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.

SEND YOUR COMPLETED REGISTRATION FORM TO DIA EUROPE, MIDDLE EAST & AFRICA CONTACT CENTRE TEAM
E-mail: diaeurope@diaeurope.org Fax: ++41 61 225 51 52 For more information please call +41 61 225 51 51

Registration fees*

Industry*
Academia/Charitable/Government/Non-profit (Full-time)*
Join DIA now

Fees*

330.00 EUR ☐
165.00 EUR ☐
155.00 EUR ☐

***All registration fees will be subject to the Austrian VAT at 20%**

Please advise your European VAT Number : _____

Registration fee includes: afternoon Coffee Break and event material

Payment is due 30 days after registration and must be paid in full by commencement of the event.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

☐ Prof ☐ Dr ☐ Ms ☐ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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, Event ID #15118 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. By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on <http://www.diahome.org/EUTerms>.

Date	Signature
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Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe 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 Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA Europe 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 Europe 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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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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