Overview
This one-day conference will provide delegates with an understanding of the regulatory framework and highlight the challenges developing combination products including Advanced Therapy Medicinal Products (ATMPs). It will focus on the differences between device and pharma regulations and will provide examples of issues faced by manufacturers already operating on the medicinal product/medical device borderline, designing products where the regulatory framework is not immediately obvious.

Objectives
• To give delegates a clearer understanding of the regulatory options and routes that are available to manufacturers developing different kinds of medicinal and medical device combination products including ATMPs
• To provide an open forum to discuss the relative merits and drawbacks between the two regulatory frameworks, particularly in situations where there are multiple options

Key Topics
• Overview of regulatory framework in the EU and US for combination products
• Challenges in developing combination products
• Competent Authority and notified body views on their roles in regulating combination products
• Strategic moves affecting drug and device regulations at the European Commission level
• Case studies

About the Drug Information Association (DIA)
DIA serves more than 30,000 biopharmaceutical professionals from industry, academia and regulatory agencies worldwide. Through its domestic and international meetings, training courses, workshops and webinars, DIA provides a neutral global forum for the exchange of information critical to the advancement of the drug discovery and lifecycle management processes.

Headquartered in Horsham, PA, USA, and with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India, and Beijing, China, the Association is led by its volunteer-based Board of Directors and executive management team. For more information, visit www.diahome.org or call DIA in Europe +41 61 225 51 51.
TUESDAY | 9 NOVEMBER 2010

09:00  Registration and Welcome Coffee

09:30  Session 1

OVERVIEW OF THE REGULATORY FRAMEWORK FOR COMBINATION PRODUCTS
Session Chairperson:
Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd., Switzerland

This session provides an overview of the current legislations for combination products and addresses the appropriateness and shortcomings of the current system from the regulators’ as well as industry perspective.

Regulatory Framework for Combination Products in EU/US
Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd., Switzerland

Regulator View on the Future Development of European Legislation
Sabina Hoekstra-van den Bosch, Senior Advisor, Ministry of Health, Welfare and Sport, Department of Pharmaceutical Affairs and Medical Technology, The Netherlands

Industry Position on Current Regulation and Future Needs
Ian Purdy, Vice President Regulatory, Boston Scientific, USA

Panel Discussion

11:00  Coffee Break

11:15  Session 2

DEVICE COMBINATION PRODUCTS IN THE EU
Session Chairperson:
Sabina Hoekstra-van den Bosch, Senior Advisor, Ministry of Health, Welfare and Sport, Department of Pharmaceutical Affairs and Medical Technology, The Netherlands

This session provides an overview of the stakeholders involved and their roles and responsibilities in the evaluation and approval of combination products classified as medical devices.

The EU Drug/Device Combination Labyrinth: The various avenues and where to get help
Amanda Maxwell, Manager, SFL Regulatory Affairs Consulting, UK

Notified Body Expectations and Responsibilities in Assessing the Medical Device Part of a Combination Product
Gert Bos, Head of Regulatory and Clinical Affairs, BSI, UK

The Role of National Competent Authorities in Reviewing and Overseeing Combination Products
Wing Cheng, PhD, Medical Products Agency, Sweden

Panel Discussion

12:45  Lunch Break

13:45  Session 3

COMBINATION MEDICINAL PRODUCTS IN THE EU
Session Chairperson:
Mark Hope, Head of EU/ROW Program Management & EU/ROW Head of Oncology, F. Hoffmann-La Roche AG, Switzerland

This session provides case studies and EMA experience about the combination products classified as medicinal products including medicinal products, medical devices, in vitro diagnostics, advanced therapy medicinal products and medical device combination products.

Industry Experience: The successful development and approval of a combination medicinal product
Kirsten Nielsen Tallerup, Senior Regulatory Project Manager, Novo Nordisk A/S, Denmark

Personalised Medicine: Development of medicinal products combined with diagnostics
Mark Hope, Head of EU/ROW Program Management & EU/ROW Head of Oncology, F. Hoffmann-La Roche AG, Switzerland

EMA View and Experience in Assessing and Approving Combination and Advanced Therapy Medicinal Products
Marie Helene Pinheiro, Scientific Administrator, Regulatory Affairs and Organisational Support Sector, European Medicines Agency, EU

Panel Discussion

15:15  Coffee Break

15:30  Session 4

REQUIREMENTS FOR DRUG- AND DEVICE-TYPE COMBINATIONS/EU
Session Chairperson:
Margit Widmann, Head of Medical Device Division, Swissmedic, Switzerland

This session provides an overview of clinical, quality and post-marketing requirements to be considered in the development of combination products.

Points to Consider for Designing Clinical Studies for Combination Products
Ian Purdy, Vice President Regulatory, Boston Scientific, USA

Quality Systems Requirements for Combination Products
Gert Bos, Head of Regulatory and Clinical Affairs, BSI, UK

Post-market Requirements for Combination Products
F.W. (Waldo) Weijers, Secretary/Coordinator Consultation Procedures Medicated Medical Devices, Medicines Evaluation Board, The Netherlands

Panel Discussion

17:00  End of Conference

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 Drug Information Association.

Speakers and agenda are subject to change without notice.
Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.
HOTEL INFORMATION

The Mövenpick Hotel Zurich Airport is holding a block of rooms at the reduced rates below for the DIA event attendees:

Single room EUR 185.00 (CHF 265.00)
Rates including breakfast plus VAT/service/taxes plus city Tax of EUR 1.75 (CHF 2.50)

Please book your room at the Mövenpick Hotel Zurich-Airport, Walter-Mittelholzerstrasse 8, 8152 Zürich-Glattbrug, Switzerland directly by

Email: susanne.richter@moevenpick.com
Phone: +41 44 808 80 61
Fax: +41 44 808 80 62

Please quote the booking reference: DIA 08.11.2010

Important: To be assured of accommodation at the Mövenpick Hotel Zurich-Airport, registrants are recommended to complete their reservation by **11 October 2010**.

In case of cancellation:
Cancellation of the hotel bedroom booking must be made in writing directly to the hotel 7 days prior to the arrival date. Cancellations made at least 7 days prior to arrival will not incur any cancellation charges.
Any cancellation made less than 7 days prior to arrival will be subject to the first night being charged at the full agreed rate.
All no shows will be billed for the entire stay.

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Upcoming DIA events in Europe

1st Joint DIA/EMA Workshop on Statistical Methodology in Clinical R&D
27-29 September 2010 | Vienna, Austria

Joint EFGCP Children’s Medicines Working Party 6th Annual Conference and DIA 4th Paediatric Forum
*Current and Future Medical Child Care: Visions, Daily Challenges, Ways Forward*
28-29 September 2010 | London, UK

Joint DIA/EFGCP Pharmacovigilance Audit and Inspection Workshop - Opportunities for Patient Safety
1 October 2010 | London, UK

4th European Cardiac Safety Conference and Exhibition
25-26 October 2010 | Nice, France

Combination Products – Finding the Right Regulatory Strategy
9 November 2010 | Zurich, Switzerland

2nd Joint DIA/EMA/CMD(h) Conference on Variations
23 November 2010 | London, UK

2nd Joint DIA/European Medicines Agency Innovation Forum: Is the EU Regulatory Framework Ready?
29-30 November 2010 | London, UK

11th Conference and Exhibition on European Electronic Document Management - *The New Frontiers*
1-3 December 2010 | Nice, France

9th Middle East Regulatory Conference MERC 2011
1-2 February 2011 | Amman, Jordan

DIA/IFAH Global Animal Health Conference
23-24 March 2011 | London, UK

23rd Annual EuroMeeting
28-30 March 2011 | Geneva, Switzerland
**REGISTRATION FORM**

Conference on Drug & Device Combination Products – Finding the Right Regulatory Strategy
9 November 2010 | Mövenpick Hotel Zurich-Airport, Switzerland

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes lunch and coffee breaks of EUR 125.00 per day.

Register for the Conference on Combination Products (9 November 2010) #10114 and the Medical Devices Training Course (10-12 November 2010) #10547 and receive up to 20% discount on the total registration fee. Discount incorporated in rates below.

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**重要：**

酒店和旅行预订应仅在收到书面注册确认后进行。

**HOW TO REGISTER**

请在收到电子邮件下载说明后的五个工作日内联系DIA。

**CANCELLATION POLICY**

所有取消必须在DIA注册截止日期17:00 CET前以书面形式提交。

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全注册费：行业（会员/非会员）= 1,000.00政府/学术/非营利（会员/非会员）= 500.00。注册者需在取消前支付全部会议注册费。如取消日期超过原计划，DIA有权更改会议日期。

**Transfer Policy**

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**IMPORTANT:**

酒店和旅行预订应仅在收到书面注册确认后进行。

**STUDENT RATES AND GROUP DISCOUNTS ARE AVAILABLE! PLEASE CONTACT THE DIA IN EUROPE.**

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SMEs also receive a special discount, please contact DIA in Europe.

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