# Combination Products Workshop

## Anticipating the New Regulatory Landscape for Drug/Device Combinations and Drug/Companion Diagnostics: An Overview of the Current and Likely Future EU Rules

Event #12120
18 September 2012
Hotel Bildungszentrum 21, Basel, Switzerland

## Programme Co-chairs

**Shayesteh Fürst-Ladani**
Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd, Switzerland

**Carole Burnier**
Global Regulatory Affairs CCR Team Leader, Novartis Consumer Health SA, Switzerland

## About the DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

## Continuing Education

The DIA is a global association of approximately DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available on request from the DIA registration desk.

## Overview

This one-day workshop will provide delegates with an understanding of the current regulatory framework for drug/device combinations and drug/companion diagnostics, and of the anticipated impact of the revision of this framework, taking into account the latest discussions at European Commission level on the revision of the European medical device and in-vitro diagnostics (IVD) legislation.
The meeting will focus on the differences between device and pharma regulations and highlight challenges facing manufacturers who need to comply with elements of both regulatory structures and as well as give guidance to those who operate on the drug/device borderline where it is not immediately obvious which regulatory framework applies.

## Key Topics

- Overview of the current regulatory framework for combination products in the EU, and outline of the situation in US
- Overview of anticipated changes to the EU's Medical Devices Directive and IVD Directive, and how these are likely to impact industry
- Competent authority and notified body views on their roles in regulating drug/device combinations and drug/companion diagnostics
- Regulatory challenges in developing combination products and drug/companion diagnostics, with case studies
- Insight into clinical development requirements for companion diagnostics in the US

## Who Will Attend

- Pharma, medical device and diagnostic industry professionals
- Health authority representatives
- Notified body representatives
- Regulatory, clinical and other professionals responsible for developing drug/device combinations and companion diagnostics

## Objectives

- Highlight regulatory options and routes that are available to manufacturers developing drug/device combinations and drug/companion diagnostics
- Give an overview how the latest EU regulatory developments impact drug/device combinations and companion diagnostics
- Provide an open forum to discuss the relative merits and drawbacks between the different regulatory frameworks

# FINAL PROGRAMME

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## TUESDAY | 18 SEPTEMBER 2012

**08:45** **REGISTRATION AND WELCOME COFFEE**

**09:15** **Welcome and Introduction**
Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd, Switzerland

**09:30** **Session 1**

### OVERVIEW OF CHANGING THE REGULATORY FRAMEWORK FOR COMBINATION PRODUCTS, MDD AND IVD

Session Chair:
**Carole Burnier**, Global Regulatory Affairs CCR Team Leader, Novartis Consumer Health SA, Switzerland
This session will provide an overview of the revision of the Medical Device Directives, including the In Vitro Diagnostics Directive and of how the changes are likely to impact the regulation of drug/device combinations and companion diagnostics from the regulators' as well as industry's perspective.

**Overview of Commission Discussions on the Proposed Revision of Medical Device Directives and Current and Changing Regulatory Framework for Combination Products in EU/US**
Shayesteh Fürst-Ladani, Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd, Switzerland

**Regulator Experience of Current European Legislation for Combination Products: Areas that need strengthening**
Waldo Weijers, Coordinator Consultation Procedures Medicated Medical Devices, Medicines Evaluation Board, the Netherlands

**Industry View on the Anticipated Changes to Regulatory Framework for Combination Products**
Carole Burnier, Global Regulatory Affairs CCR Team Leader, Novartis Consumer Health SA, Switzerland

**Panel Discussion**

**11:00** **COFFEE BREAK**

**11:30** **Session 2**

### REGULATORY REQUIREMENTS FOR COMPANION DIAGNOSTICS IN THE EU

Session Chair:
**Amanda Maxwell,** Manager, SFL Regulatory Affairs Consulting, UK

This session will provide an overview of the development and approval of Companion diagnostics.

**Overview of Commission Discussions on the Proposed Revision of In Vitro Diagnostics Directive**
Amanda Maxwell, Manager, SFL Regulatory Affairs Consulting, UK

**Regulators' Expectations for Development of a Companion Diagnostic with Drug**
Marisa Papaluca-Amati, Head of Scientific Support and Projects, European Medicines Agency, Europe

**Challenges Industry Faces Developing Companion Diagnostics**
Irmela Radtke, Senior Regulatory Affairs Manager, F. Hoffmann-La Roche AG, Switzerland

**Panel Discussion**

**13:00** **LUNCH BREAK**

**14:00** **Session 3**

### STAKEHOLDERS' ROLES IN ASSESSING COMBINATION PRODUCTS IN THE EU

Session Chair:
**Shayesteh Fürst-Ladani**, Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd, Switzerland
This session will give an overview of future regulatory expectations among Notified Bodies, National Regulatory Agencies and the EMA, and of their experiences to date with combination products. It will also give an outline of legal criteria for determining the correct classification of borderline products.

**National Competent Authorities' Role in Assessing Drug/Device Combinations**
Waldo Weijers, Coordinator Consultation Procedures Medicated Medical Devices, Medicines Evaluation Board, the Netherlands

**Notified Body's Role in Assessing Drug/Device Combinations**
Christian Schuebel, Head of Medical Affairs, i.Dras GmbH, Germany

**Overview of the Legal Criteria and the Principles of Interpretation for Borderline Determinations**
Erik Vollebregt, Attorney, Axon Lawyers, The Netherlands

**Panel Discussion**

**15:30** **COFFEE BREAK**

**16:00** **Session 4**

### PRACTICAL TIPS FOR ACHIEVING APPROVAL OF COMBINATION PRODUCTS

Session Chair:
**Marisa Papaluca-Amati**, Head of Scientific Support and Projects, European Medicines Agency, Europe
This session will provide a snapshot of how to choose the right regulatory pathway and an opportunity to share industry experience in achieving successful registration of combination products.

**Case Study: Successful development and approval of drug/device combinations classified as drugs**
Teresa Pepper, International Regulatory Affairs Senior Manager, Amgen Ltd, UK

**How to Address Specific Issues such as PIP and PV for Combination Products?**
Genevieve Michaux, Counsel, Covington & Burling LLP, Belgium

**Case Study: Drug Device Combination Product (DDCP) – Regulated as a device**
Toni Joergensen, Head of Corporate Regulatory Affairs, Institute Straumann AG, Switzerland

**Panel Discussion**

**17:30** **END OF WORKSHOP**

Unless otherwise disclosed, DIA Europe 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 Europe.

Speakers and agenda are subject to change without notice.
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## PRESENTATIONS AVAILABLE ONLINE

You should have received an email from diaeurope@diaeurope.org with instructions on how to download presentations on Tuesday, 11 September 2012.

Please note: If you cannot find a presentation online, it is because:
- The presenter did not yet provide DIA Europe with a slide presentation to upload
- The presenter did not agree to share the presentation with meeting attendees
- You have not paid the registration fee

Registered participants will be able to download the updated presentations after the conference. DIA Europe will send you an email with instructions on how to access presentations on Tuesday, 25 September 2012.

## CERTIFICATE OF ATTENDANCE

Pick up your Certificate of Attendance!

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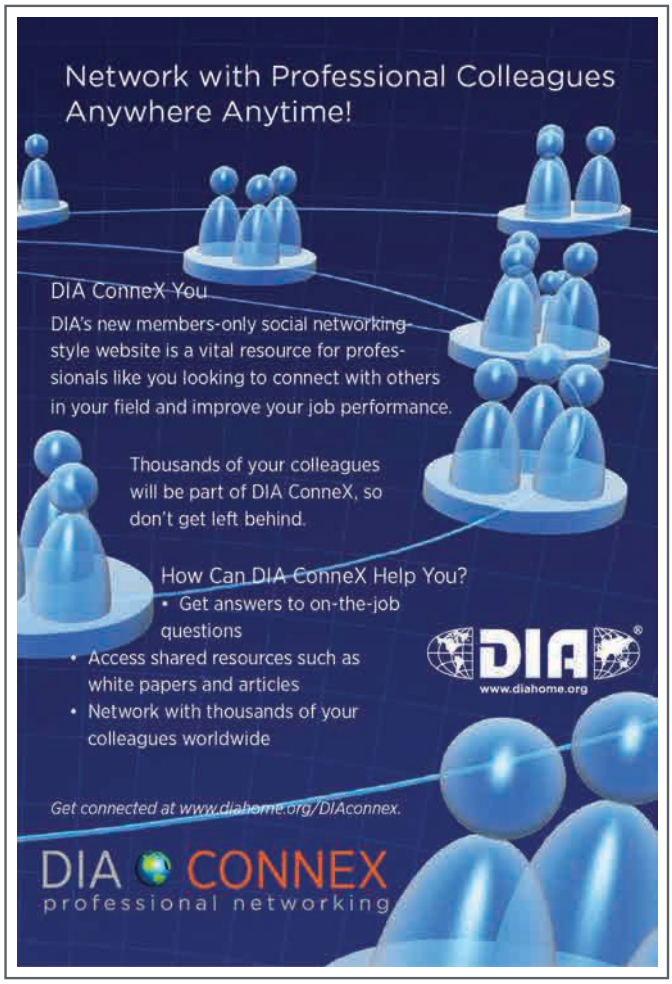
If you would like to receive your certificate after the conference please call us on +41 61 225 51 51

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## Devices and Diagnostics SIAC

You can now join the Devices and Diagnostics SIAC (Special Interest Area Community) and maximise the benefits of your DIA Membership!

The Devices and Diagnostics SIAC aims to increase awareness and contribute actively to shaping global legislation of Medical Devices, In-Vitro Diagnostics and Drug/Device Combination Products.

Joining the SIAC will enable you to:
- Network with colleagues and specialists around the world
- Exchange vital information
- Stay on the pulse of hot topics and shared learning
- Be better informed about speaking opportunities
- Help DIA identify your professional development needs

To join a SIAC, go to www.diahome.org, log in to My DIA, click on **Manage My SIACs** and join the communities of your choice.

For more information about DIA SIACs, go to *www.diahome.org* > Networking and Communities > Special Interest Area Communities, or contact Kaija Kurki-Suonio on *kaija.kurki-suonio@diaeurope.org* or +41 61 225 51 53.

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