Conference on Combination Products - Finding the Right Regulatory Strategy

9 November 2010 I Mövenpick Hotel Zurich-Airport, Switzerland

Programme Co-Chairs

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

Sabina Hoekstra-van den Bosch
Senior Advisor, Ministry of Health, Welfare and Sport
Department of Pharmaceutical Affairs and Medical Technology, The Netherlands

This one-day conference will provide delegates with an understanding of the regulatory framework and highlight the challenges developing combination products. 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.

DIA®
www.diahome.org

Objectives

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

Key Topics

- Overview of Regulatory Framework in EU and US for Combination Products
- Challenges in Developing Combination Products
- Competent Authorities and Notified Body views on their Roles Regulating Combination Products
- The Political Tug of War between Drug and Device Regulations and Strategic Moves at the European Commission Level
- Case Studies

Who Will Attend

- Pharma companies and medical device manufacturers
- Health authorities
- Notified bodies
- Regulatory, clinical, and project professionals responsible developing combination products

FOR REGULAR PROGRAMME UPDATES, PLEASE VISIT WWW.DIAHOME.ORG

Contact: sandra.gsponer@diaeurope.org

REGISTER NOW!

www.diahome.org > "Conferences / Meetings" in the left hand navigation menu > "Find a Meeting" > "Keyword" 10114