**DIA Training Course on** 

## **Paediatric Investigation Plans** (PIP)

Course #13503 15-16 April 2013 Mercure Hotel Amsterdam City, the Netherlands



## Faculty

#### Mette Due Theilade

(Course Director) **Principal Scientist** Novo Nordisk A/S, Denmark Former Paediatric Coordinator, European Medicines Agency, EU

#### Ann Marie Kaukonen

Paediatric Committee (PDCO) alternate Senior Researcher / Pharmaceutical Assessor Finnish Medicines Agency (Fimea), Finland

## Overview

Overview of the Paediatric Investigation Plan (PIP) procedure, including in-depth discussion of specific scientific/regulatory issues in relation to PIPs, case-studies and instructor-led group work on specific cases.

This course will provide a full introduction to PIPs and the EU Paediatric Regulation. The course faculty are European-based leading experts from EMA and industry. Topics will be presented through interactive lectures and hands-on workshop training.

## **Key Topics**

- EU paediatric regulation
- PIP lifecycle
- · How to get your PIP approved
- PIPs after approval

#### Who Will Attend

Professionals in regulatory affairs, clinical research, project management, toxicology, product development. Participants should preferably have a fair understanding of aspects of paediatric medicines development.

Level: Intermediate

## Learning Objectives

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

- Describe the EU paediatric regulation
- Discuss the PIP approval procedure
- Identify the expectations and requirements from the Paediatric Committee (PDCO)
- Demonstrate how to prepare a PIP eligible for evaluation by PDCO
- Explain the modification of an agreed PIP procedure
- Describe the compliance check procedure
- Demonstrate an overview of procedures after initial PIP approval

## **Continuing Education**

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.

This course has limited capacity. Register early.

PharmaTrain recognised





## MONDAY | 15 APRIL 2013

#### 08:00 REGISTRATION

#### 09:00 Session 1

#### INTRODUCTION AND DEFINITIONS

- EU paediatric regulation
- PIPs, waivers, deferrals, PDCO
- Guidelines and EMA website
- EMA PIP experience

#### 10:30 COFFEE BREAK

### 11:00 Session 2

#### THE PIP LIFECYCLE: PART 1

Introduction: Preparation, submission, amending PIP after Day 60, opinion

- How to build your PIP and/or waiver request
- Conditions/indications
- How to answer the PDCO Request for Modifications at Day 60
- Company Interactions with PDCO

#### 12:30 LUNCH

## 14:00 Session 2 continued

Group work

• How to ensure a global paediatric plan

THE PIP LIFECYCLE: PART 1

• Definition of conditions/indications

### 14:45 Session 3

#### THE PIP OPINION

- Key binding elements
- Best practice for synopsis/outline

#### 15:30 COFFEE BREAK

#### 16:00 Session 4

#### THE PIP LIFECYCLE: PART 2

PIPs after approval:

- Modifications
- Changing the scope of the PIP ("Merging & splitting")
- Validation and compliance check
- · Annual deferral reports
- Rewards Supplementary protection certificate (SPC) extension

#### Group work

How to minimise the number of modifications of your PIP

#### 17:30 DRINKS RECEPTION

#### 18:30 END OF DAY ONE

## TUESDAY | 16 APRIL 2013

#### 09:00 Session 5

#### **SPECIAL ISSUES**

- Paediatric pharmaceutical forms and formulations
- Non-clinical studies to support paediatric development
- Paediatric clinical studies specific issues
- PK/PD in children
- Orphan drugs
- Newborns/neonates

#### 10:30 COFFEE BREAK

#### 11:00 Session 6

**WORKSHOP ON CASE STUDIES: PART 1** 

#### 12:30 LUNCH

#### 14:00 Session 7

**WORKSHOP ON CASE STUDIES: PART 2** 

#### 15:30 COFFEE BREAK

#### 16:00 Session 8

COURSE SUMMARY

#### 16:30 END OF TRAINING COURSE

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. Recording during DIA Europe sessions is strictly prohibited without prior written consent from DIA Europe.

### HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the following hotel:

Mercure Hotel Amsterdam City Joan Muyskenweg 10 1096 CJ Amsterdam Netherlands

Email: H1244@accor.com Tel.: +31 20 72 19176 Fax: +31 20 69 48735

Website:http://www.mercure.com/gb/hotel-1244-mercure-hotel-amsterdam-

aan-de-amstel/index.shtml

at the rate of:

139.00 EUR per single room per night inclusive of breakfast, exclusive of

city tax.

To make your reservation, please use the booking form available on the DIA website.

Important: Please complete your reservation by 15 February 2013. Reservations received after this date will be subject to hotel availability and room rate may vary.



# DIA 2013 Training Courses in Regulatory Affairs

 Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe

18-20 September 2013 | Basel, Switzerland | ID 13546

 European Regulatory Affairs: In-depth review of current registration procedures in the European Union

6-7 June 2013 | Basel, Switzerland | ID 13550 21-22 November 2013 | Paris, France | ID 13553

 Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects of devices

10-12 June 2013 | Amsterdam, the Netherlands | ID 13547

 Health Authority Interactions - Preparation, consultation and implementation

15-16 October 2013 | Vienna, Austria | ID 13575

■ Health Technology Assessment (HTA)

26-27 November 2013 | Zurich, Switzerland | ID 13561

■ Paediatric Investigation Plans (PIP)

15-16 April 2013 | Amsterdam, the Netherlands | ID 13503

■ The Impact of Regulatory Affairs on Chemistry, Manufacturing & Controls (CMC)

2-4 October 2013 | Basel, Switzerland | ID 13532

 US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US

6-8 November 2013 | Paris, France | ID 13552

#### **ABOUT DIA**

DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China.

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

## **REGISTRATION FORM**

DIA Training Course on Paediatric Investigation Plans (PIP) 15-16 April 2013 | Hotel Mercure Amsterdam aan de Amstel, Amsterdam, the Netherlands



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FEES		Member* Non-Me	mber*
Industry		€ 1'365.00 □ € 1'480.	00 🗖
Academia/Charitable/Government/Non-profit (Full-time)		€ 683.00 □ € 798.	00 🗖
Join DIA now to qualify for the member rate		€ 115.00 🗖	
*All fees will be subject to the Dutch VAT at 21 %	If DIA cannot verify your membe the non-member fee.	ership upon receipt of registration form, you will be o	:harged
Please advise your European VAT number:	Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.		
	Registration fee includes: refresh	ments, lunches and training course material.	
TOTAL AMOUNT DUE:	Payment is due 30 days after regist	ration and must be paid in full by commencement of the	e course.
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DIA reserves the right to include your name and affiliation on the attendee list.			

#### **Cancellation Policy**

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- $\bullet \ \ \text{Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member)} \in 100.00$
- Tutorial cancellation € 50.00

If you do not cancel five working days 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.