

## Paediatric Drug Development

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How to meet the new regulatory requirements and benefit from the new commercial incentives by skillful development of products for use in children.

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### What Is The Course About?

This course is ideal for you if you need to be on top of the new EU paediatric drug development regulations that came into force in January 2007. It covers not only the regulations but also the medical and scientific background, enabling delegates to gain an all-round understanding of this critical area.

By the end of the course you will be able to:

- Understand the regulatory requirements introduced in the new regulations, together with the associated commercial incentives.
  - Assess which products are affected and when.
  - Appreciate the ethical issues involved.
  - Take a science-based approach to compiling a Paediatric Investigation Plan.
  - Evaluate formulations for use in children
  - Understand the complementary roles of PK, PD, safety and efficacy data
  - Plan the timing of paediatric development on the basis of ethical and scientific principles together with the concept of deferment.
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### The Trainer

Dr Ian Dews

Ian is a qualified medic with more than 25 years of experience of drug development as both an investigator and a pharmaceutical physician. He is a director of a small consultancy company providing drug development and regulatory support to the pharmaceutical and medical device industries. Ian's previous role was as European Director of Drug Development for a global, full service CRO where he was responsible for working with clients to develop compounds from the discovery stage through to the conclusion of clinical research.

Prior to this, Ian was the European Medical Director of a global, full service CRO. In this role he was involved in the writing of Clinical Development Plans and Expert Reports and was responsible for the supervision of global drug development programmes.

He has acted as an investigator in more than 50 hospital clinical trials in the fields of heart failure, angina, hypertension, arrhythmia and clinical pharmacology. He is a key Rostrum trainer, and has been delivering successful courses since its inception in 1987. Ian is a Fellow of the Faculty of Pharmaceutical Medicine and acts as a Senior Specialist Adviser within the Higher Medical Training programme of the Faculty.

#### **Course Fee: £599 +vat**

If you book on the course more than 9 weeks in advance, a 10% discount will be applied.

Location: The Regency Hotel, 100 Queens Gate, South Kensington, London, SW7 5AG

For more information about this or any of our other courses or services, please call us on +44 (0)118 975 4512 or visit our website [www.rostrumtrainingsolutions.com](http://www.rostrumtrainingsolutions.com)

# Programme

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### Introduction & Objectives

#### Why develop drugs for children?

- The medical background
- The social need
- The new regulatory requirements
- The new commercial incentives
- When is it NOT needed?

#### How to do it

- Ethical issues
- The Paediatric Investigation Plan
- The importance of formulation
- Pharmacokinetics
- Pharmacodynamics
- Safety
- Efficacy
- Pharmacovigilance

#### When to do it

- Planning the development
- Conducting the studies
- Submitting the results

#### The regulatory processes

- Submitting the PIP
- The Paediatric Committee
- Waivers and deferments
- Free scientific advice
- Choice of incentive for patented products
- PUMA for off-patent products
- Updating of current authorisations