Cost

The cost is £295 plus VAT, including course materials, break time refreshments and lunch.

How to book

Online, with secure credit card payment: at http://www.i-regulatory.com

By telephone: +44 (0)1438 730890

By fax: please fax this form to +44 (0)1438 730891

By post: please mail this form to iRegulatory Ltd, 1 Viewpoint Office Village, Babbage Rd, Stevenage, Hertfordshire, UK, SG1 2EQ

Course joining instructions will be sent on receipt of the booking

Title	
Forename	
Surname	
Position	
Company	
Address	
City / town	
Postcode	
Telephone	
Fax	
Email	
Special requirements	(e.g. dietary restrictions etc)
Payment	Cheque enclosed, payable to iRegulatory Ltd ❑ Bank transfer on receipt of invoice* ❑

*Payment must be received by 31st October 2007 for the booking to be confirmed.

Terms and conditions. The percentage of course fees refunded in the event of cancellation will be 75% for cancellations more than 4 weeks before the course date and 50% for cancellations 2-4 weeks before the course date. Course fees for cancellations less than 2 weeks before the course date are not refundable. Delegates can be substituted at any time at no additional cost. iRegulatory Ltd reserves the right to cancel or reschedule the event, or to provide a different course facilitator or make changes to the programme. In the event of cancellation, compensation will be restricted to a full refund of the course fee. In the event of rescheduling, delegates will be offered the choice between a place on the rescheduled course or a full refund of the course fee.

iRegulatory

Real life eCTD: what every regulatory professional should know

A unique training seminar based on 5 years of contract regulatory publishing experience

Tuesday 6th November, 2007

Fielder Centre, University of Hertfordshire, Hatfield, UK

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Who should attend?

This course is intended for regulatory affairs professionals with little or no previous experience of eCTD and no specialist IT skills. Group size is restricted to just 24 delegates. The course will be run in a practical, interactive and informal way, with a stimulating mixture of presentations, practical exercises and group discussion.

The emphasis will be on business and practical aspects of eCTD. Delegates will gain a basic understanding of the nature of eCTD, together with an appreciation of how working practices in regulatory affairs departments are likely to change with the shift from paper CTD submissions to eCTD. Whilst the course is suitable for professionals at all levels, it will be especially useful for managers who are taking on responsibility for managing the transition from paper CTD to eCTD in the short to medium-term.

Course facilitator

Dr Martin Moxham is the founder and Managing Director of iRegulatory Ltd, one of the UK's leading contract regulatory publishing companies. iRegulatory has gained extensive experience with eCTD and other electronic submission formats over the last 5 years. Dr Moxham has over 15 years of experience in pharmaceutical regulatory affairs in positions with SmithKline Beecham, Merck Generics [UK], Akos International Consultancy, Mitsubishi Pharma Europe and iRegulatory. He has an unusual mix of regulatory and IT knowledge and experience, and is uniquely qualified to speak and advise on eCTD from the business, practical and technological perspectives.

Course materials

Delegates will receive a course folder containing copies of all presentations, together with practical exercise sheets. This will be a valuable source of reference for the future.

Course programme

Registration and coffee will be at 09:00. The course will begin at 09:30 and finish by 17:00.

09:30: Session 1 – eCTD fundamentals

Components of an eCTD
Acceptability of eCTD in different territories
Regional differences in eCTD
Methods for building eCTDs

10:45: Break

11:00: Session 2 – eCTD in more depth

More about XML
More about the folder structure
More about regional differences
Impact of proposed changes to the eCTD specification

12:30: Lunch

13:30: Session 3 – eCTD lifecycle management

How life cycle management works
Challenges associated with life cycle management

15:00: Break

15:15: Session 4 – eCTD best practices

Preparing for eCTD – business processes
Document authoring
Document management
Granularity
eCTD publishing
eCTD life cycle management

17:00: Close of meeting