

## Real Life e-Submissions: what every regulatory professional should know

**7<sup>th</sup> November 2008     Corus Hotel, Hyde Park, UK**

### Who should attend?

This seminar is intended for regulatory affairs professionals with little or no previous experience of e-submissions (eCTD and non-eCTD electronic submissions [NEES]) and no specialist IT skills. Group size is restricted to just 24 delegates. The seminar 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 and NEES. Delegates will gain a basic understanding of the nature of eCTD and NEES, 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 or NEES. Whilst the seminar 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 and NEES in the short to medium-term.

### Facilitators

Dr Martin Moxham is the founder and Managing Director of iRegulatory Ltd, one of the Europe'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 various positions.

Andre Neu is currently Global Key Account Manager for LORENZ Life Sciences, a leading provider of electronic submission management software. He has account management responsibility for key players in the healthcare industry and, together with a team of LORENZ professionals, successfully supports their regulatory departments. Through his current position and more than 12 years of working within the IT industry, he has expert knowledge of the electronic submissions field and a broad technical, operational and regulatory background.

## Materials

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

## Programme

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

### **09:30:     Session 1 – e-Submissions Fundamentals**

- Components of an eCTD
- Acceptability of eCTD in different territories
- Regional differences in eCTD
- eCTD versus non-eCTD electronic submissions (NEES)
- Methods for building eCTDs and NEES
- Building an eCTD with docuBridge

### **11:10:     Break**

### **11:30:     Session 2 – eCTD In More Depth**

- More about XML
- More about the folder structure
- More about regional differences

### **12:30:     Lunch**

### **13:30:     Session 3 – e-Submissions Exercises**

### **14:20:     Session 4 – eCTD Lifecycle Management**

- How life cycle management works
- Challenges associated with life cycle management

### **15:20:     Break**

### **15:45:     Session 5 – eCTD and NEES Best Practices**

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

### **17:00:     Close of Meeting**

## Cost

The cost is £395 plus VAT, 17.5% in UK [£464.13 inclusive] - including materials, break time refreshments and lunch.

## How to book

**It's quicker online! Secure credit card payment at [www.i-regulatory.com](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

**Joining instructions will be sent on receipt of the booking**

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Terms and conditions. Payment must be made in UK pounds, net of bank charges, in advance. The percentage of fees refunded in the event of cancellation will be 75% for cancellations more than 4 weeks before the seminar and 50% for cancellations 2-4 weeks before the seminar. Fees for cancellations less than 2 weeks before the seminar 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 facilitator or make changes to the programme. In the event of cancellation, compensation will be restricted to a full refund of the fee. In the event of rescheduling, delegates will be offered the choice between a place on the rescheduled seminar or a full refund of the fee.



## Real Life e-Submissions: What Every Regulatory Professional Should Know

A unique training seminar based on practical experience from two leading companies

*7<sup>th</sup> November 2008, London*

