# OVERVIEW OF THE ECTD

**19 November 2010, Conf. No. A11-4110** **W**

MANAGEMENT FORUM

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## YOU MAY REGISTER BY:-

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If you have NOT received confirmation seven days after registering, please contact Registration Department.

## REGISTRATION INFORMATION

**Dates**
19 November 2010 Start: 09.30 – Finish: 17.00

**Registration & Coffee**
19 November 2010 09.00

**Venue**
The Rembrandt Hotel, 11 Thurloe Place, London SW7.

**Directions**
Opposite V&A Museum.
Nearest Underground station: South Kensington.
Map available on Website under Hotels and Venues.

**Accommodation**
A limited number of bedrooms have been reserved at The Rembrandt Hotel, 11 Thurloe Place, London SW7, at a special rate of £133.92 (Superior), £152.18 (Executive) both including English breakfast. Excluding VAT – subject to availability.
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax: +44(0)20 7225 3476.
Email: reservations_rembrandt@sarova.co.uk
**All bookings should be made directly with the hotel or online at www.sarova.com/rembrandt, quoting promo code 'manforum'.**

**Fee**
**£575 + VAT.** The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

**Conference No. A11-4110**

**Discounted Rates**
Available on application for personnel from non-profit making organisations and registered charities.
**Group discount available on request.**

**Cancellation Policy:**
Over 14 days prior to the Seminar: Cancellation fee of £75. 7/14 days prior to the Seminar: 50% of the fee. Fewer than 7 days or if no notification received: Registrant liable to pay FULL seminar fee.
**NB: Cancellations must be received in writing by registrations@management-forum.co.uk.**

In the event of circumstances beyond its control, Management Forum reserves the right to alter the programme, the speakers, the date or the venue.



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MANAGEMENT FORUM

# AN OVERVIEW OF THE ECTD

## Are You Up to Date?

### Topics to be covered include:

- Introduction and overview of the eCTD
- What are the main components of the eCTD
- The ICH and European eCTD specifications
- Transitioning from paper submissions to the eCTD
- Considerations when selecting tools for the eCTD
- Process changes for the eCTD
- Practical experiences of submitting eCTDs

With
**Dr Geoff Williams,** e-Regulatory Liaison, Roche

**Register on-line at www.management-forum.co.uk or telephone +44 (0)1483 730071, fax 730008**

CPD CERTIFIED
The CPD Certification Service

**19 November 2010**
**The Rembrandt Hotel, London**

## WHY SHOULD YOU ATTEND

This one day meeting is designed to be an introduction to the topic of the electronic Common Technical Document (eCTD). The day is a mix of presentations on the subject, including detail about the specification itself and practical considerations for implementing the eCTD in your organisation.

## WHO SHOULD ATTEND

The course is primarily aimed at those involved in the creation and submission of eCTDs, from both a business/regulatory background and IT/support aspect. However, the course content will also be of interest to managers in these groups or to the creators of submission content or anyone else who wants to understand the eCTD better.

## DOCUMENTATION

Delegates will receive a course material folder containing comprehensive documentation provided by the speaker, which will be a valuable source of reference for the future.

## ATTENDANCE LIMITED – EARLY REGISTRATION RECOMMENDED

This limitation, a unique feature of all MANAGEMENT FORUM seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

**A Certificate of Attendance for Professional Development will be given to each participant who completes the course.**

## COURSE LEADER

***Dr Geoff Williams*** is currently e-Regulatory Liaison in the Global Regulatory Operations group at Roche. In this role Geoff is responsible for working in a number of areas in the wider pharma industry and bringing this information into Roche to use in their regulatory strategy and individual projects. In particular, this includes the work that Geoff undertakes as the EFPIA Deputy Topic Leader in ICH M2 (Electronic Standards for the Transmission of Regulatory Information) on the eCTD. Geoff also has input to global reg ops initiatives within Roche, such as the data and systems strategy and PIM, and is leader of their Regulatory Electronic Submissions Initiative.

Before joining Roche in April 2005, Geoff held regulatory operations positions at Johnson & Johnson Pharmaceutical Research & Development, GlaxoSmithKline and SmithKline Beecham.

Along with his membership of ICH, Geoff is also currently the chairman EFPIA eCTD Topic Group and is a member of the EFPIA Product and Regulatory Information Management Ad hoc Group (PRIMAG).

## FORTHCOMING EVENTS

For a full list of forthcoming conferences and seminars please visit our website at: **www.management-forum.co.uk.** You may make a registration and request a brochure on-line.

**Reserve your place online at www.management-forum.co.uk or telephone +44(0)1483 730071. If you require any further information please contact Sarah Spanswick sarah@management-forum.co.uk .**

## PROGRAMME

09.30 ▸ **Welcome and Introduction**
**Introduction and Overview of the eCTD**
- Overview of the eCTD
- Relationship to the CTD
- e-submissions and the eCTD
- Overview of the business case for the eCTD
- Short history of the eCTD
- Current status

10.45 ▸ **Coffee**

11.00 ▸ **The eCTD in More Detail**
This session will focus on the main components of the eCTD and provide a more detailed review of the key requirements in both the global Modules 2-5, covered by the ICH specification, and also the regional parts covered by EU and US specifications
- The ICH eCTD specification
- Files: Leaf files and their main characteristics
- Folders: The structure for storing the files
- The XML backbone: Attributes and metadata and how this information is used in the eCTD
- Utility files: DTDs and stylesheets, what they are and how they are used
- The Regional specifications
- Additional considerations for the creation of the regional components of the eCTD

12.30 ▸ **Lunch**

13.30 ▸ **Getting Started with the eCTD**
The eCTD specification is quite clear about the technical requirements for a valid eCTD submission. In this session you will learn more about the areas that will you will need to consider to successfully implement the eCTD in your organisation. As a result, the presentations will be a mix of information and questions that you will need to answer based on your vision for the eCTD within your organisation. We will cover a range of topics that will help you prepare to make you an eCTD submission, as well as some considerations about what happens after your first eCTD
- Transitioning to the eCTD
- Where to start
- What might make a good initial submission
- What you may need to continue to prepare alongside your eCTD eg paper volumes
- eCTD Tools and Efficient Processes
- eCTD Lifecycle Management – next steps to consider after you have completed you first eCTD

15.15 ▸ **Tea**

15.30 ▸ **The eCTD: A Case Study**
Practical experience gained from implementing the eCTD and submitting their first dossier.

17.00 ▸ **Close of Meeting**