

eCTD Submission

Hands-on One-day Training Program

ID# 14662 | April 25 and 26, 2014
Scitech Center | Mumbai, India



For more information visit www.diahome.org/India-eCTD2014



Join us for this one-day hands-on training program. Please specify which date you would like to attend - either April 25 or 26 - on the registration form.



Trainer

Ralf-Peter Berg
Director
Education & Services
EXTEDO

The eCTD Hands-on Workshop is an opportunity to learn.

This workshop is focused on enabling the participants to compile, publish and validate eCTD submissions with insights on Life Cycle Management and STF compilations. Hands-on training also enables participants to understand regional differences and global submission strategies. Compilation of US M1 and EU M1 is discussed in detail to empower users with updated information on these major ICH regions. This course is designed for anyone pursuing or intending to pursue Regulatory Affairs, Regulatory Operations, Submission Management, and Electronic Publishing.

LEARNING OBJECTIVES

At the conclusion of this workshop, participants will be able to:

- Compile a technically validated eCTD for various regions
- Maximize the reuse of compiled content
- Understand eCTD publishing and technical validation
- Understand the differences in the regional interpretations of electronic submissions
- Consider the impact of various regional interpretations of eCTD specifications and guidelines on global submissions strategy

WHO SHOULD ATTEND

Professionals in:

- Regulatory Affairs
- Regulatory Operations
- Submission Management
- Electronic Publishing

KEY TOPICS

- eCTD Compilation
- eCTD Publishing
- eCTD Validation
- eCTD Life Cycle Management
- Compiling Study Tagging Files (STFs)
- Regulatory Strategy
- Regional Differences in eCTD Requirements
- Coordinating Global eCTD Submissions

India Office

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Mumbai, India | Tokyo, Japan
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*All attendees will receive a
DIA Certificate of Attendance
at the conclusion of the event.*





Agenda

8:30-9:00	<i>Registration, Arrival of Participants</i>
9:00-9:15	<i>Welcome and Introduction</i>
9:15-10:00	Getting Started <i>Terminology and Basics: The eCTD Backbone</i> <i>Starting the Application - User Login</i> <i>eCTD Environment and User Interface</i>
10:00-10:45	Compilation of a Product Master Dossier (CMC: eCTD Modules 2 and 3)
10:45-11:00	<i>Tea/Coffee Break</i>
11:00-1:45	Hyperlinks
1:45-12:30	Compilation of Module 1 for a National Submission in Europe
12:30-1:30	<i>Networking Lunch</i>
1:30-2:30	eCTD Life Cycle Management <i>Submission Life Cycle</i> <i>Document Life Cycle [Add/Replace/Delete/Append]</i> <i>Filters and Other Tools</i>
2:30-3:00	Compilation of Nonclinical and Clinical Studies via Node Extensions
3:00-3:15	<i>Tea/Coffee Break</i>
3:15-3:45	Submission Export, Validation of an EU Submission, and Submission Import
3:45-4:45	US-FDA Submission Specifics <i>Compilation of Module 1 [Forms, SPL]</i> <i>Study Tagging Files</i>
4:45-5:00	<i>Final Discussion</i>
5:30	<i>Training Adjourned</i>

About The Trainer



Ralf-Peter Berg is the Director of EXTEDO's Education & Services team, responsible for all training courses. He has a long and successful career as a project manager and trainer in EXTEDO.

The goal of this training course is to train users on the main functionality of eCTD, following typical business scenarios. During the training course the trainees will have the opportunity to gain hands-on experience.

About this eCTD Training Course

This training course covers all of the necessary processes to create an eCTD for an EU and FDA submission.

After a brief introduction in the eCTD basics, the trainees will learn how to create a Product Master Dossier, covering the Quality-relevant part of an eCTD.

To complete the submission, the trainees will add regional information (EU Module 1) and compile non-clinical and clinical studies. Finally, the EU-submission will be exported and validated.

In the last session the trainees will learn about the differences when submitting to US-FDA.

VENUE DETAILS

Scitech Center | Mumbai India
7, Prabhat Nagar, Jogeshwari West, Mumbai. ****Land Mark: Next To Unichem Limited**

CONTACT

Kanchan Patel, Senior Manager, Operations:
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MEETING MANAGER

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DIA (India) Private Limited
cell: +91 98.1977.7493
Manoj.Trivedi@diaindia.org

CANCELLATION POLICY: On or before APRIL 14, 2014

Cancellations must be in writing and received by April 14, 2014. Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Upon cancellation, the administrative fee that **FULL MEETING CANCELLATION All refunds will be issued in the currency of original payment**
will be withheld from refund amount is: 75% of the Delegate fee

PLEASE CONSIDER THIS FORM AS AN INVOICE
eCTD Submission - Hands-on One-day Training Program
Meeting I.D. # 14662 | April 25 and 26, 2014 | Scitech Center | Mumbai, India

REGISTRATION FEES

Registration fee includes refreshment breaks, luncheons.

Join DIA now to qualify to save on future events and to receive all the benefits of membership. To see all the benefits of DIA membership, visit www.diahome.org and click on Membership.

A limited number of student registrations are available.

A student is an undergraduate/graduate who can document enrollment in a Signature accredited, degree granting, academic program. Please send completed registration form, copy of student identification, and payment.

DELEGATE REGISTRATION

	BASIC RATE	SERVICE TAX	TOTAL
Industry	6000	742	6742 INR
Academia/Government	4000	494	4494 INR
Student	3000	371	3371 INR

TOTAL AMOUNT: _____

ORGANISATION PAN No.: _____

REGISTRATION TERMS AND CONDITIONS: Registration form should be duly filled, signed by the authorized person.

You are requested to email the duly filled and signed Registration Form first and then courier/mail it along with registration fees on or before 5 working days of the training program.

Please indicate day attending:

April 25, 2014 April 26, 2014

Please check the applicable category:

Academia Industry Student

PLEASE PRINT ALL INFORMATION CLEARLY

Degrees: Dr. Mr. Ms.

Last Name (Family Name)

First Name

Job Title

Affiliation (Company)

Address (Please write your address in the format required for delivery to your country.)

Business Address Home Address

Postal Code

City

State

Country

Telephone Number

Fax Number

Mobile Number

email (Required for confirmation)

Signatory

Payment contact person's Full Name

Telephone Number

email

PAYMENT INFORMATION

Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:

Bhavesh Vora | Senior Executive Accounts
Bhavesh.Vora@diaindia.org
Drug Information Association
A- 303, Wellington Business Park 1, Andheri Kurla Rd.
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