eCTD Submission Hands-on One-Day Training

Meeting ID 16662 | Mumbai | 28th November 2016
Meeting ID 16663 | Hyderabad | 30th November 2016

Please specify which date and the centre you would like to attend on the registration form

TRAINER

Ralf-Peter Berg
Director
EXTEDO

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

During the training course the trainees will have the opportunity for hands-on experience of Global eCTD submissions.

Who should attend

Professionals in:

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

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

This training 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.

Training Highlights

- 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 Module1) 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.

Learning Objective

At the conclusion of this training, 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

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 Submission

MEETING MANAGER

Manoj Trivedi
Senior Manager, Business Development
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AGENDA

8:00 – 9:00 **Registration, Arrival of Participants**

9:00 – 9:15 **Welcome and Introduction**

9:15 – 10:00 **Getting Started**

- Terminology and basics; eCTD Backbone
- Starting the application, user login, eCTDmanager environment and user interface
- Creating Dossiers and Submissions

10:00 – 10:45 **Compiling the New EU Module 1 v. 3.0.1: What has been Changed**

10:45 – 11:00 **Tea / Coffee Break**

11:00 – 11:45 **The EU Active Substance Master File (ASMF) in eCTDmanager**

11:45 – 12:30 **Hyperlinks: a chance or a burden?**

Three clever ways to create Hyperlinks in eCTDmanager

12:30 – 13:30 **Networking Lunch**

13:30 – 14:30 **eCTD Life Cycle Management**

- Submission Lifecycle
- Document Lifecycle (add/replace/delete/append documents)
- Filters and other tools

14:30 – 15:00 **Re-use ASMF files in an eCTD Application for a Pharmaceutical Product**

15:00 – 15:15 **Tea / Coffee Break**

15:15 – 15:45 **Submission Export and Validation of an EU Submission**

15:45 – 16:45 **Trends and New Developments in the eCTD World**

- eCTD in other regions (FDA, GCC, Thailand, South Africa etc.).
- a brief outlook on eCTD 4.0

16:45 – 17:00 **Final Discussion**

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Event I.D. 16662 | Mumbai | 28th November 2016 **Event I.D. 16663 | Hyderabad | 30th November 2016**

VENUE:

Monday, 28th November 2016 | Mumbai

Courtyard Marriott Mumbai International Airport
C.T.S No 215, Andheri Kurla Road, Andheri East
Mumbai 400059, India | T : +91 22 61369987

CONTACT: **PANKAJ CHAVAN,** Sales Co-ordinator
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Wednesday, 30th November 2016 | Hyderabad

Hyderabad Marriott Hotel & Convention Centre & Courtyard by Marriott Hyderabad
Opposite Hussain Sagar Lake
Hyderabad – 500080, India
T: + 91-40-27522110 / + 91-40-66522110

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MEETING MANAGER
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CANCELLATION POLICY:
MUMBAI : ON OR BEFORE NOVEMBER 13, 2016
HYDERABAD : ON OR BEFORE NOVEMBER 15, 2016

- Cancellations must be in writing and received by November 13th and 15th November 2016 for Mumbai and Hyderabad respectively.
- 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 will be withheld from refund amount is 25 % of the delegate fee

FULL MEETING CANCELLATION
All refunds will be issued in the currency of the original payment

For more details, please visit www.DIAglobal.org

REGISTRATION FEES (*Registration fee includes refreshment breaks and luncheons.*)

	BASIC RATE (INR)	SERVICE TAX 15 %(INR)	TOTAL INR
INDUSTRY MEMBER	8000	1200	9200 ❑
INDUSTRY NON- MEMBER	8000	1200	9200 ❑
ACADEMIA / GOVERNMENT	8000	1200	9200 ❑

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STUDENT REGISTRATIONS

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

DRUG INFORMATION ASSOCIATION

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PAYMENT DETAILS

Account Name: DIA (INDIA) PRIVATE LIMITED
Account No: 061010200024611
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Branch Name: Dhiraj Baug, Near Hari Niwas Circle, LBS Marg, Thane (W) – 400602
IFSC Code: UTIB0000061
MICR Code: 400211013
Swift Code: AXISINBB061

PAYMENT INFORMATION

Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:
Bhavesh Vora
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Please check the applicable category: ❑ Industry ❑ Government ❑ Academia ❑ Student

PLEASE PRINT ALL INFORMATION CLEARLY

Last Name First Name M.I. Please check one: ❑ Mr. ❑ Ms. ❑ Prof. ❑ Dr.

Job Position Affiliation (Company) ❑ Business Address ❑ Home Address

Address (Please write your address in the format required for delivery to your country.) City Postal Country/Region

Address

Telephone Number Fax Number Mobile Number (Required) Email (Required for confirmation)

IF FAXING OR MAILING THIS FORM, PLEASE PROVIDE A COPY OF REGISTRANT'S BUSINESS CARD.