e-CTD Hands on Training Workshop (One Day)

ID# 13660
February 4 and 5, 2013 Mumbai, India

PROGRAM COMMITTEE

Kent Briggs
Professional Services Director
LORENZ Life Sciences Group

Michael Schultz
Director Sales, Middle East & Asia Pacific
LORENZ Life Sciences Group

Chithra Muthukrishnan
Professional Services Consultant
LORENZ Life Sciences Group

Jayaprakash Nallasamy
Head, Sales and Business Development
LORENZ Life Sciences Group

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

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TRAINORS

Kent Briggs
Professional Services Director
LORENZ Life Sciences

Chithra Muthukrishnan
Professional Services Consultant
LORENZ Life Sciences

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, Submissions Management and Electronic Publishing.

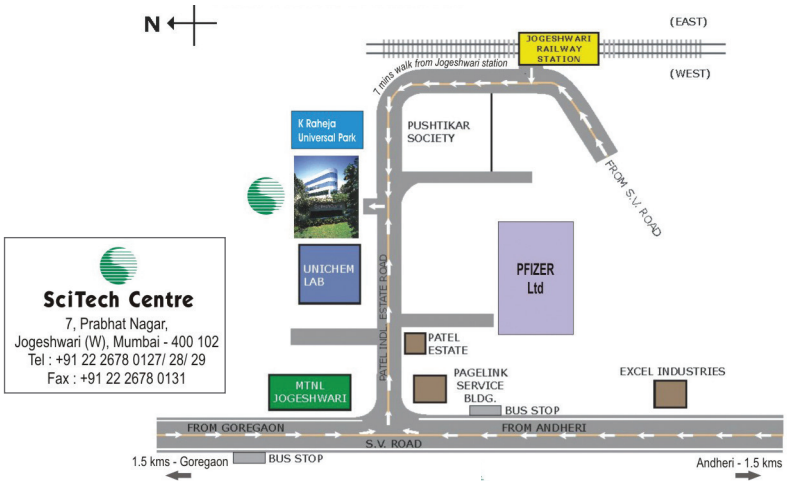
LEARNING OBJECTIVES

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

SAVE THE DATE

New Insights into Current Pharmacovigilance Challenges
March 8-9, 2013



All attendees will receive a DIA Certificate of Attendance at the conclusion of the event.

DIA®
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DAY 1 | **MONDAY, FEBRUARY 4, 2013**

8:30-9:00 AM

Registration

9:00-9:10 AM

Welcome and Introduction

9:10-9:30 AM

Getting Started
Kent Briggs
Professional Services Director
LORENZ Life Sciences

9:30-10:10 AM

Compilation of Summaries and Overviews and Quality Data (CMC)
Kent Briggs
Professional Services Director
LORENZ Life Sciences

10:10-10:40 AM

Compilation of Nonclinical and Clinical Studies as Study Tagging Files
Kent Briggs
Professional Services Director
LORENZ Life Sciences

10:40-10:55 AM TEA / COFFEE BREAK

10:55-11:25 AM

Compilation of Regional Module 1 for: US
Kent Briggs
Professional Services Director
LORENZ Life Sciences

11:25-11:55 AM

Hyperlinking
Kent Briggs
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LORENZ Life Sciences

11:55 AM-12:25 PM

Initial Submission Publishing
Kent Briggs
Professional Services Director
LORENZ Life Sciences

12:25-1:25 PM NETWORKING LUNCH

1:25-2:10 PM

US eCTD Life Cycle Management
Kent Briggs
Professional Services Director
LORENZ Life Sciences

2:10-2:40 PM

Cloning
Kent Briggs
Professional Services Director
LORENZ Life Sciences

2:40-3:10 PM

Compilation of Regional Module 1 for: EU
Kent Briggs
Professional Services Director
LORENZ Life Sciences

3:10-3:25 PM TEA / COFFEE BREAK

3:25-3:55 PM

eCTD Life Cycle Management and Submission Replication
Kent Briggs
Professional Services Director
LORENZ Life Sciences

3:55-4:15 PM

Validation of EU and US Submissions
Kent Briggs
Professional Services Director
LORENZ Life Sciences

4:15-5:15 PM

Submitting eCTDs Globally
Kent Briggs
Professional Services Director
LORENZ Life Sciences

VENUE DETAILS

Sci-Tech Center 7, Prabhat Nagar, Jogeshwari West, Jogeshwari West, Mumbai, Maharashtra 400102 **Land Mark- Next To Unichem Limited & Pfizer Limited

Contact Person: Kanchan Patel email: kanchan.patel@diaindia.org
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MEETING MANAGER: Manoj Trivedi, Senior Manager
Marketing and Program Development, DIA (India) Private Limited
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CANCELLATION POLICY: On or before JANUARY 31, 2013

Cancellations must be in writing and received by January 31, 2013. 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:

FULL MEETING CANCELLATION ***(All refunds will be issued in the currency of original payment):***
75% of The Delegate fee

PLEASE CONSIDER THIS FORM AS AN INVOICE

e-CTD Hands on Training Workshop (One Day)

Meeting I.D. # 13660 – February 4 & 5, 2013 – Sci-Tech 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.

	BASIC RATE	SERVICE TAX	TOTAL
Standard Membership	1768	182	❑ INR 1950
Student Membership*	445	55	❑ INR 500

DELEGATE FEE			
	BASIC RATE	SERVICE TAX	TOTAL
Industry	6000	742	❑ INR 6742
Academia	3560	440	❑ INR 4000
Student*	2825	175	❑ INR 3000

***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.

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 workshop.

Please indicate day attending:
❑ February 4, 2013 ❑ February 5, 2013

Please check the applicable category:
❑ Academia ❑ Industry

PLEASE PRINT ALL INFORMATION CLEARLY

PAYMENT INFORMATION

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

Manoj Trivedi, Senior Manager Marketing and Program Development, DIA (India) Private Limited
Cell: +91.98.1977.7493, Tel: +91.22.6765.3226
email: Manoj.Trivedi@diaindia.org

Degrees: ❑ Dr. ❑ Mr. ❑ Ms.

Last Name (Family Name)

First Name M.I.

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