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→ OPENeCTD forum →

May 14th – 16th, 2007
Le Méridien, Budapest, HU



May 14th, 2007

(Sponsored ½ day workshops)

Morning Sessions (9:00 – 13:00)

WS 1

A practical introduction into PIM

Speaker:

Mr. Farzad Shabestari and
Mr. Shei Dattner, EXTEDO – IABG-LSS, DE
Mr. Matthias Heyn, SDL International, BE

PIM is an evolving European standard for the electronic submission and management of drug approval labelling documents. This session represents an approach to provide a rather practical perspective onto the creation and management of PIM submission. The workshop session will cover hands-on practices for the attendees.

The workshop is divided into three sessions:

1. An introduction to PIM
2. Creating an initial PIM submission
3. Translation management and LC considerations of PIM submissions

WS 2

Building eCTDs - a practical workshop

Speaker:

Hugues Trapp, Datafarm Inc., UK

Datafarm solutions are used throughout the world by small, medium and global pharmaceutical companies to create e-submissions. The Datafarm workshop will provide you with guidance and examples of how technology can be used to create your initial eCTD submission, submit a variation as a sequence, and manage the life cycle.

The workshop is divided into three sessions:

1. Creating your initial eCTD submission
2. Building sequences
3. Managing the life cycle

WS 3

Integrating Document and Submission Management into one seamless lifecycle

Speaker:

Mr. Ken Hayward, QUMAS, USA

Topics to include:

- Document management - keeping the needs of each functional area of R&D in mind (Clinical, Non-Clinical, CMC, RA)
- Managing all of your publishing needs with one publishing tool
- Benefits of a prime contractor approach
- Benefits of integrated content management and submission management solutions
- What to look for in content management and submission management integrations
- The needs of document collaboration with internal and external authors
- Intelligent Authoring Templates: Help your authors focus more on content and less on guidances

Coffee & tea breaks in the morning and in the afternoon

Lunch break 13:00 – 14:00

Attendees can join two preselected workshops.





May 14th, 2007

(Sponsored ½ day workshops)

Afternoon Sessions (14:00 – 18:00)

WS 4

Validation and viewing of eCTDs via EURS is Yours

Speaker:

Dr. Gerhard Neurauter and

Mr. Schei Dattner, EXTEDO – IABG-LSS, DE

EURS is Yours represents the eCTD reviewing system selected by EMEA and various NCAs for the electronic review and management of eCTDs. EXTEDO – IABG-LSS offers a base license of *EURS is Yours for Industry* at no license costs for applicants. In order to get in touch with EURS is Yours and its ability to support the eCTD based submission process of your company this workshop provides a set of beneficial aspects. This workshop session will cover hands-on practices for the attendees.

The workshop is divided into three sessions:

1. An introduction to EURS is Yours
2. Validating and viewing submissions
3. Regulatory activities and LC management via EiY

Who should participate?

All Regulatory Affairs experts and assistants who are involved in the assembly and compilation of regulatory submissions.

WS 5

Planning and implementing electronic Document Management Systems (eDMS) in regulatory environments

Speaker:

Mr. Andreas Treptow and

Mr. Stephan Grande,

OPTIMAL SYSTEMS GmbH, DE

Presentation of the basic functions of an electronic document management system (eDMS) using OS.5|ECM.

Experience how, as a platform for eCTD, an eDMS supports the creation, reworking, release and distribution of regulated and non-regulated documents, and how each document's lifecycle is continuously depicted. Controlled and dynamic processes support documentation processing and SOP management, with each processing step recorded in an audit trail. The final documents to be submitted can be transferred to a Submission Management System and the finished dossier fully filed in eDMS.

WS 6

Preparing compliant eCTD submissions

Speaker:

Antoinette Azevedo,

e-SubmissionsSolutions.com, USA

Receiving a refuse-to-file (RTF) from a regulatory authority can be very expensive. This presentation will provide an overview of best practices to enable a sponsor to prepare a compliant eCTD for regulatory authority review, based on a case study of a California biotech.





May 15th, 2007

(OPeNeCTD - Main Conference Day)

1/2 hour presentations (9:00 – 18:00)

Agenda day 2

- 09:00 Welcome
(Mr. Tore Bergsteiner, EXTEDO - IABG-LSS, DE)
- 09:05 Welcome and Introduction
(Mr. Hans van Bruggen, eCTDconsultancy, UK)
- Chair
- 09:10 Welcome and „The eCTD in Hungary“
(Prof. Tamás L. Paál, OGYI, HU)
- 09:30 eCTD – Its all about planning...
(Mr. Shy Kumar, Datafarm Inc., USA)
- 10:00 Practical experiences with eCTD from
the point of view of an R.a.D. manager
(Dr. Tamás Szüts, ELECDOC, HU)
- 10:30 eCTD validation at the agencies in the
US, EU and Canada
(Mr. Harv Martens, ING America Inc., USA)
- 11:00 coffee and tea break
- 11:30 Compilation of a DCP dossier at MEDA
Pharma GmbH & Co. KG
– exemplified illustration of working
procedures and processes
(Dr. Jaroslava Paraskevova, MEDA Pharma
GmbH & Co. KG, DE)
- 12:00 Best practice for the use of eCTD in MRP
and DCP
(Mr. Kevin Wing, eCTDconsultancy, UK)
- 12:30 Experience gained during a test period of
working with electronic submissions at a
national authority
(Mrs. Karin Gröndahl, Medical Products
Agency, SE)
- 13:00 lunch break
- 14:00 Current status and future directions of
PIM
(Mr. Timothy Buxton, EMEA European
Medicines Agency, UK)
- 14:30 An applicant's experience with a PIM
submission
(Mr. Andrew P. Marr, PhD, GSK, UK)
- 15:00 The experience of a PIM submission: the
agencies' perspective
(Mrs. Claire Holmes (Edwards), EMEA European
Medicines Agency, UK)
- 15:30 coffee and tea break
- 16:00 Successful transitions – a focus on eCTD
(Mr. Farouk Bouaziz, Thomson Scientific, UK)
- 16:30 Lifecycle management considerations
from a multiple country perspective
(Mr. Erick Gaussens, Product Life SARL, FR)
- 17:00 Building US NDA and Canadian NDS sub-
missions based on European eCTDs
(Mr. Ted Hanebach, CanReg Inc., CAN)
- 17:30 HL7 Regulated Product Submissions
(RPS) and the ICH eCTD
(Mr. Andrew P. Marr, PhD, GSK, UK)

Who should participate?

This conference will particularly benefit life sciences professionals who work in regulatory affairs: directors, heads and managers of regulatory affairs as well as IT managers focusing on optimizing information management systems in pharmaceutical and biotechnology regulatory departments.





May 16th, 2007

(eCTDmanager - User Group Meeting)
(9:00 – 16:00)

Chair

Mr. Tore Bergsteiner,
Managing Director EXTEDO – IABG-LSS, DE

Mr. Andreas Suchanek,
Managing Director EXTEDO – IABG-LSS, DE

Mr. Lee Knoch,
CEO EXTEDO Inc., USA

Topics covered on day three:

- Welcome
- Case Studies
- eCTDmanager 2.4 – new functions
- New training concept of EXTEDO – IABG-LSS
- Ask the experts session
- Wish list and priorities



Who should participate?

This user group meeting is addressed to current and future users of the eSubmission Management System eCTDmanager. RA experts who are involved in the eCTDmanager-based compilation and publishing of submissions will get an idea of future developments. The user group meeting will influence the priorities for future functionalities to be covered by the system.

Objectives of the OPENeCTD forum

The OPENeCTD has been initiated to provide a forum for openly discussing and progressing the eCTD standard. OPENeCTD is recognized as a leading conference and education platform addressing submission management and eCTD relevant topics from a distinguished industry and authority perspective. The 2007 program, selected by an independent steering committee, covers the most important items affecting business critical eCTD projects and experiences today and in the future. The program is case study based and will present real-life scenarios, challenging questions and new developments. The goal of the OPENeCTD conference is to progress the overall acceptance of the eCTD standard. This goal is in the interest of all of the actively involved players.



Coffee & tea breaks in the morning and in the afternoon
Lunch break 13:00 – 14:00



Information

Location

Hotel Le Méridien Budapest
Erzsébet tér 9-10, 1051 Budapest, Hungary
Phone : *36-1-4295500 Fax : *36-1-4295660

Fee

Day I € 400 Day II € 800 Day III € 400
(+ VAT, including documentation pack, certificate, lunch and coffee & tea breaks) A maximum of 2 authority members per agency are free of charge!

Accommodation

The hotel Le Méridien Budapest has allocated a block of bedrooms at a special rate for attendees. Reservations have to be done directly at the hotel. Please use the attached dedicated reservation form. For other hotel recommendations please check our website: www.openectd.org

Registration and Information

Complete the registration form and return it to

EXTEDO - IABG Life Sciences Solutions GmbH
Einsteinstraße 30, 85521 Ottobrunn, Germany
OPENeCTD forum
Andrea Beeker, Conference Manager
Telephone: *49-89-2351202-15 Fax: *49-89-1890826-79
E-mail: beeker@extedo.com

www.openectd.org

Confirmation

Register early. Since space is limited please await the written confirmation of your registration.

Cancellation

Your notice of cancellation must be received in writing (letter or fax) 10 working days before the conference in order to transfer your event pass to someone else in the waiting list. We will be pleased to transfer your registration to another member of your company at any time. No cancellations will be accepted after that date.

Registration

Please complete and return it to:
EXTEDO - IABG Life Sciences Solutions GmbH
Einsteinstraße 30, 85521 Ottobrunn, Germany
OPENeCTD forum
Andrea Beeker, Conference Manager
Fax: *49-89-1890826-79

Title _____

Name/First Name _____

Position
/Department _____

Company
(correct invoice address) _____

Company VAT ID No. _____

Street _____

Zip-Code/City _____

Country _____

Telephone _____

Fax _____

E-mail _____

Date/Signature: _____

- Day I € 400,00
Please choose two workshops:
 WS1 WS2 WS3 (morning)
 WS4 WS5 WS6 (afternoon)
- Day II € 800,00
 Day III € 400,00

(+ VAT, including documentation pack, certificate, lunch and coffee & tea breaks)

Since space is limited please await the written confirmation of your registration.



Goldsponsor



Silversponsor



Associations

The following associations are supporting the OPENeCTD forum 2007:

MittelEuropäische Gesellschaft für Regulatory Affairs (MEGRA) e.V. (<http://www.megra.org>)

TOPRA The Organisation for Professionals in Regulatory Affairs (<http://www.topra.org>)

HURAS Hungarian Regulatory Affairs Society
<http://www.huras.hu>

Members will receive a 10 % discount.