

The eCTD

Presentations & computer demonstration on dossier submission

Topics

- NeeS or eCTD - the principles & the acceptance in Europe
- eCTD compilation for European submissions - the authorities' national peculiarities
- eCTD for national submissions in Bulgaria
- Hands-on exercise - first compilation of an eCTD and follow-up submissions

eCTD mandatory for the CP as of 1st January 2010 - as of when mandatory in Bulgaria?

Your speakers

Assoc. Prof. Tatyana Benisheva-Dimitrova
Faculty of Public Health,
Medical University-Sofia,
Bulgaria

Holger Spalt
Extedo GmbH,
Ottobrunn, Germany

Dr. Maren von Fritschen
PharmaLex GmbH,
Repräsentanz Berlin,
Germany

Aims and objectives

As of 1st January 2010, eCTD will be mandatory for all centralised procedures. Many national authorities also accept only electronic submissions of marketing authorisation application dossiers, either as an eCTD or as a NeeS (Non-eCTD electronic submission). Also the Bulgarian authority will follow this path.

This seminar gives detailed information on the preparation and compilation of an eCTD and describes the differences between eCTD and NeeS.

In a practical session a step-by-step creation of an eCTD is demonstrated and potential pitfalls are explained. Do not miss this opportunity to receive a thorough update on the theory and practice of the eCTD!

Who should attend?

This seminar will be of benefit to everyone working in regulatory affairs in the pharmaceutical industry. Especially those dealing with dossier compilation and submission will profit from this course.

Limitation

This seminar is restricted to 30 participants. This limitation, a feature of all FORUM seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

Your speakers

**Assoc. Prof.
Tatyana Benisheva-Dimitrova**
Faculty of Public Health,
Medical University-Sofia, Bulgaria

More than 15 years experience in drug regulatory affairs and consultant of the single-source regulatory data base IDRAC of Thomson Reuters.

Holger Spalt
Extedo GmbH,
Ottobrunn, Germany

Senior Consultant;
EXTEDO is a key services and solutions provider in the field of regulatory data and document management for Life Sciences industries and authorities.

Dr. Maren von Fritschen
PharmaLex GmbH,
Repräsentanz Berlin, Germany

Director Regulatory Affairs;
PharmaLex was founded in 1998 by experts working in Regulatory Affairs at Boehringer Mannheim. The idea to support the pharmaceutical industry in drug registration met with instant success and with registration procedures becoming increasingly complex, PharmaLex has grown into a dynamic and successful company.

Programme 9.00 h - 17.30 h

> 9.00

CTD, NeeS and eCTD - the key principles

Dr. Maren von Fritschen

- eCTD structure: XML backbone/Table of contents/Envelope
- NeeS structure according to the new guideline
- NeeS and eCTD - two competing standards?

> 10.00

eCTD implementation - the European roadmap

Holger Spalt

- Are all national authorities capable of reviewing eCTDs?
- Is the eCTD the "state of the art"?
- eCTD submissions in other ICH regions (USA/Japan) and non-ICH regions in comparison

> 10.30 Coffee break

> 10.45

Peculiarities in the eCTD compilation for European submissions

Dr. Maren von Fritschen

- National peculiarities of the authorities
- Practical experience in European procedures (CP, MRP and DCP)
- Sequence tracking tables & best practice guide
- Strategic planning and consequences for lifecycle management

> 11.45

Preparing an eCTD compilation: a practical example (Demonstration on one PC)

Holger Spalt

- First compilation of an eCTD and follow-up submission
- Step by step through the dossier - Which documents need to be inserted?
- Setting hyperlinks
- Validation and export of an eCTD Sequence 0000
- eCTD as a basis for paper submission
- Useful hints for the first eCTD compilation

> 12.45 Lunch

> 14.00

eCTD submissions - the Bulgarian regulatory requirements

Assoc. Prof. Tatyana Benisheva-Dimitrova

> 15.00

Continuation:

Preparing an eCTD compilation

Holger Spalt

> 16.00 Coffee break

> 16.15

Optimal preparation for the validation phase - potential pitfalls

Dr. Maren von Fritschen

- Pilot submissions/reformatting
- Hyperlink strategies
- Document workflow
- Scanned documents ("legacy documents")

> 17.30 Seminar end

Registration under
registration@forum-institut.com or
Fax +49 6221 500-555

Registration Form

Yes, I will attend the Seminar

☐ The eCTD

☐ I am interested in more information about FORUM-Events
and I agree that this information is sent to me by e-mail.

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at office

Date, Signature

How to register

■ **Registration: +49 6221 500-501**

■ **Conference-No. 09 06 220|**

■ **Internet:**

www.forum-institut.com

■ **Date/Venue:**

Monday, 15 June 2009 in Sofia
8.30 h Registration; 9.00 h - 17.30 h Seminar
Rila Hotel
Kaloyan Street, 6, · BG 1000 Sofia
Tel. +359 2 93 791 · Fax +359 2 980 48 13

■ **Fee:**

€ 390,00

The fee includes course documentation as well as
mid-session refreshments and lunch. Invoice and
confirmation will be forwarded to you.

Bank details:

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Please quote the invoice number upon payment.

Any Further Questions?



I am gladly at your disposal should
you have any further questions
about the seminar.

Dr. Henriette Wolf-Klein

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Cancellation Policy

Our general terms and conditions apply (as of
19 December 2008) and are available upon request.
We can send them to you anytime or you can find them on
the internet at www.forum-institut.de/agb_en

We recommend taking out a seminar cancellation insurance.
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