

eCTD 2010 – 10 years of eCTD – where are we today?

5th May 2010
Mannheim, Germany
Course No. 6309

The first discussions about eCTD took place at the ICH in the year 2000, today it is a commonly used term in regulatory affairs. After 10 years of use everyone in regulatory affairs should be an eCTD expert.

BUT:

Only from January 2010 companies applying for approval of a new drug through the centralized procedure (EMA, formerly EMEA) are obliged to use the electronic CTD. For the majority of existing products approved by national Health Authorities in national or MR/DC Procedures the guidelines are much more heterogeneous. As a result companies, esp. in Europe, are still implementing eCTD very conservatively. However, there is no doubt left, that regulatory submissions in eCTD format will be the future. The national agencies in Europe also have their distinct roadmap towards eCTD, and other countries in the rest of the world are following.

Making
Science
Work

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Target Group

Scientists and Senior Managers from
Regulatory Affairs, Global Regulatory
Operations, Submission Management,
Life Cycle Management and Electronic
Publishing

eCTD 2010 – 10 years of eCTD

A seminar organised by the APV focus group
Drug Regulatory Affairs

Programme

Wednesday, 5th May 2010
09.00 to 17.00 h

Welcome

Detlev Rhäsa, PhD
YES Pharmaceutical Development
Services GmbH
Friedrichsdorf, Germany

Implementing an eCTD system at a global pharmaceutical company (Systems/Technical point of view)

Sven Harmsen
e-DRA Harmsen
München, Germany

Being ready for eCTD? – Introduction of eCTD in a mid-sized pharmaceutical company (Processes and procedures)

Ursula Schickel, PhD
Merz Pharma GmbH
Frankfurt, Germany

Recent experiences of implementing eCTD in MRP/DCP: The opportunities and challenges of the best practice guidance.

Andrew Marr, PhD
GlaxoSmithKline
Harlow-Essex, United Kingdom

Current experience with e-submission (eCTD & NeeS) and future plans within the EU – authorities point of view

Christa Wirthumer-Hoche, PhD
AGES PhamMed, Institut LCM
Wien, Austria

European & Swiss roadmap to eCTD: overview of guidelines and practical experience from MRP/DCP/NP

Dietmar Boecker, PhD
Bayer Schering Pharma AG
Wuppertal, Germany

The implementation of eCTD in Switzerland: First experiences, Updates and Future Plans

Zerobin Kleist, PhD
Swissmedic Schweizerisches Heilmittelinstitut
Bern, Switzerland

Submission efficiency: moving submissions off the critical path

S. Albert Edwards
Takeda Global Research & Development Centre, Inc.
Lake Forest, IL, United States

Programme is subject to change

Course Leader

Detlev Rhäsa, PhD studied Chemistry at Georg-August-University, Göttingen, PhD in 1987.

Experience in regulatory Affairs with focus on electronic submissions since 1998 in various roles in different companies, consulting on processes and implementation of eCTD tools, support and consulting for creation of electronic submissions in eCTD and pre-NeeS – format in Europe and the US since 2001.

Objectives

This seminar welcomes speakers from well-known pharmaceutical companies from Europe and the US, who are willing to share their success and experience in implementing and using the eCTD efficiently on a daily bases.

Starting with focus on the successful introduction of a system and determination of changes to and optimization of company-internal processes you will learn from practical experiences and advantages gained in MR/DC – Procedures.

As there are some important changes planned in the European Guidelines in early 2010 these will be highlighted from the Agency's point of view including some first experience.

Finally you will get an insight into the changes the eCTD specification will undergo in the future, which still ensures that investing into eCTD is also an investment into the future: RPS, the next major version will be built upon your eCTD's!

Organisation

Date

Course No. 6309
on 5th May 2010 09.00 to 17.00 h

Location

Dorint
Kongress Hotel Mannheim
Friedrichsring 6
Mannheim, Germany
Tel.: 0621/1251-0
Fax: 0621/1251-100

Registration fee

APV member 990 EUR
Non-member 1120 EUR
(free of VAT according to § 4,22 UStG)
Coffee breaks, lunch and proceedings included

Accounts

Dresdner Bank AG Mainz
Account No. 2 325 159 00
Bank Code 550 800 65

Postbank Frankfurt/M.
Account No. 127 35-606
Bank Code 500 100 60

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
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You will receive a confirmation of your registration with the invoice.

Members of authorities pay half of the APV member's and Non-member's registration fee respectively.

Hotel reservation

Dorint
Kongress Hotel Mannheim
Friedrichsring 6
Mannheim, Germany
Tel.: 0621/1251-0
Fax: 0621/1251-100

Participants are asked to make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate:
21st April 2010.

Special rate: Single room excl. breakfast
EUR 130,00 per night.

Mainz, January 2010