

# eCTD Current Status and Applications in the World & Turkey

April 13th, 2010 - Nippon Hotel - ISTANBUL

**PROGRAM:**

9:00-10:30 **SESSION I** Moderator: **Sven Harmsen**

**Raoul A. Lorenz**, Lorenz Life Sciences GERMANY  
eCTD, Current Practices and Worldwide Overview

**Rachel Harrington**, Astellas Pharma EUROPE  
CTD/eCTD in the USA and Canada: A Brief Summary

**Dr. Andrew P. Marr**, GlaxoSmithKline ENGLAND  
The status of implementation of e-submissions (eCTD and Nees) in the European Centralized, Decentralized, Mutual Recognition and National Procedures.

10:30-11:00 Coffee Break

11:00-12:30 **SESSION II** Moderator: **Dr. Murat Hamzakadi**

**Sven Harmsen**, e-DRA Harmsen GERMANY  
Regulatory (Clinical) Document Management all the eSystems you need

**Inge W. Andersen & Jorn Andersen**,  
IWA Consulting DENMARK  
eCTD Life Cycle Management

12:30-13:30 Lunch Break

13:30-15:00 **SESSION III** Moderator: **Raoul A. Lorenz**

**Dr. Ferhad Farsi**,  
Abdi Ibrahim Pharmaceuticals TURKEY  
eCDT implementation from industry perspective

**Dr. Michael Braun**, Exalon GERMANY  
Realizing eCTD capability with external providers:  
Points to consider

15:00-15:30 Coffee Break

15:30-17:00 **SESSION IV** Moderator: **Dr. Andrew P. Marr**

**Yasemin KARABEY**, Ministry of Health TURKEY  
Status of CTD / eCTD in TURKEY

**Dr. Murat Hamzakadi**,  
Astellas Pharma Europe THE NETHERLANDS  
eCTD vs (p)CTD-Practical Experiences & Roadmap  
for Successful Implementation

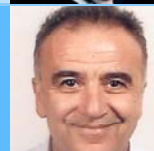
**Umut Gümüšbaş**, MK Consulting TURKEY  
Electronic Applications & Feasibility  
Assesments in Turkey

17:00-18:00 **CONCLUSION BY MODERATORS**

**Raoul A. Lorenz** has completed his BA (hons) in European Business Administration at European Business School of London, UK. During his studies, He also worked for BHF Bank (UK), Lehman Brothers (UK), Editions Bauer (France) and Aquarius (Germany) [Today, it is known as: Fujitsu Siemens Computers] He started to work at Lorenz Archiv Systems GmbH in 1996 in project management. Since then, he holds positions in LORENZ Group companies around the globe as Managing Director, VP, Director and CEO.



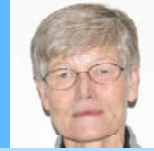
**Dr Murat Hamzakadi** graduated from the Medical Faculty of Istanbul University in 1987 and he started working as GP for the Ministry of Health for 2 years. Dr Hamzakadi joined pharmaceutical industry in 1997 and since then he held various positions in different functional areas like Clinical Research, Project Management and Regulatory Affairs in several companies and organizations. In his current position as Associate Regulatory Operations Director at Astellas Pharma Europe R&D, he is mainly responsible for the eCTD and other eSubmissions, electronic Lifecycle Management as well as for the development and implementation of all new Regulatory Operations related activities.



**Sven Harmsen** was graduated from Wuerzburg University, master of Business Administration in 1994. From 1995 to 2008, he worked at several companies such as CSC Ploenzke AG, Documentum Inc, Open text GmbH and Astellas Pharma GmbH in several positions like a consultant, engineer and a manager. On January 2008, he established his company, e-DRA Harmsen. He is still working as a senior consultant at the company from that time.



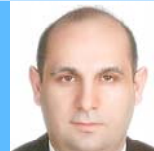
**Inge W. Andersen** was graduated from Royal Danish School of Pharmacy in 1976. Formerly, she worked at the RA Departments of Novo Nordisk Denmark and USA as a manager. She is the president of the IWA Consulting regulatory Affairs since 1997.



**Jorn Andersen** has completed his B.Sc Degree in Electronic Engineering. After that he has worked in several companies related to his area. He has been working at IWA since 1998. He has been working with eCTD's since 2005 when docuBridge was first installed at IWA Consulting. IWA Consulting has submitted app. 1000 sequences to the EU as well as eIND's. IWA Consulting has also participated in NDA's in USA, CA and EU.



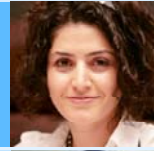
**Dr. Ferhad Farsi** who has been working in pharmaceuticals industry since 1993, currently works at Abdi Ibrahim Pharmaceuticals as R&D Director mainly responsible for generic product development comprises analytic & formulation development, bioequivalence, intellectual property & patent, technology transfer. He graduated from Hacettepe University Faculty of Pharmacy in 1990 and made his master of science in pharmaceutical technology between 1990 and 1993 concerning sustained release tablet formulations. He was rewarded in "the fourth liposome research days conference" for his vivo studies on humans was realized between 1993-1997 during his Ph. D study. For the time being he has 15 PCT patent applications.



**Dr. Andrew P. Marr** has worked in Regulatory Affairs for 26 years in a variety of roles within GSK and its heritage companies. Andrew's responsibilities include contributing the external regulatory input in to the design, implementation and the management and use of electronic document and submission publishing systems throughout GlaxoSmithKline. He is currently Director of Global e-Regulatory Development in Global Regulatory Operations at GlaxoSmithKline R&D, based in the UK.



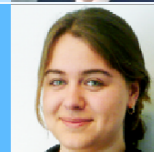
**Yasemin KARABEY** is the Head of Legislation and EU Harmonization Department in General Directorate of Pharmaceuticals and Pharmacy (GDPP) which takes place in the body of Turkish Ministry of Health. She worked as a dossier assessor between 2005 and 2007. Since 2007 she has been involved in the IEGM-2007 Project which aimed to create the infrastructure of electronic document management system and electronic submission.



**Dr. Michael Braun** studied Microbiology/Biotechnology at University of Saarbruecken (Germany) and graduated in 1998 (MSc). From 1998 to 2003 he made his PhD studies and worked as postdoctoral research scientist at University of Tuebingen (Germany). He joined the global pharmaceutical industry in early 2004 working as RA manager at ALTANA Pharma (later Nycomed). Since 2007 he is working as Managing Director and Regulatory Operations Consultant at Exalon. Michael has been responsible for multiple eCTD and other electronic submission projects for all registration procedures and application types worldwide since 2004. He is member of the German Association for Drug Regulatory Affairs (DGRA) and the Regulatory Affairs Professional Society (RAPs).



**Rachel Harrington** is a graduate of Marquette University (USA). She has worked in the pharmaceutical industry since 2002 and in Regulatory Affairs since 2005. She has submitted, maintained and developed processes for eCTD dossiers in North America, including IND, NDA and NDS applications. Since 2008, she has worked in Regulatory Operations at Astellas Pharma Europe R&D, managing European submissions in eCTD and Nees formats.



**Umut Gümüšbaş** who graduated from Middle East Technical University, Department of Biological Sciences, has completed METU Neurophysiology Master Program in 2003. He is working in the pharmaceutical sector since 2004 and continue his career as a freelance consultant. Gumusbas, who served in many projects as a specialist in preparation, submission and follow-up of the registration application dossiers in Turkey, also specialized on European Regulatory Procedures (CTD submission, eCTD, CP.DCP, MRP, NPs of European Countries) by joining an exchange program between Regulanet and Farmavita partners in Europe.





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I S T A N B U L

## Learning Objectives:

Filing submissions is a time consuming, laborious task for industry and regulators alike. The sheer size of each submission leads to costly time delays at every stage of the submission process. Using electronic formats has been proven to speed your data through the approval process, saving you valuable resources and time. The electronic formats and eCTD will become mandatory at EMEA starting from January 01, 2010 and it can only be a matter of time before it is mandatory on a global scale, including Turkey.

## At the end of this 1 day seminar, participants should be able to:

- Discuss emerging and future trends in electronic submissions including eCTD and country specific electronic formats
- Identify challenges and benefits of transitioning to eCTD
- Identify the various methods of submitting electronic submissions to global health authorities
- Identify the status of the process in several regions in the world (EU, USA, Canada, Turkey)

## Who Should Attend:

This seminar is designed for experts in the pharmaceutical and biotechnology industries involved in the preparation and review of marketing applications for submission to regulatory agencies. This includes regulatory affairs staff, medical and scientific writers, personnel responsible for assembling and collating documentation, as well as managers and supervisors of departments responsible for generating and approving these documents. These departments include, but are not limited to:

- Regulatory Affairs, Manufacturing
- Nonclinical Pharmacology, Pharmacokinetic, Toxicology
- Clinical and Medical Research
- Quality Control and Quality Assurance
- IT and other personnel involved in eCTD development
- Project Management

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eCTD

## REGISTRATION FORM

**Please fill and fax to: +90 212 251 19 61  
or email to: [mk@mkistanbul.com](mailto:mk@mkistanbul.com)**

Name / Surname : .....

Title : .....

Company : .....

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E-mail : .....

Date : ...../...../20..... Signature & Seal :

**The registration fee: 490 Euro + 18% VAT  
Early registration fee and date: 390 Euro +  
18% VAT before February 26th, 2010**

Transfers should be made to Turkiye Garanti Bankasi, Galatasaray Branch (Branch Code: 068), EUR Account No: 908 82 92 (Account holder is MK Danismanlik Egitim Tibbi Urunler Ltd. Sti.) IBAN No: TR28 0006 2000 0680 0009 0882 92

- The seminar will be in ENGLISH.
- The registration fee includes course documentation, lunch and mid-session coffee breaks. No refunds will be given in case of a cancellation but change in the name of the delegate will be possible. In the event of circumstances beyond its control, MK Consultancy Training reserves the right to change the date and/or cancel the programme; in this case fees will be refunded.