

gold sponsor:

silver sponsor:



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



07



OPENeCTD forum – HU  
Call for Paper



Progressing the eCTD standard

Dear colleague!

We need your support, your expertise and your ideas!

The OPENeCTD - HU - 2007 is currently in the process of selecting exciting topics and presentations to finalize the agenda for the upcoming event.

To putting your interesting topic into consideration please provide us with the following information due to February 28th, 2007:

- name and job title of the presenter
- topic of the 30 min presentation and
- a 75 - 150 word abstract



## OPENeCTD - HU - 2007

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

OPENeCTD is recognised 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 as of today and in future. The program is case study based and will present real-life scenarios, challenging questions and new developments, delivered by leading experts and speakers, who will share with you how they achieved success, solved problems and gained value. Presentations will be delivered by senior executives from authority, industry, eCTD consultancies and solution providers.

\* The Independent Steering Committee consists out of  
Tore Bergsteiner/ EXTEDO - IABG-LSS, Timothy Buxton/ EMEA,  
Hans van Bruggen/ eCTDconsultancy and Shy Kumar/ Datafarm.

## Topics to be covered include

- › eCTD readiness of the various ICH based agencies
- › eCTD crossing the borders of recognized ICH regions
- › eCTD based case studies – lessons learnt and best practices
- › SOPs to adequately cover an eCTD based compilation and submission process
- › The ETICS project and the impact on consolidating eCTD compliance requirements
- › Lifecycle Management considerations from a multiple country perspective
- › Integration of Product Information Management (PIM) into the electronic submission process
- › Lessons learnt with regard to national, centralized and MRP based eCTD submissions
- › The eCTDs impact on the authorities working process
- › Technical writing aspects with regard to the eCTD in an early phase
- › Integration of legacy documents into an eCTD based submission process
- › Long term archival and quality measures of electronic documents and many more.



## Contact

EXTEDO – IABG Life Sciences Solutions GmbH

Einsteinstrasse 30  
85521 Ottobrunn, Germany

→ Andrea Beeker, Conference Manager

Phone: +49-89-2351202-15  
Fax: +49-89-1890326-79

e-Mail : [beeker@iabg-lss.com](mailto:beeker@iabg-lss.com)

→ Tore Bergsteiner, Managing Director

Phone: +49-89-2351202-10  
Fax: +49-89-1890326-79

e-Mail : [bergsteiner@iabg-lss.com](mailto:bergsteiner@iabg-lss.com)

→ Internet : [www.openectd.org](http://www.openectd.org)



## Impressions OPeNeCTD - BE - 2006

March 28th, 2006  
Brussels, BE

