



EXTEDO Press Release

FOR IMMEDIATE RELEASE

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EXTEDO Hosting Fourth Annual OPENeCTD Forum on September 28-29, 2009, in Nice, France

Munich/ Ottobrunn, Germany – September 2, 2009 – [EXTEDO](#), a key eSubmission solutions provider for life sciences firms, today announced that they will be hosting the fourth annual OPENeCTD forum on September 28-29, 2009, in Nice, France.

The OPENeCTD forum is a must attend event for regulatory affairs professionals in the life sciences industry. Attendees will learn about the many key developments and the latest news around the eCTD standard and related eRegulatory developments by a distinguished panel of industry and authority experts.

“If you have not attended in the past, be prepared for an event that will set new standards – with top-level speakers, up-to-date information and many networking opportunities,” said Tore Bergsteiner, Managing Director for EXTEDO.

The following regulatory authority experts (alphabetical order) will be presenting the latest national and regional status information as well as upcoming requirements:

- Caroline Auriche, Afssaps, FR
- Karin Gröndahl, MPA, Sweden
- Claire Holmes, EMEA, EU
- Dr. Stephan Järman, Swissmedic, CH
- Yoshihiko Inazumi, PMDA, Japan
- Yasemin Karabey, TMH, Turkey
- Lidija Makarova, LSAM, Latvia
- Dr. Norman R. Schmuff, FDA, USA

Also presenting will be leading experts from btconsult, CanReg, Celgene, Comply Services, eCTDconsultancy, EXTEDO, Genzyme, GSK, Ipsen, Klever/Angelini, LSCP, Merck-Serono, MSD, PharmaLex, ProductLife Groupe, Qdossier, Roche, SAFE-Biopharma, SDL, SP-MSD

Topics will include:

- The global eCTD: Submitting eCTDs to the FDA, HC and the EU
- Validation Requirements and how to adopt internal business processes
- Paper Publishing Requirements – Best Practices, Clinical Report and Study Publishing
- eCTD Collaboration between Companies – Interoperability of eCTDs
- Submission Planning and Tracking – How to manage registrations
- Hyperlinking – Requirements and Best Practices
- The Product Lifecycle Dossier – Considerations beyond a single application
- Global Labeling – Requirements & Best Practices
- Status of the EU regulations – Readiness of EU regulations (various countries)
- Worldwide electronic Submissions – The eCTD outside the ICH & Non ICH electronic Submissions
- Best Reviewing Practices of Nees + eCTDs

Sponsoring companies to date include - [NextDocs](#), [OpenText](#), [Optimal Systems](#), [ProductLife Groupe](#), and [QUMAS](#).

For more information please visit: <http://www.openectd.org>.

About EXTEDO

For nearly 15 years EXTEDO has been a key services and solutions provider in the field of regulatory data and document management (CTD, eCTD and other formats) for Life Sciences industries and authorities (Pharmaceutical, Crop Science, Chemicals). Based on well-founded expertise and many years of experience, EXTEDO provides highly standardized as well as customized solutions in the area of electronic Regulatory Affairs.

EXTEDO, being globally represented, serves more than 600 Life Sciences organizations in more than 50 countries.

For more information visit www.extedo.com.

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