DIA 8th Annual Electronic Submissions Conference Addresses Current Developments in eCTD around the World

The Drug Information Association will host the 8th Annual Electronic Submissions Conference from November 17- 19, 2009 in San Diego, CA.

Horsham, PA (Vocus) October 10, 2009 -- The Drug Information Association (DIA) will host the 8th Annual Electronic Submissions Conference from November 17- 19, 2009 in San Diego, CA.

Electronic CTD is poised to become the preferred format for regulatory submissions in many regions, from South-central Asia to the Pacific Rim to Latin America. Australia and Switzerland have both issued statements of intent to accept eCTD, while many other regions are basing both paper and electronic submission formats on the CTD structure. This three-day conference will include two parallel tracks featuring the following sessions:

- Efficient Creation of eCTD Content
- Changing Your business Model to Get the Most Out of Your eCTD
- Submission Project Management
- Study Tagging Files: Their Vital Role in Submissions to FDA
- Not Your Everyday eCTD
- Perspectives on CDISC: Standards for Data and Metadata in Submissions
- Advanced Lifecycle Management
- CTD-Aligned Submission Formats
- DIA'S Document Reference Model and eCTD Publishing

In addition, six concurrent pre-conference tutorials on November 17 will cover:

- EU Regulatory Review Procedures and Their Implications for eSubmissions Publishing
- INDs in eCTD Format
- eCTD Basics
- US-EU eCTDs (Creating eCTDs for the US and EU): Differences and Similarities
- eCTD Lifecycle Management
- Metadata and Standards: How Metadata Is Used from Protocol Definition to Regulatory Submission

The opening plenary sessions will feature speakers from FDA, the European Union, and Health Canada to present up-to-date information on FDA's standards, expectations, and experiences with eCTDs, as well as plans for eCTDs and eSubmissions in the US, EU, and Canada.

"Electronic CTD-formatted submissions have taken hold in the US and are on their way to doing the same in Europe," says Gary M. Gensinger, MBA, Deputy Director, Office of Business Process Support, CDER, FDA. "The 8th Annual Electronic Submissions Conference will discuss current developments in eCTD in the US and Europe, filing CTD-formatted submissions in other markets, and emerging technologies affecting electronic submissions."

Click here to register.
For exhibiting opportunities, contact Shannon Lewis at +1-215-442-6149 or Shannon.Lewis(at)diahome.org.

About the Drug Information Association (DIA)
DIA serves more than 30,000 professionals involved in the biopharmaceutical industry and regulatory affairs worldwide. Through its domestic and international meetings, training courses, workshops and webinars, DIA provides a neutral global forum for the exchange of information critical to the advancement of the drug discovery and lifecycle management processes. Headquartered in Horsham, PA, USA, and with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India, and Beijing, China, the Association is led by its volunteer-based Board of Directors and executive management team. For more information, visit www.diahome.org or call 215-442-6100.

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