ISI Europe to Host eCTD and NeeS Readiness Workshops in Spain

Submitted by: Sarum Consultancy
Friday, 1 May 2009

- Following the January 2009 mandate to publish regulatory submissions electronically in Spain, ISI's new workshop programme provides practical help and advice for pharma companies targeting the Spanish market -

Eschborn, Germany – April 30th, 2009 – Image Solutions Inc. (ISI), a leading provider of electronic submissions management and publishing solutions for the life sciences community, has today unveiled a timely programme of workshops to ease the transition to electronic publishing formats for regulatory submissions in Spain. These will be held in early May in Madrid and Barcelona.

As of January 1, 2009, Spain's authorities have mandated that regulatory submissions must now be made in electronic format, preferably the eCTD (electronic Common Technical Document) standard.

Recognising the time-consuming complexity associated with managing this transition, ISI Europe has announced a series of workshops designed especially for pharma companies publishing submissions in the Spanish market.

The workshops, to be held in Madrid on Thursday May 7 and Barcelona on Friday May 8th, will cater for both the eCTD standard, and Non-eCTD Electronic Submissions (NeeS), as Spain currently supports both options.

The instructor-led, half-day sessions, to be followed by optional hands-on sessions, are free to Life Sciences companies and independent regulatory consultants, and will cover the following:

• An eCTD overview, introducing the fundamental concepts of eCTD as well as ISI's eCTDXPress system for creating compliant eCTD submissions
• Practical and Technical Aspects of eCTD Implementation
• PDF document readiness and NeeS creation, based on ISIToolbox
• Active discussions covering business challenges, process and technology.

The formal morning session will cover key eCTD topics of interest to the European market, and is designed for industry professionals with little to no experience with eCTD, who may be involved with the development of an eCTD submission or the selection of an eCTD technology solution. This includes professionals who may be responsible for regulatory affairs, dossier and document management, IT and data management, compliance, publishing and submission management. Attendees will receive a reference manual for future use.

The sessions will be led by field-experienced consultants who have industry expertise in eCTD systems selection, implementation and, ultimately, eCTD compilation. With experience compiling over 1,000 eCTD submissions through their global outsourcing teams, ISI is uniquely able to share field-tested experience and best practices with workshop participants.

An optional post-conference hands-on workshop, meanwhile, will take an in-depth look at the practicalities of NeeS compliance. From 1 January 2009, Spanish authority, AEMPS, has mandated electronic submission of Regulatory Dossiers, at a minimum in the Non-eCTD electronic Submission (NeeS) format.

This practical session will explore specifically how Image Solutions' ISIToolbox solution can help bring pharma organisations in line with these requirements. The workshop will cover building a NeeS submission from scratch, as well as modifying a NeeS submission for local content (as in the case of MRP or DCP).

This workshop is intended for those individuals who are responsible for building compliant NeeS submissions for their registration dossiers. Space is limited to 15 participants.

Workshop timings:

Thursday, May 7, 2009
10:00 am – 5:00 pm
ME Madrid Rema Victoria
Plaza De Santa Ana, 14
28012 Madrid
Tel: (34) 91 701 60 00
http://www.memadrid.com/

Friday, May 8 2009
10:00 am – 5:00 pm
ME Barcelona
Diagonal/Pere IV, 272-286
08005 Barcelona
Tel (93) 367 20 50
http://www.me-barcelona.com

Agenda:

10:00 am – 14:00 pm – eCTD Readiness Training
14:00 pm – 15:30 pm – lunch
15:30 pm – 17:00 pm – optional NeeS Training

"We are delighted to be able to extend this invaluable programme to pharma organisations targeting the Spanish market," commented ISI's European MD, Adam Sherlock. "These are challenging times, especially in Europe where eCTD requirements currently vary considerably and are changing all the time, so ISI is pulling out all the stops to deliver solutions and services that lighten the load for this already heavily burdened industry."

For more information on the Spanish workshop sessions, or to sign up, please visit http://www.imagesolutions.com/workshop

About Image Solutions, Inc.

Founded in 1992, Image Solutions, Inc (ISI) is a proven market leader in providing submissions solutions, process services and consulting to Life Sciences companies as a way to improve clinical and regulatory processes that bring new medicines to market. ISI was among the first professional services firms to deliver electronic submissions to the industry and since has delivered thousands of electronic and eCTD submissions. ISI serves the top 50 pharmaceutical and biotech organizations as well as the top companies in other regulated industries.

ISI is a privately held company with headquarters in Whippany, New Jersey and operations throughout the U.S., Europe and Asia. ISI also remains committed to giving back to society and sharing its success with others by donating 10 percent of annual net profits to over 20 recognized charitable organizations. For more information, visit the company website at www.imagesolutions.com.

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