ISI Helps Spanish Companies Handle Electronic Submissions,

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• ISIToolBox®, along with specialised workshops, helps organisations make the transition to electronic submissions quickly and with minimal investment

• ISI's range of services and outsourcing solutions help European Local Operations to establish business processes as they embrace local electronic submission standards; manage submissions in the NeES/eCTD format

Eschborn, Germany – February 9th, 2009 – Image Solutions, Inc. (ISI) a leading provider of software and services to streamline the regulatory approval process, has come to the aid of Spanish life sciences companies following the country's 2009 mandate for electronic submissions (NeeS or electronic Common Technical Document – eCTD – based), which came into effect 1st January 2009. Spain is the latest European country to make the transition, following countries like the UK, Belgium, France, Portugal, Iceland, the Netherlands and the Czech Republic.

As part of its solution, the company has introduced a new workshop to demonstrate how ISIToolBox® can help them bring local submissions activities in line with national requirements – quickly and simply. Prior to the workshop, companies can download an evaluation copy of the software, bring their laptop and their own source documents and participate in an interactive workshop, where ISI's electronic submission experts walk them through the submission compilation so that they can experience what's involved – and how easy it is to make the transition with the right support.

ISIToolBox is a comprehensive Adobe Acrobat-based toolset enabling life sciences organisations to manipulate PDF files to meet the requirements of NeES and eCTD format submissions. This includes creating hypertext links and bookmarks, enhancing the quality of scanned files, and allowing automation of some of these tasks. ISIToolBox, which is currently used by the top 25 global pharmaceutical companies, has been shown to achieve efficiency gains of almost 70% in file preparation time and 75% reduction in the time needed to conduct quality assurance of a submission, thus achieving faster market approval.

The Market Environment

The European regulatory environment is complex and fast changing as the 27 countries that make up the European Union (EU) continually revise their approach to handling submissions. 2009 will be a crucial year as more deadlines pass for electronic submissions, including eCTD.

In this environment, local affiliates of large global biopharma companies as well as smaller regional pharma companies have a daunting challenge ahead as most top- tier pharma operations have already made the transition to electronic processes. According to a Gens and Associates 2008 eCTD Organisational Survey, greater than 80% of Top 50 biopharma see the Headquarters/Hub to Affiliate relationship changing with more transparency around what has been submitted to which markets and a majority moving toward a common dossier program.

“Keeping track of the European submissions landscape is a full-time job,” says Kate Wilber, Director of Regulatory Services Europe at ISI, noting the particular burden faced by already overstretched local affiliates. “Many pharmaceutical companies rely on affiliate or partner operations to manage national requirements throughout Europe. These companies may be staffed with just 5-10 people, whose remit includes everything from regulatory affairs management to marketing and distribution. As electronic submissions become the norm, the management demands will grow. This will lead to distraction from their main work, duplication of effort from country to country, the risk of inaccuracies and inconsistencies, and varying document quality from one location to the next.”

Services Offerings Help Define Path Forward

In addition to ISIToolBox and the workshop, ISI also provides an extensive portfolio of solutions to help life sciences companies respond to the constantly evolving European submissions standards. ISI also offers a broad range of consultancy and outsourcing services, providing complete support to life sciences companies or their affiliates as they embrace new ways of working and regardless of their path forward.

Services include:

- Business Process Consulting and Workshops
- Submission Outsourcing
- Training and education

ISI can centralise an organisation’s submissions activities, removing the burden from under-resourced local teams. ISI can also act as an outsourcing partner, helping to define a strategy and ease the transition to consistently managed electronic submissions. Then, if the company wants to take the capabilities back in house, ISI can provide software, training and hand-holding during the transition.

For more information on ISIToolBox and the workshops, contact ISI at infoeurope@imagesolutions.com

About ISI

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 firm to deliver electronic submissions to the industry and since has delivered thousands of submissions. The company has a 53 percent market share among Top 50 global pharmaceutical for its flagship submission product, eCTDXPress, and 4 of the top 10 pharma now have ISIPublisher.

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 organisations. For more information, visit the company website at www.imagesolutions.com.

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