

Tools of the Trade



NEW ELECTRONIC AND
WEB-BASED APPLICATIONS,
SITES, AND TECHNOLOGIES

By Carolyn Gretton

▶ FDA Provides Online Resource for Regulated Industries

TREND: The FDA continues its goal toward improving transparency and communications with the industry by making basic information about the regulatory process more accessible and in a user-friendly format.

FDA BASICS FOR INDUSTRY is a Web-based resource provided by the Food and Drug Administration with the goal of helping companies save time and resources in their interactions with the agency.

The website, fda.gov/FDABasicsforIndustry, provides information about the regulatory process, including information that is frequently requested by the industry.

The website is part of the agency's ongoing transparency initiative launched in June 2009 by FDA Commissioner Margaret Hamburg, M.D., in response to President Obama's commitment to openness in government and steps taken by the U.S. Department of Health and Human Services to make transparency a priority.

"Clarity and consistency are pillars of an effective regulatory system that efficiently regulates products essential to health," Dr. Hamburg explains. "The FDA must clearly communicate standards and expectations to the industries it regulates."



Dr. Margaret Hamburg

Dr. Hamburg discusses the new initiative via video on the agency's website at <http://www.fda.gov/ForIndustry/FDABasicsforIndustry/default.htm>.

▶ For more information, visit fda.gov.

"We believe that to ensure an accurate and successful clinical trial, vendors must offer technologies that are as diverse and varied as the clinical trials themselves," Mr. Blakely adds.

▶ For more information, visit ert.com.



Phil Hodges

Metrics' PHARMAVISION

monitoring service provides secure, Web-based streaming video and accompanying real-time, two-way audio, giving clients remote, man-in-the-plant oversight of their contract development and manufacturing projects.

ing projects.

PharmaVision addresses the need to have a company representative who works on site overseeing responsibilities such as auditing documents, inspecting materials, or confirming batch records.

"Technology introduced us to time- and travel-saving conveniences such as teleconferences and webinars, so it makes sense to use technology to work even more closely and collaboratively with clients worldwide," says Metrics President Phil Hodges.

▶ For more information, visit metricsinc.com.

Real-Time Data Solutions



John Blakeley

ERT recently launched a comprehensive suite of **EPRO SOLUTIONS** that provides a range of technological modalities, enabling clients to choose the ePRO tool that best suits the requirements of the trial and ensures its accuracy and success.

The VIAPad solution has the capacity for complex diaries, questionnaires, and visual scales, along with the ability to streamline mid-study changes.

ERT's VIAPen is a digital pen that offers the simplicity of paper-based methods with the dual advantage of digital data collection.

The VIAWeb tool enables patients to use a standard Internet browser at home or work to securely log into their study diary or assessment and complete necessary information, rather than taking the time and expense to visit a clinical trial site. Patients also have the option to provide trial feedback via landline or mobile phone using ERT's VIAPhone interactive voice response (IVR) device.

John Blakeley, executive VP and chief commercial officer at ERT, observes that one size does not fit all when considering ePRO tools.

In other technology news...

Elsevier has made available a large selection of



Suzanne BeDell

its e-book titles through the recently launched **GOOGLE EBOOKS** store. **GOOGLE EBOOKS** users can access and read purchased book content via a Web browser on their computer or mobile device, as well as through native applications for e-reader devices such as the iPad.

Suzanne BeDell, managing director of science and technology books at Elsevier, notes that the addition will significantly improve the reach and accessibility of Elsevier content.

"Elsevier was an early participant in Google Book Search, a program providing access to a



Ammy Vogtlander

small part of the e-book's content for browsing purposes only," adds Ammy Vogtlander, Elsevier's VP of Web strategy and business development. "We are pleased that Google has now made the strategic move to partner with the publishers

to offer customers the option to purchase full access to the content they have discovered through Google's search services."

▼ For more information, visit elsevier.com

Purdue Pharma's enhanced version of its popular educational website, **PARTNERSAGAINST-PAIN.COM**, provides streamlined access to an expanded portfolio of valuable pain management information, resources, and tools. In addition to information on medical conditions that cause pain, the enhanced site features customized sections for patients, caregivers, and healthcare professionals, with each section offering a wide range of content and special downloadable features.



Dr. Craig Landau

"The information on the new Partners Against Pain site can help facilitate communication between patients, caregivers, and healthcare professionals so that together they may successfully manage pain," says Craig Landau, M.D., chief medical officer and VP of medical research, risk management, and regulatory affairs. "We hope the

enhanced site will empower those touched by persistent pain to seek out the latest information and become advocates for appropriate and effective pain management."

▼ For more information, visit purduepharma.com.

Digital marketing agency **Intouch Solutions** has unveiled a redesigned website featuring user-centric design technologies and the latest in emerging media. The website integrates the key specialties of the agency — digital strategy, creative, social, mobile, content, user experience, and search marketing — to showcase its talent and provide perspective on the latest industry developments.

The site also features a new agency blog, In-

touch Soul, that provides industry insights from a range of Intouch Solutions' subject matter experts. The blog, point-of-view briefs, and other features contribute to a content-rich site that can be shared via social media through Intouch Solutions' proprietary share»send»save tool.



Faruk Capan

"Redesigning intouchsol.com was the perfect opportunity to showcase our knowledge and talents — and, in some cases, do things that our highly regulated clients are not able to — in order to fully leverage all the digital channel has to

offer," notes Intouch Solutions CEO Faruk Capan.

▼ For more information, visit intouchsol.com. PV

E-UPGRADES AND ENHANCEMENTS ►

Version 4.2 of **Aptuit's CLINICOPIA** clinical supply management software includes enhanced data integration capabilities and new packaging functionality that lets users consolidate their packaging jobs, resulting in more efficient material handling while reducing the number of batch records that need to be prepared and executed during the process. The latest version also contains new features for label design and printing, distribution, and other key areas.

▼ For more information, visit aptuit.com.

iMany has released an enhanced version of its **CONTRACTSPHERE** platform, a unified set of solutions to help clients manage complex commercial and government contracting and compliance strategies. Version 7.5 of ContractSphere includes enhancements that streamline the authoring, management, and storage of enterprise contract documents, as well as expanded capabilities for calculating government pricing and advanced reimbursement/rebate scenarios.

▼ For more information, visit imany.com.



marcus evans Summits deliver the ultimate meeting point for modern decision makers. Offering a comprehensive dynamic programme in the comfort of a luxurious five star venue, **marcus evans** Summits bring together esteemed industry thought leaders and solution providers to highly focused and interactive business events.

4 – 6 May 2011
The Westin Diplomat Resort & Spa Hollywood
FL, USA

summits@marcusevanscy.com
www.pharmamarketingsummit.com/PHVad

I found the potential new business contacts to be amazing

President, ACCESS Medical LLC

The intelligence behind the
world's leading business events
www.marcusevans.com

marcusevans