



## FDA LAUNCHES New Drug Information Website

As part of its continuing efforts to ensure that patients and consumers have the information they need to make informed choices, the U.S. Food and Drug Administration has

launched a new easy-to-use Website to help consumers and health professionals find information about FDA-approved drugs more quickly and efficiently.

The new interface, Drugs@FDA, is a searchable database that includes information on approved prescription drugs, some over-the-

counter drugs, and discontinued drugs. Located on the Web page of the FDA's Center for Drug Evaluation and Research (CDER), it is the first Web resource to offer a comprehensive overview of a drug product's approval history.

"Better information for consumers and health-care practitioners is one of this agency's top priorities," says Mark B. McClellan, M.D., Ph.D., former FDA commissioner. "Consumers, healthcare professionals, and product developers can now locate the complete profile of a product with just a few easy clicks."

Drugs@FDA makes all drug-approval information available on one site so that users no longer have to visit several Web pages for information on brand name and generic drugs. The database incorporates information from all parts of CDER's Website, including consumer information sheets, medication guides, labeling, and other information for patients. Eventually information on recalls, warnings, and drug shortages also will be included.

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## Ness Technologies Unveils SMARTSOURCING

Ness Technologies' life-sciences division has introduced a new service offering, Ness SmartSourcing For Life Sciences, which allows life-sciences companies to combine the benefits of IT services, offshoring, and outsourcing. The offerings are distinctive in that they comprise a flexible combination of CMM level 5-certified offshore development facilities and the local pharmaceutical domain expertise provided by Ness.

Ness SmartSourcing For Life Sciences comprises three different programs — SmartSourcing Development Centers (SDC), application life-cycle support, and project services — that allow life-sciences companies to lower IT services costs while continuing to maximize the efficiency of their most mission-critical operations, from research and development and drug portfolio management to FDA compliance and sales and marketing to content and document management.

SmartSourcing Development Centers allows life-sciences firms to extend their IT organization through an experienced team that has both life-sciences domain and technical expertise. Ness can develop and operate offshore, client-branded facilities on a nontransactional basis using a build-operate-transfer model.

Application life-cycle support allows life-sciences companies to offload ongoing and often tedious life-cycle support, thus freeing internal IT resources to focus on key areas important to companies, such as IT project design and innovation.

Project services for life-sciences companies includes such offshore services as custom application development, package integration, application integration, data warehouse, business process outsourcing, validated testing, and data quality.

"While life-sciences companies are just beginning to investigate offshore outsourcing, most realize that the changing climate in their industry is making it imperative that they work it into their information technology mix," says Drew Wright, senior VP at Ness Technologies.



*"With regard to regulatory scrutiny, FDA, HIPAA, and Sarbanes-Oxley regulatory experts have indicated in recent studies that the location of IT projects is not a factor in regulatory compliance, provided that full regulatory procedures are followed," says Drew Wright, Senior VP, Ness Technologies. "Offshore outsourcing also can reduce costs, allowing funds to be applied to core business processes such as R&D and clinical trials."*

## Datatrak and Research Dynamics Begin EDC CERTIFICATION PROGRAM

Datatrak International Inc., an application service provider (ASP) in the electronic data capture (EDC) industry, and Research Dynamics, a specialty contract research organization, are initiating a joint consulting service designed to assist clinical-trial sponsors in modernizing their standard operating procedures (SOPs) as their organizations transition from paper-based clinical trials to EDC. Datatrak and Research Dynamics have branded this initiative as eMerge.

This EDC certification program of eMerge leverages the complementary strengths of Datatrak, which is focused on the delivery of global technology solutions for the e-clinical environment, and of Research Dynamics, which has extensive experience in conducting high-quality, successful clinical trials, education, and SOP development. These companies are creating a blueprint on how SOPs should be streamlined to take full advantage of EDC implementations in clinical trials while eliminating the time and expense of redundant activities that can persist when new technology simply overlays old processes.

The goal of eMerge is to assist customers in advancing their SOPs to properly leverage technology and eliminate redundancy. This will position their organizations to fully realize the value of EDC.

Lorraine D. Ellis, president and CEO of Research Dynamics, believes the eMerge certification pro-

gram represents a major paradigm shift in the conduct of clinical trials.

"It is apparent that the inefficiency and lack of control inherent in most clinical trials conducted today is a significant problem," she says. "The eMerge program has evolved from our combined vision to deliver more reliable, cleaner data faster and more cost effectively."

"Gaps in what we have termed 'data awareness' for an investigational drug or device obviously impact reaction time and could affect overall patient safety, because what you don't know, you can't assess," says Dr. Jeffrey A. Green, president and CEO of Datatrak. "These gaps in awareness can be easily rectified with EDC while simultaneously reducing the time and cost of product development. Upon review of information such as this, customers have decided to take the steps toward EDC certification."



**Dr. Jeffrey A. Green**

*The reason for certification is exemplified by many of our ongoing clinical trials where thousands of data fields go completely unreviewed for as long as six months because clinical-monitoring staffs are waiting for a scheduled physical visit before even looking at the information.*

## Industrial Information Resources Produces **PHARMACEUTICAL INDUSTRY TRACKER**

Industrialinfo.com, powered by Industrial Information Resources Inc., has integrated its pharmaceutical and biotechnology industry coverage into a Web-based solution that provides an intelligent tool for companies tracking plant and project opportunities within the industry.

The new online product, Pharmaceutical Industry Tracker, includes premium industry news and daily industry news coverage based on editorials from Industrialinfo.com's research staff; industrial plant coverage, including 1,030 operational locations and 225 plants under development; and capital and maintenance project coverage with more than 300

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along with plant and project spending analysis.

currently active projects and about 500 projects released on an annual basis.

Pharmaceutical Industry Tracker also includes key management contacts, including more than 6,000 key plant management and corporate decision makers identified at each plant and on every project report.

The company also supplies the 2004 Pharmaceutical & Biotech Forecast, a comprehensive regional, historical, and future spending analysis tool that identifies emerging trends and highlights corporate, economic, and regulatory issues

## Applied Biosystems Releases **ENHANCED VERSION OF LABORATORY SOFTWARE**

Applied Biosystems, an Applera Corp. business, has released the latest version of its laboratory information management system (LIMS) software, SQL\*LIMS version 5.0, which includes an enhanced user interface delivered via a Web-services application that provides a comprehensive, enterprise-accessible productivity solution for pharmaceutical manufacturing organizations. Additionally, the new SQL\*LIMS software includes enhancements, such as instrument calibration, user qualification, and reagent inventory tracking.

SQL\*LIMS software, installed in more than 1,000 laboratories throughout the world, is a complete laboratory information management system that automates sample tracking, laboratory processes and workflow, data access and storage, and regulatory compliance.

The new, open platform Web-services application was built using industry standard technology, including the Oracle Application Server 10g, Database 9i, and provides an extensible J2EE standards-based application.

"The latest version of our SQL\*LIMS product offers pharmaceutical R&D organizations an enterprise-accessible system that should enable increased productivity across manufacturing groups and even global sites," says Michael W. Hunkapiller, Ph.D., president of Applied Biosystems. "As a result, decisions about such important issues as drug formulation, production stability, and product lot quality can be made more easily and efficiently within a system that supports regulatory compliance requirements."

## Saflink and Documentum DEVELOP DOCUMENT LIFE-CYCLE SECURITY SOLUTION

Saflink Corp., a developer, marketer, and integrator of biometric security solutions, is partnering with Documentum Inc. to develop secure Webtop components

targeted toward meeting the security needs of the pharmaceutical industry while at the same time meeting federal compliance requirements.

Documentum, a division of EMC Corp., is a provider of enterprise content management (ECM) solutions with products that address

compliance goals, drive down operational costs, and reduce the risk of noncompliance for pharmaceutical firms.

As a Documentum technology partner, Saflink is developing a collection of components for secure authentication that are designed to be integrated into Documentum's browser-based content-management services.

Saflink intends to develop Documentum Webtop components through its SAFAuthenticator Software Development Kit (SDK) to add a secure authentication framework to Documentum's enterprise applications.

According to Saflink executives, through the use of biometrics, this framework is designed to guarantee the identity of a person participating in the creation and management of critical business documents and to provide the level of irrefutable identification required in many highly regulated industries.

Once in place, Saflink's solution simplifies and strengthens system logon procedures by replacing a user's passwords with a unique individual characteristic, such as a fingerprint or iris scan.

This type of authentication helps to control and document the identities of users accessing business information, signing an action, or using an application.

"Our past experience with pharmaceutical companies has shown that Saflink's authentication products cannot only resolve the management headaches of traditional passwords, but they can also deliver an almost immediate return on investment by dramatically reducing the time required to digitally sign a document or action," says Cliff Kittle, director of emerging markets for Saflink. "In teaming with Documentum, we believe we can provide the level of security required in one of today's most heavily regulated industries, both economically and efficiently."

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## Serono LAUNCHES INFERTILITY WEBSITE

Serono Inc. has launched seronofertility.com, a newly designed Website for people who are concerned about their fertility health. The Website provides clear, customized information about the causes and treatment of infertility.

"We created seronofertility.com to support individuals at every stage of the patient journey, whether they're just beginning to learn about infertility or they're undergoing treatment," says Bharat Tewarie, M.D., executive VP reproductive health, at Serono. "This site is part of Serono's commitment to continually improve fertility health by developing patient-friendly products and services."

Seronofertility.com provides people with information to address their concerns about fertility, including a guide to finding infertility treatment centers by ZIP code, questions to ask a doctor about fertility health, fertility updates by e-mail, and information about using Serono products. The Website includes downloadable brochures that cover emotional aspects of infertility, financial issues, male factor infertility, and procedures such as *in vitro* fertilization.



**Serono's new Website can provide people with a full range of information to address their various concerns about fertility.**

## Follow up

**APPLIED BIOSYSTEMS**, Foster City, Calif., is an Applera Corp. business and serves the life-sciences industry and research community by developing and marketing instrument-based systems, consumables, software, and services. For more information, visit [appliedbiosystems.com](http://appliedbiosystems.com).

**DATATRAK INTERNATIONAL INC.**, Cleveland, Ohio, is a worldwide ASP for the EDC industry, providing a suite of software products supporting the use of Datatrak EDC and related services to the pharmaceutical, biotechnology, and medical-device industries. For more information, visit [datatraknet.com](http://datatraknet.com).

**DOCUMENTUM INC.**, Pleasanton, Calif., is a division of EMC Corp. and provides enterprise content management (ECM) solutions that enable organizations to unite teams, content, and associated business processes. For more information, visit [documentum.com](http://documentum.com).

**FOOD AND DRUG ADMINISTRATION**, Rockville, Md., promotes and protects the public health by helping safe and effective products reach the market in a timely way and monitoring products for continued safety after they are in use. For more information, visit [fda.gov](http://fda.gov).

**INDUSTRIAL INFORMATION RESOURCES INC.**, Houston, is an information provider that is dedicated to serving the marketing and sales information needs of companies. For more information, visit [industrialinfo.com](http://industrialinfo.com).

**NESS TECHNOLOGIES**, Hackensack, N.J., is a global IT services provider, specializing in the development and integration of software solutions, IT outsourcing, and consulting. For more information, visit [ness.com](http://ness.com).

**RESEARCH DYNAMICS**, Rochester, N.Y., is a privately held CRO conducting Phase I-IV clinical trials for the pharmaceutical, biotechnology, and medical-device industries. For more information, visit [resdync.com](http://resdync.com).

**SAFLINK CORP.**, Bellevue, Wash., offers software solutions designed to protect intellectual property, secure information assets, and eliminate passwords. For more information, visit [saflink.com](http://saflink.com).

**SERONO INC.**, Rockland, Mass., is the U.S. affiliate of Serono, a global biotechnology company with headquarters in Geneva, Switzerland, that has a full portfolio of fertility drugs for every stage of the reproductive cycle. For more information, visit [serono.com](http://serono.com).