



Underwriters Laboratories Initiates **REGULATORY COMPLIANCE SERVICE**



With the launch of the Complete Regulatory Compliance Solution, manufacturers can more quickly gain clearance of their products for market entry, says Harvey Rudolph, Ph.D., Program Manager of Medical Devices, Underwriters Laboratories.

Underwriters Laboratories Inc. has launched Complete Regulatory Compliance Solution, a portfolio of services for medical-device companies.

Independent third parties, or notified bodies (NB), frequently assess and document a manufacturer's claim of compliance. UL's affiliate NB is the first established by a U.S. company. This allows the company to provide all of the services necessary for manufacturers to secure access to the European Union, North America, Asia, and Latin America.

Included in the solution: FDA 510(k) reviews for the United States Notified Body service for CE marking, CMDCAS service for Canada, the INMETRO Mark for Brazil, testing and certification for Japan, and ISO 13485 certification.

A key feature includes combined audits for EU market access, follow-up U.S. safety inspections, and management system certification delivered by a local dedicated project team.

inChord Launches **STONEFLY COMMUNICATIONS GROUP**

New agency will use customer-centric business model.

inChord Communications Inc. has launched a new full-service advertising agency: Stonefly Communications Group, which will focus on marketing and advertising for pharmaceutical and biotechnology brands worldwide.

"inChord is fortunate to have established many great relationships with leading companies in the healthcare and pharmaceutical industry," says Blane Walter, chairman and CEO of inChord. "The opening of Stonefly Communications Group provides yet another way for clients to tap into our marketing and creative resources and access innovative, customized solutions."

Stonefly is led by John Racik, who joined inChord two years ago to oversee Blue Diesel, inChord's interactive agency. In his new role as group president of inChord, Mr. Racik continues to provide strategic and new business oversight for



The key customer account model supports our vision by ensuring that Stonefly's clients will always have access to smart, experienced professionals who are intimately familiar with their business, says John Racik.

Blue Diesel, while also leading all aspects of operations and business development at Stonefly.

Stonefly is structured around a unique customer-centric business model. For each major account, the agency will assign a senior-level key customer account (KCA) representative, who will lead the account and, in most cases, work on site at the client's office.

According to company leaders, the name Stonefly represents the agency's novel structure and business philosophy.

"A stonefly is a fly-fishing lure that allows its users to get beneath the surface of the water and attract specific varieties of fish," Mr. Racik says.

"We chose the name to reflect the deep talent and experience the agency will offer and its unique ability to help like-minded clients segment, target, and reel in new customers."

Ogilvy PR and Shire Health Group Launch **FAST4WD OGILVY**

Ogilvy Public Relations Worldwide and Shire Health Group have jointly established Fast4wD Ogilvy, a clinical-trial recruitment and retention firm devoted to addressing the pharmaceutical industry's need for global clinical-trial support.

Fast4wD Ogilvy brings together the expertise in health communications and patient advocacy of Ogilvy PR's Washington, D.C., office with the extensive clinical-trial support capability in Europe and Asia of Shire's existing specialty company, Fast4wD, UK.

"The result is the first marketing company able to offer specialized patient-recruitment and retention support for clinical trials worldwide," says Marcia Silverman, CEO of Ogilvy PR.

Fast4wD Ogilvy serves pharmaceutical companies that need global support for their worldwide clinical trials.

"There is a rapidly growing need for a seamless global approach," says Shire Health Group CEO Gloria Gibbons. "Several years ago, the Shire Health Group, which is part of the Ogilvy Worldwide network, created Fast4wD, a specialized patient-recruitment and retention clinical communications agency with capability in Europe and Asia. Because of the success we have been experiencing in those markets, many of our clients have been asking for additional U.S. solutions to meet their global needs."

Ms. Silverman says the joint venture allows Fast4wD Ogilvy to draw on the expertise and in-country capability of Ogilvy PR's global network to help pharmaceutical companies reach their recruitment goals across the world.

Fast4wD Ogilvy has offices in Washington, D.C., and Oxford, United Kingdom. Chris Shreeve, Ogilvy senior VP, leads the Washington, D.C., office. Michelle Argument heads the Europe/Asia office from Oxford.



Through the Ogilvy PR healthcare worldwide network, we are uniquely positioned to help pharmaceutical companies move rapidly through the patient-recruitment bottleneck and retain participants in their studies, says Marcia Silverman, CEO of Ogilvy PR.

Ventiv Health EXPANDS SUITE OF SERVICES THROUGH ACQUISITION



The Franklin Group has a strong eight-year operating history and a brand name that is well-recognized throughout the pharmaceutical industry, says Terrell Herring, President and Chief Operating Officer of Ventiv Pharma Services.

Ventiv Health Inc., a provider of comprehensive marketing and sales solutions to the pharmaceutical and life-sciences industries, has completed the acquisition of Franklin Group Inc., a provider of pharmaceutical compliance services and innovative patient-assistance programs.

"The combination of Ventiv and Franklin establishes an expanded suite of offerings with an unprecedented level of integrated compliance oversight embedded into these services," says Eran Broshy, CEO of Ventiv Health. "It also provides new oppor-

WHAT'S NEW ON THE SHELVES



- ▶ **THE TRANSPLANT MASTERFILE** — a database of transplant professionals.
Published by **Medical Marketing Service Inc. (MMS)**, this comprehensive file includes more than 1,200 records of transplant professionals, including administrators and program directors of U.S. transplant centers/programs and subscribers to Transplant News. The Masterfile, which is updated twice annually, is available for one-time direct marketing use (direct mail, telemarketing, fax) and unlimited annual use. E-mail broadcast service is also available for select records. For more information, visit mmslists.com.
- ▶ **NAVIGATING GOOD CLINICAL PRACTICES** — FDA's Guidelines for Clinical Trials, Volumes I and II — guidelines for better management of clinical trials.
Published by **FDA News**, this two-volume set will help professionals: ensure adequate monitoring of clinical investigations; prepare for pre-investigation visits; conduct research in emergency settings; handle clinical holds and combination products; collect race and ethnicity information; manage accurate, complete and current subject records; identify and select control groups; conduct safety assessments of medical imaging agents; and speed new products to market by effectively designing and managing clinical trials. For more information, visit fdanews.com/wbi/bookstore/.

tunities for growth and supports our goal of providing full-service programs to companies in the pharmaceutical and biotechnology areas."

Franklin operates as a division of Ventiv Pharma Services.

"Adding the capabilities of Franklin to Ventiv's broad offerings is highly complementary and responds to our clients' needs," says Terrell Herring, president and chief operating officer of Ventiv Pharma Services.

1/2 page ad

PRA International Launches **PROJECT ASSURANCE CAMPAIGN**



We have created a structure that prioritizes the role of our project managers and provides them with unprecedented access to every PRA resource, says David Dockhorn, Executive VP of Global Operations, PRA International.

PRA International Inc. has initiated Project Assurance — The Project Assurance Difference, which is PRA's commitment to consistently plan and conduct fast and dependable clinical trials while delivering the right economic solution.

"Project Assurance is a promise to our clients that PRA will commit all of its resources to the success of every single trial we undertake," says Pat Donnelly, president and CEO. "We've found that our companywide, inter-office focus on individual project success has created a reliability that our clients value."

The backbone of Project Assurance is a global, unified communications infrastructure

and a drive to continuously measure, refine, and leverage best practices.

NEW ASSOCIATION SETTLES ON NAME and Board of Directors

The Clinical Providers Consortium is the name of a recently formed association that will focus on enhancing sponsor-provider relationships to improve clinical development. The consortium also announced the selection of its proposed officers. Officers include: Brian Langin, cochairman, senior manager of business development and strategic alliances, Averion; Mark Levine, cochairman, director of business development, Averion; Gillian Marlette, secretary, communications specialist, Averion.

The proposed board of directors includes: John Cline, CEO, etrials; Lance Converse, CEO, ePharma-Learning; Scott Freedman, president, Monitor-ForHire.com; Sharon Godwin, director of strategic development, PharmaTech Solutions; Bruce Maloff, chief clinical officer, Lifetree; John Shillingford, managing director, IMFORM; and Mark Weinsten, president and CEO, Biolmaging.

Stinson - Brand Innovation offers **BRAND CONSULTING**

Mark Stinson, a healthcare branding executive, has formed Stinson - Brand Innovation Inc. to offer life-sciences companies a new level of access to talent and ideas with unique financial accountability.

Clients can benefit from customized delivery of: brand strategy, brand expansion idea development, brand-building creative campaigns, and brand team motivation, says Mr. Stinson.

"Over the past six months, I have worked to organize a group of world-class industry professionals from every marketing discipline," Mr. Stinson says.

Services are complemented by proprietary methodologies and approaches in market research, technology, and patient/consumer loyalty programs.

Kendle Opens Offices in **CENTRAL EASTERN EUROPE**



In addition to lowering the overall costs to conduct clinical trials, expansion into Central Eastern Europe also provides access to well-qualified investigators and highly motivated patients, says Candace Kendle, Pharm.D., Chairman and CEO.

Kendle International Inc. has opened offices in Bucharest, Romania, and Sofia, Bulgaria, expanding the company's growing presence in Central Eastern Europe. Kendle entered this region in December 2000 with the establishment of an office in Warsaw, Poland. The two new offices further enhance the company's ability to conduct regional and global drug-development programs for its biopharmaceutical customers.

Follow up

CLINICAL PROVIDERS CONSORTIUM, Boston, is an industry association of providers that service and support pharmaceutical, biotechnology, and medical-device companies in bringing their products to market. For more information, contact Averion Inc., at 508-416-2638.

FRANKLIN GROUP, Somerville, N.J., is a pharmaceutical-specific consulting firm. For more information, visit franklingroupinc.com.

KENDLE INTERNATIONAL INC., Cincinnati, is one of the world's largest global clinical research organizations, delivering innovative and robust clinical-development solutions. For more information, visit kendle.com.

OGILVY PUBLIC RELATIONS WORLDWIDE, Washington, D.C., is a global marketing communications firm with offices in more than 60 cities around the world. For more information, visit ogilvypr.com.

PRA INTERNATIONAL INC., McLean, Va., is a clinical-development organization with more than 2,500 employees working from offices in North America, Europe, South America, Africa, and Australia. For more information, visit prainternational.com.

THE SHIRE HEALTH GROUP, London, is a specialized healthcare communications group of companies. For more information, visit shirehealth.com.

STINSON - BRAND INNOVATION INC., Chicago, is a life-sciences brand consultancy that offers four services: strategic expression, idea facilitation, brand construction, and team motivation. For more information, call 312-953-3586.

STONEFLY COMMUNICATIONS GROUP, Columbus, Ohio, is a unit of inChord Communications Inc., a global group of communications companies providing customized marketing solutions with a single point of accountability. For more information, visit inchord.com.

UNDERWRITERS LABORATORIES INC., Northbrook, Ill., is an independent, nonprofit product safety certification organization that has been testing products for more than 110 years. For more information, visit ul.com.

VENTIV HEALTH INC., Somerset, N.J., is a provider of outsourced sales and marketing solutions to leading pharmaceutical companies, as well as to emerging and specialty pharmaceutical and biotech organizations. For more information, visit ventiv.com.