WHAT'S NEW

NEW HEALTHCARE-RELATED PRODUCTS, SERVICES, AND COMPANIES

inVentiv Offers INTEGRATED SUITE OF REMS SERVICES

While all pharmaceutical companies share a common focus on patient safety, each product will have its own strategy based on its unique risk profile, says Terry Herring.

inVentiv Health's recently launched risk evaluation and mitigation strategy (REMS) offering provides pharmaceutical and biotechnology clients with a customizable suite of REMS-related services that can be delivered through a single, integrated program.

In an effort to assure safe use of prescription drug products, the FDA now requires pharmaceutical companies to submit a REMS for select products to ensure the benefits of the drug outweigh the risks and side effects. Companies that fail to submit a sufficient REMS response may experience approval delays, face significant restrictions in how they are permitted to promote their products, or be denied approval entirely.

inVentiv's REMS services suite includes input from experts with broad experience in risk management and encompasses a full range of capabilities, including strategy development, program design, implementation of all program components, and evaluation and measurement. Offerings include a wide range of programs such as safety and pharmacovigilance initiatives; patient registries; education and awareness efforts targeting healthcare providers, patients, and pharmacists; and database development and management.

"There is no cookie-cutter approach for REMS," notes Terry Herring, president and chief operating officer of inVentiv Health. "As a result, manufacturers are intently evaluating how best to respond to the FDA's requirements and design a REMS strategy."

GfK Healthcare Adds BRAND POSITIONING, MANAGED MARKETS TOOLS

New GfK unit, Brand BEAT, provides cost-effective, modular monitoring of pharmaceutical brand health.

GfK Healthcare's Brand BEAT (Brand Equity Assessment & Tracking) is a complete package of healthcare-specific brand positioning diagnostic tools for measuring the cognitive and emotional strengths of a brand.

Grounded in the latest branding theories, Brand BEAT differs from other brand tracking tools in that it offers product managers a modular approach with the ability to measure and monitor a pharmaceutical brand's health along a variety of different dimensions.

"With all the flexible options that Brand BEAT offers, a brand's strength can be assessed at any given stage throughout the product life cycle, and within any scope of a particular market's competitive dynamics," says Jeff Cartwright-Smith, Ph.D., senior VP of marketing science.

More traditional approaches to brand equity assessment and tracking are limited in that they commonly offer a single, comprehensive approach that is not adaptable to a client's specific challenge at a given moment, says Dr. Jeff Cartwright-Smith.

At the new product's core is the brand equity assessment, which offers a holistic evaluation of brand equity by calculating brand cognition, comprised of rational and logical elements, together with brand heart, or emotional elements.

This exercise is intended to serve as a reliable predictor of physicians' future prescribing intentions and behavior.

The Brand BEAT assessment includes two additional modules: the brand attrition funnel, which provides insight into a brand's strengths and weaknesses and includes metrics such as a brand's presence — awareness levels; consideration — trial conversion; prescription volume — share; and loyalty — bonding; and brand driver analysis, which determines precisely what is driving a brand's market share.

According to Dr. Cartwright-Smith, Brand BEAT differs from other brand assessment exercises in that it measures brand personality rather than physicians' emotions.

He says this approach allows physicians to choose from a larger pool of possible associations to describe the brand.

In other moves, GfK Healthcare has introduced Managed Markets Delegates on Demand, a quarterly omnibus study offering pharmaceutical marketers the ability to regularly access and query a panel of key managed markets decision makers and obtain the information they need to drive successful managed markets strategies.

Marketers can use the quarterly study to assess impact of an unanticipated market event on formulary design, check on a hypothesis senior management is pursuing, and generally pose those questions that may not be robust enough for a formal primary research study, but are important enough to ask.

NanoInk Contract Research Offers PROTEIN ARRAY SERVICES

NanoInk has launched a contract research program as part of its Nano BioDiscovery division, using its Dip Pen Nanolithography (DPN) platform to provide miniaturization and multiplex protein analysis services.

Drawing on NanoInk's expertise in array fabrication and protein analysis, the new contract research program includes a wide range of protein array services.

Bruce Dudzik, senior director for business development, explains that the typical Nano BioDiscovery assay development project begins with the client specifying proteins of interest.

"Working in close consultation with the customer at each step of the process, the company's contract research scientists then develop the custom assay protocol, fabricate the custom nanoarrays, conduct on-array assays, extract and analyze data, and develop a comprehensive final report that includes image files and raw data," Mr. Dudzik adds.

By combing DPN nanofabrication technology with optimized substrates and next-generation detection systems for a total system solution, Nano BioDiscovery helps its customers address major proteomic challenges.

Algos Preclinical Services Focuses on **DRUG DISCOVERY, PRODUCT DEVELOPMENT**

Algos Therapeutics has changed its name to Algos Preclinical Services as a result of a shift in its business model from developing proprietary pain therapy products to pure contract research.

Serving customers in the pharma and biotech sectors, Algos Preclinical Services provides a wide range of services for companies seeking to contract preclinical pharmacology and physiology testing. The company's expertise in pain research, combined with a customer-centric approach, and dependable, definitive results make it a potential partner for pharma and device companies with pain treatment programs.

Algos' transformation is evidenced in its newly remodeled Website and integrated marketing communications materials, as well as its modernized logo and revised tagline, all of which reflect the firm's pedigree as a high-quality, preclinical, in vivo pain-research specialty organization.

"Our new site helps reposition Algos as the go-to CRO for pain research," says Frank Eichmann, director of marketing. "Together with other elements of our integrated brand identity, it represents a great step forward in elevating Algos' image and extending our reach to big pharma and the medical device manufacturing industry."

GxP Consulting Expands **CUSTOMER SERVICES AND SUPPORT**

GxP Consulting is expanding services and support to customers in the United States and United Kingdom to help businesses rise to the economic challenges currently being faced across the industry.

As part of the expansion, GxP Consulting has unveiled a new facility in Irvine, Calif., to support increased activity in North America. In addition, expansion in the United Kingdom has led GxP Consulting to move its U.K. headquarters into a larger, purpose-built facility in Nottingham. With a dedicated team of 40 consultants in place, GxP Consulting is ideally placed to move forward with its new growth strategy and improved customer support in both regions.

We are looking to build on our success over the past 12 months and extend our customer support throughout Europe and North America, says Mark Stevens.

Mark Stevens, managing director of GxP Consulting, is spearheading the expansion efforts. "This is an exciting time for GxP Consulting," says Mr. Stevens, an original founder and director of GxP Consulting. "We are looking to build on our success over the last 12 months, extend our customer support throughout Europe and North America, and continue to grow our portfolio of services."

New Agency, **STRIKEFORCE COMMUNICATIONS**, Launches

The new agency has adopted a sharpshooter approach to target client needs and trim costs, says Mike Rutstein.

Industry veteran Mike Rutstein has created a new kind of agency for today's economic climate. Called StrikeForce Communications, the company is designed to eliminate the bloated agency structure and costs that threaten to stifle healthcare marketing today. Modeled on a "SWAT Team" approach, StrikeForce, according to Mr. Rutstein, uses a select group of talented people to pinpoint problems and deliver effective solutions.

"We believe in the power of precision," he says. "That means that every client or project is linked to exactly the team it needs. With no wasted time or resources, there are no cookie-cutter solutions and no unnecessary costs. The results are faster, more affordable, and more effective."

In addition to precision pairing, the new agency uses behavioral science rather than packaged goods' strategies to reach consumers.

"For the pharmaceutical manufacturer, the challenge is to turn awareness into action, encouraging the patient to seek treatment," Mr. Rutstein says.

Catalent Unit Combines **ANALYTICAL SCIENCE, REGULATORY CONSULTING**

Catalent Pharma Solutions has established a new development and clinical services unit dedicated to helping customers bring new pharmaceutical and biologic products to market.

The new segment brings together Catalent's analytical and science services and regulatory consulting services, formerly part of its sterile technologies segment, with its clinical supply services business, formerly included in the packaging services segment.

The new service unit builds upon Catalent's expertise and experience in supporting the development and testing of drugs and biologics through scientific, regulatory, and clinical trial supply chain services.

> I expect to bring even more value to our customers through a sharpened focus and an integrated approach to solving the challenges our R&D customers face.
>
> JOHN CHIMINSKI

For drugs, Catalent provides services that extend from the first steps characterizing a drug molecule to delivery of drugs to the investigator site through the final submission of regulatory filings.

For biologics, Catalent's offerings include advanced bioanalytical services, the advanced GPEx technology and cell-line development services, biomanufacturing, and specialized cold chain distribution for clinical trial materials.

For both drugs and biologics, the new segment provides global regulatory consulting and support; respiratory delivery formulation, development and manufacture; early-phase injectables manufacture.

"I expect the development and clinical services segment to bring even more value to our customers through a sharpened focus and an integrated approach to solving the challenges our R&D customers face, and believe that this will result in significant new growth for the segment," says President and CEO John Chiminski.

"As we have been involved in more than a third of NDAs and BLAs approved by the FDA in the last seven years, we know what it takes to bring a customer's drug or biologic to market each step of the way," he says.

Scott Houlton has been appointed group president for the new segment. Mr. Houlton most recently served as chief operating officer of Aptuit.

AROUND THE GLOBE

- Global clinical research organization **CHILTERN INTERNATIONAL has a new office in Edinburgh.** Led by Manager Jonathan Kinnell, the Edinburgh office marks the fourth new office that Chiltern has opened in 2009, having welcomed staff to locations in Belgium, Hungary, and Brazil.

  For more information, visit chiltern.com.

- Drug development services provider **COVANCE has established clinical development offices in Sao Paulo and Mexico City, further expanding its comprehensive range of services across Latin America.** These new sites in Brazil and Mexico, along with recently opened offices in Santiago, Chile and Lima, Peru, are supporting staff in their countries, Central America, and the Caribbean, as well as the regional network of field-based clinical research associates in the region. Covance has been providing clinical trial support in Latin America since 1997, with the company's first office in Buenos Aires, Argentina.

  For more information, visit covance.com.

- **GLOBAL PHARMACEUTICAL SERVICES (GPSI), a provider of research and development support to the worldwide pharmaceutical and biotechnology industries, has entered into an exclusive partnership with Mumbai-based Abridge Clinical Research Pvt. Ltd.** The pact includes end-to-end clinical development services, with study status updates available in real time for all clients.

  For more information, visit globalpharm.com.

- **MICROMASS COMMUNICATIONS, an agency that uses behavioral science to shape pharma marketing solutions, has joined Worldwide Partners Inc. (WPI) in an effort to increase its global outreach.** MicroMass selected WPI because of its strength overseas and its collaborative approach, which allows each independent partner to own shares in the network. WPI, which consists of 94 agencies, provides advertising and related services to clients in 54 countries around the world.

  For more information, visit micromass.com.

- **PFIZER has announced two initiatives aimed at supporting China as it becomes one of the leading contributors to healthcare innovation worldwide.** Pfizer has entered a joint initiative with the Shanghai Institutes for Biological Sciences (SIBS) to support fundamental research in China. As part of the initiative, Pfizer China will provide $500,000 each year over three years to fund health-related fundamental research projects at SIBS and its application to drug discovery and development programs in the country.

  Pfizer also is partnering with Fudan University to establish a graduate program in clinical data management and statistical programming. This three-year master's degree program, a first of its kind in China, is designed to develop qualified professionals to support the country's rapidly growing clinical-research field.

  For more information, visit pfizer.com.

- Clinical development services provider **PHARMANET DEVELOPMENT GROUP has opened an office in Manila, further enhancing its presence in the Asia Pacific region.** PharmaNet already has two offices in India; two offices in China; offices in South Korea, Singapore, and Taiwan; and field-based staff in Australia, Malaysia, and Thailand.

  For more information, visit pharmanet.com.

- Global contract research organization **PPD has opened a global central lab facility in Singapore, strengthening its ability to provide biopharmaceutical clients an extensive range of customized laboratory services in Southeast Asia, a high-growth region for clinical research.** The lab facility joins PPD's existing office in Singapore, where for more than 10 years it has provided a range of clinical development services, including clinical trial management and monitoring, patient recruitment, site identification, and regulatory affairs.

  For more information, visit ppdi.com.

- Biopharmaceutical services company **QUINTILES has entered into a strategic alliance agreement with the University of Pretoria in South Africa as part of the Quintiles Prime Site program, an initiative to accelerate the development of new and more effective medicines.** The University of Pretoria is the third location in the Quintiles Prime Site program, which already includes Queen Mary's College in London and the Washington Hospital Center in Washington, D.C.

  In other moves, Quintiles has opened an expanded regional facility near Edinburgh as part of its strategy to enhance service offerings throughout Europe. The purpose-built facility consolidates three buildings into a single state-of-the-art complex.

  For more information, visit quintiles.com.

- **STUDYMANAGER, a developer of integrated clinical trial management software (CTMS) and electronic data capture (EDC) solutions, recently expanded operations into China, a move capped by sales of its Sponsor Edition product to two separate Chinese CROs.** To ensure premium application performance, StudyManager has opened a data center in Shanghai, from which Chinese companies can run the StudyManager EDC/CTMS system in a secure, compliant manner.

  For more information, visit studymanager.com.

- **ZS ASSOCIATES has opened its second office in India.** Located in Gurgaon, a satellite city to New Delhi, the new office focuses on business operations projects such as incentive compensation administration, business intelligence, and call planning for global ZS clients.

  Jude Konzelmann, a ZS principal, guides the leadership team in New Delhi as office managing principal. ZS has an existing office in Pune, India.

  For more information, visit zsassociates.com.

ON THE SHELVES

- The 2009 edition of Barnett Educational Services' **MEDICAL DEVICE DEVELOPMENT: REGULATION AND LAW** provides an updated analysis of U.S. medical device and diagnostics development and approval requirements. The reference guide is written by Jonathan Kahan, partner at Hogan & Hartson and co-director of the firm's food, drug, medical device, and agriculture group.

  Some of the recent regulatory and legal developments addressed in the updated edition include The Medical Device User Fee and Modernization Act of 2002, which covers user fees, third-party inspections, reprocessed single-use devices, and the establishment of the Office of Combination Products; and The Food and Drug Administration Amendments Act of 2007, including unique device identifiers, ClinicalTrials.gov registration, pediatric device promotion, and postmarket surveillance and medical device reporting changes.

  For more information, visit barnettinternational.com.

- Barnett Educational Services has released **PAREXEL'S BIO/PHARMA R&D STATISTICAL SOURCEBOOK 2009/2010**, a resource for statistics, trends, and proprietary market intelligence and analysis on the biopharmaceutical industry. This updated edition is available in print and electronic formats and includes new proprietary analysis on U.S. clinical trial starts and overall active clinical trials; emerging data on worldwide and company-specific R&D pipelines and product launch trends; and an all-new, comprehensive analysis of clinical research offshoring revealing which pharma companies are now locating their new clinical trials overseas.

  For more information, visit barnettinternational.com.

- **BIOTECH 2009-LIFE SCIENCES: NAVIGATING THE SEA CHANGE**, Burrill & Co. Founder and CEO G. Steven Burrill's annual book on the state of the biotechnology industry, contains analysis and perspectives on the performance of the industry in 2008 in the midst of the financial market turmoil, and projections for 2009 and beyond.

  According to Burrill's report, the capital markets have permanently restructured in the wake of this turmoil, making access to capital more difficult and expensive for biotech startups.

  For more information, visit burrillandco.com.

- **JOURNAL OF COMMUNICATION IN HEALTHCARE**, a new journal from Henry Stewart Publications, showcases peer-reviewed articles on how to improve communication management in all aspects of the healthcare business, healthcare delivery, and health promotion. Guided by Editor-in-Chief Mario Nacinovich, each quarterly, 100-page issue publishes in-depth articles, applied research, and real case studies on how to communicate with patients, staff, the public, and media.

  For more information, visit henrystewart.com.

- **PHYSICIANS' DESK REFERENCE (PDR)**, the iconic compendium of FDA-approved information for commonly prescribed drugs, is merging with the Health Care Notification Network (HCNN), which delivers FDA-required drug alerts to physicians and other prescribers online. The combination, which operates as the newly formed PDR Network, creates an end-to-end solution fulfilling manufacturers' need to deliver FDA-approved product safety information to prescribers and also prescribers' need to know this information on a reference and real-time basis. FDA-approved drug labeling, product-safety alerts, recalls, and information for prescribers on required REMS programs will be delivered.

  For more information, visit pdrnetwork.net.

- Putnam Associates, in celebration of its 20th anniversary, has published **THE FIRST TWENTY YEARS ARE THE HARDEST: TWO DECADES IN HEALTHCARE STRATEGY.** The book is a collection of essays from a cross-section of experts in healthcare, and they provide insights, background, and recommendations regarding the complex and interwoven industries of healthcare, including managing risk, dealing with globalization, and addressing changes in relationships with doctors, managed care, and the government.

  For more information, visit putassoc.com.

Follow up

ALGOS PRECLINICAL SERVICES is an independent contract research organization specializing in preclinical in vivo pain research and program consulting. For more information, visit algosinc.com.

CATALENT PHARMA SOLUTIONS is a global provider of advanced technologies and development, manufacturing, and packaging services for pharmaceutical, biotechnology, and consumer healthcare companies. For more information, visit catalent.com.

GFK HEALTHCARE provides fully integrated custom healthcare marketing research. For more information, visit gfkhc.com.

GXP CONSULTING is a provider of compliance services to the pharmaceutical and biopharmaceutical industries. For more information, visit gxpus.com.

INVENTIV HEALTH INC. provides commercialization services to the global pharmaceutical and healthcare industries. For more information, visit inventivhealth.com.

NANOINK INC. is an emerging growth technology company specializing in nanometer-scale manufacturing and applications development for the life-sciences and semiconductor industries. For more information, visit nanoink.net.

STRIKEFORCE COMMUNICATIONS specializes in consumer advertising for prescription products, as well as OTC and medical devices. For more information, visit strikeforcenyc.com.