

## Medsite Introduces PHARMACEUTICAL SERVICES DIVISION

Medsite Pharmaceutical Services LLC (MPS) is a new division of Medsite Inc., which offers a zero-cost, zero-risk option for marketers by using a gain-share methodology for promoting brands, maximizing visibility among physicians, and ultimately increasing revenue.

Through a blend of marketing techniques, specialty pharma companies and brands in highly competitive categories can reach more than 400,000 physicians in Medsite's established network. MPS channels, such as interactive detailing, market research, and Medsite Rewards, reach targeted audiences at multiple points of contact. Since MPS clients pay in proportion to incremental prescriptions written, common risks associated with promoting niche brands, or those competing in large categories are significantly reduced.

"The MPS program creates a market presence for brands with limited sales support," says Sundeep Bhan, founder and CEO of Medsite. "Niche and specialty brands are equally critical to physicians — and ultimately the patients — that rely on these products to treat a wide variety of medical conditions. Because MPS is paid for through the incremental revenue it generates, it is an extremely viable and attractive option for marketers and brand managers with narrow budgets or other resource constraints."

## Brand Institute Establishes New Subsidiary to **MINIMIZE MEDICATION ERRORS**

The FDA's Jerry Phillips joins private sector to continue risk-management work.

Brand Institute has launched a new subsidiary — Drug Safety Institute (DSI) — to address risk assessment and management issues associated with pharmaceutical product nomenclature, labeling, and packaging. Heading up DSI is Capt. Thomas G. (Jerry) Phillips, who has retired from the Food and Drug Administration. Capt. Phillips was the associate director for medication error prevention in the office of drug safety and the acting director of the FDA's division of medication errors and technical support.

For the past 11 years, Brand Institute has specialized in the brand name development of pharmaceutical and biotechnology products. The new division further extends Brand Institute's long-held dedication to risk assessment and management and preventing prescription errors.

"Our emphasis at DSI will be safety first and foremost," says James L. Dettore, president and CEO of Brand Institute.

"I am excited by the opportunity to continue my work in improving patient safety by preventing

**Capt. Thomas  
G. (Jerry) Phillips**



*The Drug Safety Institute will offer medication error prevention analysis for new product labels and packaging and unique expertise in various risk-management strategies.*

medication errors, but from a different vantage," Capt. Phillips says. "At DSI, our plan is to make the company's methodology for brand-name safety testing even more reflective of the FDA's review process."

Capt. Phillips joined the Food and Drug Administration in 1988. He contributed to the recent FDA rule that requires pharmaceutical product bar coding and the 1999 IOM report "To Err is Human."

He has been the FDA representative and chairman of the national coordinating council for medication error reporting and prevention and is an expert member on two USP committees: the nomenclature and labeling committee and the safe medication use committee.

Capt. Phillips also has collaborated with the World Health Organization to provide adverse event data for certain medication errors that have occurred worldwide. Additionally, he has been involved in quarterly videoconferences with the European Union, Canada, and Australia to discuss pharmacovigilance activities and shared adverse drug events.

## Quintiles Launches **CARDIAC SAFETY SERVICE** Amid Growing Demand for High-Level Data

Quintiles Transnational Corp. has launched a new service, Integrated Cardiac Safety Services, which is designed to meet the increasing demand for cardiac safety data in the drug approval process.

"Pharmaceutical and biotechnology companies must prepare for higher expectations regarding cardiac safety data from United States and European regulatory agencies as well as the International Committee on Harmonization (ICH)," says David Dworaczky, Ph.D., Quintiles' senior VP of integrated technologies. "Quintiles' extensive cardiac safety capabilities can help sponsors evaluate cardiac safety of drugs at any place in the development continuum, from preclinical through Phase IV."

In the past 10 years, regulatory agencies have withdrawn or denied approval to several drugs that adversely affect the heart, prolonging what is called the QT interval. The QT interval measures the duration of ventricular repolarization. A prolonged QT interval can lead to a potentially fatal arrhythmia. The ICH guidelines, which describe tests to determine

whether drugs prolong the QT interval, are now well into the ICH review and approval process and will be further refined in the next year. When finalized, the regulations would require that all drugs, regardless of therapeutic area, be thoroughly evaluated for cardiac safety.

"Our continuum of service focuses on three key elements: preclinical cardiac safety pharmacology, Phase I clinical pharmacology, and centralized ECG analysis, monitoring, and reporting," Dr. Dworaczky says. "We integrate these elements into a seamless process that can help every organization, regardless of size, generate and interpret the right data from all phases of development, saving time and money in the development of their drug."

Quintiles' ECG services are available 24 hours a day, seven days a week, 365 days a year with a full-time cardiologist on staff at all times. Quintiles' international ECG help desk also is available around the clock and offers support in more than 35 different languages.

## New **HEALTH NEWS AND EDUCATION COMPANY** is Formed

Health communications veteran Robert Enteen, Ph.D., has founded Medical News Focus, an independent health news, education, and Website content creation company.

Medical News Focus offers a different approach to health communications by creating customized, in-depth audio and video interviews with the world's leading physicians, biomedical scientists, and key opinion leaders in every diagnostic and therapeutic category. Interviews are conducted one-on-one or as moderated panel discussions and are designed to be of interest to either patient or professional audiences.

"Our programs are unparalleled for credibility, accuracy, timeliness, and impact, because we enable key audiences to hear directly from the most respected authorities, on the topics of greatest importance to



***Dr. Robert Enteen is producing and anchoring customized, in-depth audio and video interviews with the world's leading physicians and biomedical scientists — the key opinion leaders in every diagnostic and therapeutic category.***

those audiences as the news is being made," Dr. Enteen says. "Interview topics and guest experts are selected based on their relevance to our clients' communication strategies."

The thought-leader interviews, conducted either in National Public Radio studios or at medical meetings throughout the world, are used by communications, education, and Web professionals in pharmaceutical and biotechnology companies; patient advocacy organizations; medical education, public relations, and advertising companies; medical societies, hospitals, medical centers, and teaching institutions; and managed-care companies.

In addition to English-language programs, Dr. Enteen also has produced multilingual interviews for non-English speaking audiences.

### WHAT'S NEW ON THE SHELVES



► **PART 11 AND DRUG DEVELOPMENT** — A Q&A Reference Guide analyzes the implications of the recent shift in the Food and Drug Administration's (FDA) approach to Part 11 requirements.

Published by **Barnett Educational Services**, which is a division of Parexel International Corp., the guide is designed for clinical, regulatory, quality assurance, and other drug-development professionals. The new pocket-sized handbook, authored by industry experts, provides answers to the most common, emerging, and difficult questions regarding the FDA's new approach to the Part 11 guidance.

To receive more information or to order, visit [barnettinternational.com](http://barnettinternational.com).

## Amgen Opens BIOTECHNOLOGY RESEARCH CAMPUS

Amgen Inc. has opened a new state-of-the-art research and development campus. The 750,000-square-foot facility was designed in collaboration with scientists as an environment for the creation of breakthrough therapies.

The biotechnology company's Helix campus, located on the waterfront of Seattle's Interbay neighborhood, is home to researchers, process-development scientists, and support personnel.

More than 750 staff members from several locations throughout Seattle have moved into the new \$625 million Helix campus.

The new facility includes the latest technological advances in computerization and robotics to maximize efficiencies in research and process development.

"Ultimately, we're looking to accelerate the drug-discovery process to deliver groundbreaking inflammation and oncology therapies to patients as quickly as possible," says Roger M. Perlmutter, M.D., Ph.D., executive VP of research and development at Amgen.

The location of the campus further enhances scientific learning by increasing opportunities for Amgen scientists to collaborate with leading Seattle research centers such as the University of Washington, the Fred Hutchinson Cancer Research Center, and the Institute for Systems Biology.

## TAC Worldwide Introduces PHARMACEUTICAL AND LIFE-SCIENCES GROUP

TAC Worldwide Companies, a privately held staffing company, has launched a new Pharmaceutical and Life Sciences Group designed to service large and mid-market pharmaceutical, clinical, and scientific companies in the United States. Appointed to lead this new group is Nick Rossiello, who serves as VP and general manager.

The new division provides human capital and workforce management solutions to the pharmaceutical and bioscientific industries, enhancing TAC Worldwide's commitment to providing total workforce solutions.

"Growth in the pharmaceutical and life-sciences industries has continued to be strong in the United States despite the economy of the past years," says James J. Fabiano, executive VP at TAC Worldwide. "TAC Worldwide's new practice group, under the direction of Mr. Rossiello, adds a highly focused dimension to our extensive staffing solutions."

Before joining TAC Worldwide, Mr. Rossiello managed global pharmaceutical and life-sciences business development for EDS, a global outsourcing services company. He also has held a number of executive sales and business development positions at Becton Dickinson, PricewaterhouseCoopers, and GE Medical Systems.

## B. BRAUN BIOTECH Becomes SARTORIUS BBI SYSTEMS in the Americas

B. Braun Biotech Inc., an American subsidiary of Sartorius, is now going by a new company name in the Americas: Sartorius BBI Systems Inc. With its parent company Sartorius BBI Systems GmbH, based in Germany, it is a leader in the manufacture and marketing of fermenters and bioreactors for the pharmaceutical and biotechnology markets worldwide.

Sartorius Group acquired B. Braun Biotech in 2000. The name change brings the U.S. subsidiary in line with the new marketing strategy that Sartorius

AG implemented globally late last year. The company is streamlining its worldwide image to reduce complexity and strengthen the core brand.

As part of its expansion in the U.S. market, the company is nearing completion of a new 85,000-square-foot corporate headquarters and a modern production facility near its headquarters in Pennsylvania. The new facility, which will be one of the largest of its kind in the world, will open sometime in mid-2004.

### Follow up

**AMGEN INC.**, Thousand Oaks, Calif., is a global biotechnology company that discovers, develops, manufactures, and markets important human therapeutics based on advances in cellular and molecular biology. For more information, visit [amgen.com](http://amgen.com).

**BARNETT EDUCATIONAL SERVICES**, Philadelphia, is a unit of Parexel International Corp., a biopharmaceutical outsourcing organization that provides a broad range of knowledge-based contract research, medical marketing, and consulting services to the worldwide pharmaceutical, biotechnology, and medical-device industries. For more information, visit [barnettinternational.com](http://barnettinternational.com).

**BRAND INSTITUTE**, Miami, is a full-service

brand identity consultancy dedicated to the strategic and innovative development of brand nomenclature and identity solutions. For more information, visit [brandinstitute.com](http://brandinstitute.com).

**MEDICAL NEWS FOCUS**, Teaneck, N.J., is an independent health news, education, and Website content creation company. For more information, call 201-833-8949.

**MEDSITE INC.**, New York, conducts ethical and effective e-pharmaceutical marketing. For more information, visit [medsite.com](http://medsite.com).

**QUINTILES TRANSNATIONAL CORP.**, Research Triangle Park, N.C., helps improve healthcare worldwide by providing a broad range of professional services, information, and partnering solutions to the pharmaceutical, biotechnology, and healthcare industries. For more information, visit [quintiles.com](http://quintiles.com).

**SARTORIUS BBI SYSTEMS INC.**, Allentown, Pa., is the U.S. subsidiary of Sartorius BBI Systems GmbH, based in Melsungen, Germany, and has expertise in the development and production of fermenters and bioreactors for applications in the laboratory, in production, and in the corresponding automation and controlling units. For more information, visit [sartorius-bbi-systems.com](http://sartorius-bbi-systems.com).

**TAC WORLDWIDE COMPANIES**, Dedham, Mass., delivers client-focused workforce solutions, ongoing human capital management, and technical and information technology staffing services to global leaders. For more information visit [tacworldwide.com](http://tacworldwide.com).