

WHAT'S NEW

NEW HEALTHCARE-RELATED
PRODUCTS, SERVICES, AND
COMPANIES

Augme Expands MOBILE HEALTH DIVISION

Augme Technologies is expanding its Augme Mobile Health division as part of its strategy to capitalize on major growth trends in pharmaceutical mobile marketing and advertising.

Augme Mobile Health is based on Augme's patented, Web-based Ad Life platform, which gives pharmaceutical marketers and their agencies the ability to create, manage, and track two-way, HIPAA-compliant communications between traditional media and mobile phones. The division transforms existing pharmaceutical websites by formatting specifically for each type of mobile device, further supporting marketing goals by enabling mobile Web access for healthcare practitioners, patients, and caregivers. It then integrates mobile Web-based content with traditional print advertising via SMS, audio recognition, bar code scanning, and image capture, seamlessly enabling leading-edge mobile applications, such as video content delivery and coupon fulfillment.

"Pharmaceutical companies spend billions of dollars each year on traditional marketing mediums, but behaviors are changing across the pharmaceutical marketing landscape," observes Augme CEO Mark Severini. "There is a shift to new media, such as mobile marketing, that achieves brand interactivity, enhances healthcare practitioner and consumer experiences, and provides brands with immediate response metrics. Rather than rely on static, one-way communications, we create an interactive and mutually beneficial dialogue between the brand and the target audience."

As part of its expansion of Augme Mobile Health, the company has named healthcare business development expert Donna Lloyd as VP of sales. Ms. Lloyd was most recently PDR.

Service Combines Wolters Kluwer's SCIENTIFIC WRITING, PUBLISHING EXPERTISE

inScience Communications combines global reach with local knowledge.

Wolters Kluwer Pharma Solutions has consolidated its global scientific writing and communications business into a new offering, inScience Communications, that capitalizes on the company's global scale combined with its local expertise.

"By consolidating our medical and scientific communications, we can provide strategic communications services on a global scale, while incorporating critical local expertise for customized programs geared to regional markets from the United States and Europe, to Asia and Latin America," says Bryce McMurray, general manager, global medical communications for Wolters Kluwer Pharma Solutions.

inScience Communications features scientific writing services, including manuscript writing and conference coverage, as well as a variety of strategic communications, such as publication planning and meetings management. In addition, the service offers a highly experienced health outcomes team skilled at helping clients address market access issues.

The new service harnesses the growing business trend of "glocalization" by allowing Wolters Kluwer's



We're able to combine global strategy with informed local tactics, says Diana Faulds.

Objectivity and clinical relevance are integrally important to what we define as good scientific communications, says Bryce McMurray.



clients to tap the company's "glocal" capabilities: the ability to offer a global perspective and meet the specific needs of each individual market.

"For example, we can put an article into context for a local market while still maintaining all of the objectivity and integrity of the original piece," says Diana Faulds, global editorial director for Wolters Kluwer Pharma Solutions.

Compass Healthcare Marketers Focuses on FULL MARKETING PACKAGE

Compass Healthcare Communications has changed its name to Compass Healthcare Marketers to emphasize the agency's commitment to serving as a full marketing partner to its clients.

"We realized that our company name needed to better reflect the type of organization we are and the breadth of services we offer our clients," explains President and CEO Peter Nalen.

Compass has also deployed a new professional branding service to complement its existing consumer branding services.

"As pharmaceutical marketing continues to make the shift from single-dimensional to more cus-



Our job as marketers is to create and articulate the brand's identity so that it appeals to multiple audiences, says Peter Nalen.

tommer-centric marketing, we use our understanding of the different segments of our clients' audiences to deliver tailored, meaningful communications in the form or vehicle they prefer," Mr. Nalen says.

FDA Task Force Seeks Public Input on PROPOSED DISCLOSURE POLICIES

The FDA's Transparency Task Force has released a number of draft proposals for public comment on public disclosure policies aimed at helping consumers, stakeholders, and others understand how the agency operates and makes decisions.

"Our goal is to facilitate transparency that promotes public health and innovation," says Joshua

Sharfstein, M.D., FDA principal deputy commissioner and chair of the task force.

The proposals reflect the review of more than 1,500 public comments received by the FDA after two public meetings held by the task force and extensive consideration and discussion within the agency.

Tax Credit Program Supports Discovery Efforts by SMALL BIOPHARMA COMPANIES

The U.S. Department of the Treasury has instituted the Therapeutic Discovery Project Program, a program created by the Affordable Care Act that provides tax credits and grants to small firms showing significant potential to produce new and cost-saving therapies.

"This new tax credit helps advance research to find life-saving treatments and helps U.S. companies lead the way in innovative medical discoveries," says Treasury Secretary Tim Geithner.

The therapeutic discovery tax credit is targeted to projects that show significant potential to produce new therapies, address unmet medical needs, reduce the long-term growth of healthcare costs, and advance the goal of curing cancer within the next 30 years.

The credit's allocation also takes into consideration which projects show the greatest potential to create and sustain high-quality, high-paying jobs in the United States and to advance the country's



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competitiveness in the fields of life, biological, and medical sciences.

The credit covers up to 50% of the cost of qualifying biomedical research, up to a maximum credit of \$5 million per firm and \$1 billion overall.

It is effective for investments made in 2009 and 2010 and is only available to firms with less than 250 employees.

Firms can opt to receive a grant instead of a tax credit, so startups that are not yet profitable can benefit as well.

ISMPP Offers New Tools for PUBLICATION PROFESSIONALS

The International Society for Medical Publication Professionals (ISMPP) has unveiled several new tools designed to support members in their day-to-day activities as medical publication professionals.

ISMPP's advocacy platform is designed to help members understand the actions ISMPP is taking as it moves forward in driving advocacy for the medical publication profession.

The Medical Publishing Insights and Practices Initiative authors' toolkit is a guide to journal submission best practices developed by a joint journal-industry working group.

In other moves, the ISMPP has endorsed The Council of Medical Specialty Societies' recently adopted, voluntary Code for Interaction with Companies, which is intended to help ensure medical society interactions with the pharmaceutical and device industry meet the highest ethical standards as they relate to transparency and independence.

ON THE SHELVES



▶ Barnett Educational Services has released the fourth edition of its Regulatory Compliance Guide series. The newly revised version of **GOOD CLINICAL PRACTICES: GUIDE TO COMPLIANCE** provides clear recommendations for full compliance with global regulatory requirements and includes templates for standard operating procedures and other forms that can be used directly in the good clinical practices (GCP) environment, including a full set of GCP inspection sheets.

The latest edition of **GOOD LABORATORY PRACTICES: GUIDE TO COMPLIANCE** provides information and insights that help scientists and managers understand the impact of good laboratory practices (GLP) requirements on their preclinical work and assist them in achieving full compliance simply and inexpensively. The guide also references the most recent guidelines issued by the Food and Drug Administration and other regulatory authorities.

The new edition of **GOOD MANUFACTURING PRACTICES: GUIDE TO COMPLIANCE** analyzes the contents of the current versions of the Good Manufacturing Practice (CGMP) rules laid down by the United States, the European Union (EU), Canada, and Japan; as well as the guidelines published by the World Health Organization (WHO) and the International Conference on Harmonization (ICH). The GMP guide also contains references to Guidance for Industry documents published by the FDA since the last edition was completed in September 2004.

For more information, visit barnettinternational.com.

▶ **BIOTECH 2010-LIFE SCIENCES: ADAPTING FOR SUCCESS**, the

most recent edition of G. Steven Burrill's annual book on the state of the biotechnology industry, provides insight into biotech's changing environment and how not to just survive but succeed. Published by Burrill & Company, the report provides information and analysis on steps companies can take to adapt to major challenges to their business development in order to be successful in 2010 and beyond.

It also provides comprehensive 2009 industry financials, private and public capital raised, and M&A/partnering activity for life-sciences companies operating in the United States, Europe, Canada, and Asia.

For more information, visit burrillandco.com.

▶ **AN INTRODUCTION TO THE PROCESS OF DUE DILIGENCE FOR REGULATORY AFFAIRS PROFESSIONALS**, a book written by Raymond Huml, DVM, executive director of global due diligence, corporate development for Quintiles, provides a reference for regulatory professionals and pharmaceutical executives involved in the process of due diligence for product-based investments.

Published by the Regulatory Affairs Professional Society, the text is based on techniques that led to more than \$2.7 billion in capital committed to various large- and small-scale product partnering opportunities in America and Europe. It covers all major aspects of the due diligence process and provides easy-to-use checklists to use to ensure that all facets of selected functional areas of expertise are covered, including those for regulatory professionals.

For more information, visit quintiles.com.

AROUND THE GLOBE



- ▶ Global healthcare company **ABBOTT LABORATORIES** has made a number of moves toward further strengthening its global competitive position. The company has created a stand-alone established products division (EPD) concentrated on expanding the market for Abbott's established pharmaceutical portfolio outside of the United States, with particular focus on emerging markets. EPD is led by Michael Warmuth, an executive with significant experience in Abbott's pharmaceutical business who most recently led Abbott's diagnostics division. Abbott also has forged a licensing and supply agreement with Zydus Cadila of India for a portfolio of pharmaceutical products that Abbott plans to commercialize in 15 emerging markets.

In other moves, Abbott recently opened the Abbott Asia-Pacific Nutrition Research & Development Center at Singapore's Biopolis Research Park. The center is Abbott's largest nutrition R&D facility outside the United States, as well as Singapore's first nutrition R&D site creating science-based nutritional products for infants, children, and adults. The center marks Abbott's third expansion in Singapore in less than 18 months.

For more information, visit abbott.com.

- ▶ **BBK WORLDWIDE** has formed an alliance with CROèe, a Tokyo-based contract research organization specializing in enrollment management, to offer patient recruitment solutions to advance the clinical trial enrollment process in Japan. The companies are working together to support research sponsors as they develop treatment options, with the goal of accelerating time-to-market for new medicines and treatments in Japan.

For more information, visit bbkworldwide.com.

- ▶ Global contract research organization **CHILTERN INTERNATIONAL** has announced expansion plans in the Asia-Pacific region, including the opening of two new offices and the launch of operations in Australia and Singapore, with Singapore acting as the hub for its operations in Southeast Asia. Chiltern is also in the process of forming a company and establishing operations in China.

Chiltern's Asia Pacific operations are led by Umakanta Sahoo, executive director, Asia Pacific. The company also has appointed Martin Painter as the Asia Pacific region's manager of Resourcing Solutions, Chiltern's business unit designed to offer fully integrated solutions to staffing needs.

For more information, visit chiltern.com.

- ▶ **DECISION RESOURCES**, a research and advisory firm for pharmaceutical and healthcare issues, has made available an epidemiological database that provides current and 10-year forecasts of patient populations for the most commercially significant indications across the BRIC (Brazil, Russia, India, and China) markets. Combining Decision Resources' epidemiology expertise and extensive knowledge of the major emerging pharmaceutical markets, Emerging Markets PatientBase allows users to estimate current and future patient population sizes.

For more information, visit decisionresources.com.

- ▶ **DERMA SCIENCES**, a medical device and pharmaceutical company focused on advanced wound care, has established an international subsidiary, Derma Sciences Europe, and announced plans to open an office near London.

The company has also hired Maeve Kelly as managing director, EMEA (Europe, Middle East, Africa regions).

For more information, visit dermasciences.com.

- ▶ **INVENTIV CLINICAL**, a division of inVentiv Health, has announced three additions to its inVentiv Clinical Global Alliance: Protech Pharmservices Corporation (PPC), Ecron Acunova, and RDDA. These partners, along with ActivaCRO, broaden inVentiv Clinical Solutions' clinical research capabilities in Latin America, Asia, Europe, and Africa and provide CRO service coverage in more than 50 countries.

For more information, visit inventivclinical.com.

- ▶ **I3**, a global life-sciences services company and subsidiary of Ingenix, has acquired ChinaGate, a Shanghai-based contract research organization that provides product-development regulatory services for pharmaceutical, medical device, and biotechnology companies looking to enter and access the Chinese market. The acquisition gives i3's customers access to ChinaGate's on-the-ground presence and expertise in overseeing clinical trials, submitting filings, obtaining licenses, and navigating the regulatory process in China.

For more information, visit i3global.com.

- ▶ Global biopharmaceutical services provider **PAREXEL INTERNATIONAL** has opened offices in Chengdu and Guangzhou, China, to support a growing requirement for a broad range of clinical development and regulatory consulting capabilities in the country and throughout the Asia Pacific region. Parexel's existing presence in China includes offices in Beijing and Shanghai, as well as Kowloon, Hong Kong.

For more information, visit parexel.com.

- ▶ Global contract research organization **PPD** has opened a pharmacovigilance and medical communications center in Sofia, Bulgaria, aimed at delivering its full range of drug safety, medical information, and medical writing services to meet growing client demand. The new facility in Sofia is PPD's largest safety center and its third European hub for medical communications contact center services.

For more information, visit ppdi.com.

- ▶ Global communications group **PUBLICIS GROUPE** has acquired London-based strategic healthcare consultancy Resolute Communications, strengthening subsidiary Publicis Healthcare Communications Group's position in the United Kingdom. The acquisition involves merging the branding and digital expertise of London-based Publicis Life Brands with the strategic communications capabilities of Resolute Communications, with the resulting entity being named Publicis Life Brands Resolute.

For more information, visit publicisgroupe.com.

- ▶ The **REGULATORY AFFAIRS PROFESSIONALS SOCIETY** is collaborating with the University of Shanghai for Science and Technology in China to develop regulatory education content for the university. RAPS will provide some of its existing online course content currently offered through RAPS Online University, which will be adapted for USST's students, as well as guide the university in developing new regulatory curricula and providing advice and support to university faculty.

For more information, visit raps.org.

Follow up

AUGME TECHNOLOGIES INC. provides interactive media marketing platforms that enable the integration of goods and services with consumer life experiences through Internet and mobile communications. For more information, visit augme.com.

COMPASS HEALTHCARE MARKETERS is a full-service marketing communications agency focused on specialty healthcare companies. For more information, visit compasshc.com.

THE U.S. DEPARTMENT OF THE TREASURY is the executive agency

responsible for promoting economic prosperity and ensuring the financial security of the United States. For more information, visit treasury.gov.

THE U.S. FOOD AND DRUG ADMINISTRATION is the federal agency responsible for ensuring the safety and accurate representation of foods, human and veterinary drugs, biological products, and medical devices. For more information, visit fda.gov.

THE INTERNATIONAL SOCIETY FOR MEDICAL PUBLICATION PROFESSIONALS is an independent, nonprofit professional

association with members from the pharmaceutical, medical device, and biotechnology industries; publication planning and medical communications companies; academia; and medical journal staff. For more information, visit ismpp.org. **WOLTERS KLUWER PHARMA SOLUTIONS INC.**, a subsidiary of Wolters Kluwer U.S., provides clinical and healthcare data and analytics, medical publishing services, and market intelligence tools to professionals in the pharmaceutical, biotech, and medical device fields. For more information, visit wolterskluwerpharma.com.

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Oversight of Outsourced Work: A Review of Transfer of Obligations, Sponsor Responsibility and the FDA's Risk-Management Approach to Inspections

Leslie K. Ball, MD, CAPT, USPHS, *Director, Division of Scientific Investigations, Office of Compliance, CDER, FDA (invited)*

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