Former Wyeth VP Launches **PETKUS COMMUNICATIONS CONSULTANTS**

New agency specializes in strategic healthcare communications.

Doug Petkus, a seasoned public relations professional with more than three decades of experience in corporate, agency, and editorial environments, has founded Petkus Communications Consultants, a PR consultancy that provides senior-level strategic communications counsel.

Petkus Communications offers strategic communications and issues management counsel, as well as strong media relations expertise, with emphasis on healthcare and consumer products. Services provided by the agency include investor/financial relations support, media outreach plans, product-specific PR programs, and media training and message development. Mr. Petkus, who holds a law degree, is also using his expertise with complex regulatory and FDA issues to offer litigation communications support.

In this economy, seasoned PR consultants can be a cost-effective alternative for handling projects or advising senior executives, says Doug Petkus.

Mr. Petkus was VP, corporate communications, at Wyeth until its acquisition by Pfizer in 2009. He holds a J.D. from Seton Hall University.

GxP Consulting Adds **STATISTICAL ANALYSIS SUPPORT**

GxP Consulting has expanded its GCP compliance and clinical technology support portfolio to include statistical analysis support for clinical data assessment, enabling it to offer cost-effective and time-critical off-site statistical and data processing services to the clinical trials industry.

GxP Consulting's new statistical analysis support service is led by newly appointed Timothy Haley, an experienced data analyst and SAS programmer.

The new service enables cost-effective statistical processing for clinical trials.

Mr. Haley has an extensive background in data analysis, with previous posts held at Novartis, Glaxo Group Research, Wyeth Research (UK), the European Commission, and Serono.

"It is an extremely exciting time for the clinical trials industry with the adoption of new technologies and the existing challenge of multiple vendors demanding the correct and efficient management of clinical studies," says GxP Managing Director Mark Stevens.

"We are confident that our expanding clinical services portfolio and our growing team of experienced consultants will provide our clients with the necessary expertise to effectively manage the clinical trials process from specification all the way to project closure and e-submission," Mr. Steven continues.

GlobalHealth Provides **CORPORATE TRAINING, DEGREE PROGRAMS**

GlobalHealth Education & Training has been established to address the growing demand for trained employees and management within the healthcare and ancillary industries to enhance their formal education and attain advanced degrees online.

GlobalHealth's founder, Deborah Kann Schwarzberg, has decades of healthcare and career education experience. She was the founder of MedVance Institute, an allied health technical school enterprise sold to Education Affiliates in December 2009.

Ms. Schwarzberg is also the founder and president of the Richard David Kann Melanoma Foundation, a nonprofit organization providing sun safety curricula in K-12 classrooms around the country under the name SunSmart America.

"GlobalHealth is positioned to target a rapidly growing demand for higher education for existing well-trained and educated healthcare employees," Ms. Schwarzberg says. "GlobalHealth offers opportunities to make a major difference as healthcare managers and leaders seek to advance their careers."

In 2010, GlobalHealth anticipates the acquisition of a regionally accredited university to in-source educational content and enable clients and their employees to select specific modules, industry concentrations, programs, and degrees valuable to healthcare and medical services throughout the country.

NEWLY FORMED DURATA THERAPEUTICS Acquires Pfizer's Vicuron Subsidiary

Durata Therapeutics is a biopharmaceutical company recently created by a five-member venture capital syndicate to pursue late-stage clinical development of novel antibiotic programs.

The new company will pursue late-stage antibiotic programs.

As part of this mission, Durata has acquired Vicuron Pharmaceuticals from Pfizer. Durata's focus is primarily on Vicuron's antibiotic drug candidate, dalbavancin, while Pfizer retains the marketed antifungal agent, Eraxis, formerly owned by Vicuron.

Dalbavancin is a long-acting injectable lipoglycopeptide in Phase III trials for acute bacterial infections of the skin and skin structures. The drug has pharmacokinetic properties that enable convenient once-a-week dosing, and it offers potent activity against Gram-positive bacteria, including methicillin-resistant Staphylococcus aureus (MRSA).

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- What is driving the latest results among physicians who were generating negative word of mouth in some countries last year?

DATE and TIME

Thursday – April 22, 2010
10:30 am – 12:00 pm EST

SPEAKERS

Mark Sales
Head of Global Stakeholder Management
Kantar Health

Ian Hicks
Senior Vice President
Kantar Health

Andrew Brana
Senior Global Consultant
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AROUND THE GLOBE

- **U.S.-based pharmaceutical company ALVOGEN has opened an office in Shanghai to lead efforts to commercialize the company's products in China as a strategic gateway for future business development in Asia.** Alvogen China also serves as a global sourcing unit for active pharmaceutical ingredients and finished products used throughout the company's regional business units that encompass North America, Europe, and Asia.

  For more information, visit alvogen.com.

- **COVANCE has opened new clinical development offices in Seoul and Mumbai and expanded its existing offices in Tokyo and Hong Kong to accommodate growing demand for clinical development services in the Asia Pacific region.** The Seoul office allows Covance to further increase patient access in that area, while supporting its network of field-based CRAs throughout the Asia Pacific region. The Mumbai office, meanwhile, functions as the main clinical trial support hub for the Indian subcontinent.

  For more information, visit covance.com.

- **The FOOD AND DRUG ADMINISTRATION has opened a post in Mexico City as part of its continuing effort to buttress food and medical product safety in the United States by working with its regulatory partners overseas.** This is the agency's third post in Latin America and its 10th international post in the past 13 months. Staff assigned to the Mexico City office are working with their counterparts in the Mexican government to harmonize regulations and guidance standards and to work on other collaborative initiatives, including information-sharing on the respective regulatory systems and joint workshops on the safety of food and medical products.

  For more information, visit fda.gov.

- **ICON, a global provider of outsourced development services to the pharmaceutical, biotechnology, and medical device industries, is opening a translational medicine unit in Manchester, United Kingdom.** Scheduled to open in April 2010, the new hospital-based unit includes 34 beds, an on-site GMP pharmacy, a sample handling laboratory, multiple meeting and admissions rooms, and contiguous access to the accident and emergency department at the Manchester Royal Infirmary (MRI). The unit also offers fully environmentally controlled pharmacodynamic study testing suites to further enhance Icon's market leadership in the development and validation of pharmacodynamic models that assist in identifying efficacy signals in compounds.

  For more information, visit iconplc.com.

ON THE SHELVES

- Barnett Educational Services' new release, **IND SUBMISSIONS: A PRIMER,** offers guidance on writing, editing, tracking, and submitting IND applications and applicable IND amendments to the FDA. The book provides a hands-on approach that shows regulatory professionals how to work with regulations, guidance documents, content templates, and style guides.

  The primer also outlines the information needed to write the document and provides writing tips to produce a range of clearly written U.S. drug and biologics submissions that comply with FDA requirements.

  For more information, visit barnettinternational.com.

- Huron Consulting Group has released the third edition of its **INTERNATIONAL MEDICAL DEVICE COMPLIANCE CODE COMPENDIUM,** which provides regulatory guidance regarding interaction with healthcare professionals in more than 65 countries.

  In addition to analysis of medical device codes and comparisons between codes, the online compendium includes pharmaceutical codes that may affect medical device manufacturers.

  For more information, visit huronconsultinggroup.com.

- The International Society For Medical Publication Professionals (ISMPP) has announced that **GOOD PUBLICATION PRACTICE 2 (GPP2),** a guidance document for the publication of company-sponsored medical research, has been published online by the British Medical Journal (BMJ). GPP2 is an update of the original Good Publication Practice (GPP) guidelines released by ISMPP in 2003. GPP2 now provides guidance to medical device and biotechnology companies as well as pharmaceutical firms.

  The document also includes more than 25 new recommendations, particularly guidance on the role of the professional medical writer, and two new checklists that provide a balanced, up-to-date set of standards.

  For more information, visit ismpp.org.

Follow up

DURATA THERAPEUTICS INC. is a biopharmaceutical company focused on development of novel antibiotic programs. For more information, visit duratatherapeutics.com.

GLOBALHEALTH EDUCATION & TRAINING is a corporate training and degree-granting educational service focused on the healthcare industry. For more information, visit ghetraining.com.

GXP CONSULTING provides consulting and training services to the pharmaceutical and biopharmaceutical industries. For more information, visit gxpus.com.

PETKUS COMMUNICATIONS CONSULTANTS LLC provides senior-level strategic communications counsel. For more information, visit petkusconsult.com.

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FDA Address

Michael Marcarelli Director, Office of Bioresearch Monitoring, CDRH, **FDA**

The Long Tail

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Chris Anderson Bestselling Author ***The Long Tail: Why the Future of Business is Selling Less of More***

"The 2010 Partnerships in Clinical Trials agenda is timely and provocative. Combined with an opportunity to join the organizational leaders in both the service provider and sponsor arenas, the agenda makes Partnerships the necessary meeting in clinical outsourcing for 2010."

— **David Reasner, PhD,** Senior Vice President, Biostatistics, Data Management, and Health Outcomes, **SEPRACOR**

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