



PPD LAUNCHES NEW MEDICAL-DEVICE DIVISION



The rate of innovation in the medical-device arena holds substantial opportunities for business growth, says Fred Eshelman.

PPD Inc. has launched PPD Medical Device, a division of PPD Development. The new unit provides services to the medical-device industry with experience in developing stents, devices, and therapies in the areas of interventional cardiology, endovascular, neurology, and orthopedic disorders, as well as wound care.

The unit provides a full range of clinical-trial services to medical-device companies, including a number of the leading cardiovascular device manufacturers and pharmaceutical companies developing adjunctive therapies.

Services include study design and regulatory consulting by the PPD staff, who have a combined experience of more than 30 years in FDA device submission review, global trial management, data management, biostatistics, and document development.

"The rate of innovation in the medical-device arena holds substantial opportunities for business growth," says Fred Eshelman, CEO of PPD. "Our launch of PPD Medical Device enhances our ability to strengthen and expand our franchise in this important market."



Cutting Edge Information has helped numerous clients understand target marketing budgets and resource allocation for successful pharmaceutical products, says Jason Richardson, President and CEO.

Corbett Accel FORMS NEW BUSINESS UNIT

The new unit, Guidenz, uses proprietary tools to optimize healthcare business informatics to meet the competitive intelligence needs of clients.

Corbett Accel Healthcare Group, an Omnicom healthcare communications company, has formed a new business unit, Guidenz, to support the competitive intelligence needs of its clients.

Guidenz is led by William Marovitz, Ph.D., executive VP and chief scientific and technology innovation officer at Corbett Accel Healthcare Group.

According to agency officials, Guidenz takes competitive intelligence beyond simple data collection and reporting through the use of proprietary tools to create analytics that enable clients to better compete in their respective markets.

Onsite Insite and PulsePanels are two of the proprietary tools Guidenz has developed for clients. Onsite Insite is an effective way to produce competitive intelligence at medical meetings. PulsePanels is an online, quantitative marketing research tool that enables clients to quickly validate their strategic and tactical initiatives.

"Our industry is changing, and insightful companies view competitive intelligence as a driver in business strategy development," says Scott Cotherman, CEO of Corbett Accel Healthcare Group. "Guidenz provides clients with strategic informatics to better position their brands in the face of greater competition."



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Cutting Edge Information ANNOUNCES NEW SERVICES

Cutting Edge Information (CEI) is offering new consulting and marketing assessment services. By focusing on improving operations and strategy, the services are designed to assist pharmaceutical company executives with their 2005 strategic product planning.

Many product teams are underbudgeted and understaffed, and they may be focused on the wrong activities at the wrong time. CEI's new assessment model allows companies to back up budget and staffing requests with hard metrics and fact-based analysis. Using data from other successful launches, CEI helps brand managers convince key departments to provide the resources they need.

The firm's proprietary pharmaceutical marketing launch model incorporates information about budgets, headcounts, resource allocation, activity levels, skill sets, and financial and nonfinancial results.

Criterion LAUNCHES NEW BRAND IDENTITY

Criterion Inc. has launched a new corporate identity that represents a far-reaching change in the way the company thinks about business, the way it allocates resources, and the ways it communicates to the world. In conjunction with its new brand, the company has launched an updated Website that makes a personal connection with visitors and clients through the introduction of key team members and the pivotal roles they play. The easy-to-navigate site allows access to Criterion's full list of services, clients, therapeutic experience, and company news.

"Our new identity represents an expanded vision of how Criterion assists clients in ways they've never imagined," says John M. Hudak, president and founder.



Criterion's rebranding is more than a management theory or cosmetic change to our logo, Website, and collateral; it is a new chapter in Criterion's life cycle.

Integrium EXPANDS EAST COAST PRESENCE



I look forward to building a strong team in the New Jersey office — which will be complementary to our existing operations — and to integrating this into a seamless service offering to our clients, says Ines Altemose.

Integrium, a contract research organization, has opened an operations office in Bedminster, NJ. This expands Integrium's infrastructure to manage clinical-trial projects for biopharmaceutical companies and reflects a continued commitment to responsive client service.

The office is headed by Ines Altemose, Integrium's senior director of clinical operations. Ms. Altemose has more than 17 years of experience in clinical research, including significant managerial experience leading staff in executing clinical-trial projects.

The Bedminster office complements the operations staff based in the Tustin, Calif.,

headquarters.

WHAT'S NEW ON THE SHELVES



- ▶ **A GUIDE TO ACHIEVING REIMBURSEMENT** — A guide for all professionals involved in the licensing, marketing, or commercialization of a product within the U.S. healthcare system. Published by Drug & Market Development Publications and written by Boston Healthcare Associates Inc., it offers answers to the basic questions of why, how, and when company executives should look at reimbursement during product development. In addition, the book highlights recent amendments to legislation that have significantly impacted the industry. For more information, visit drugandmarket.com.
- ▶ **A GUIDE TO EUROPEAN UNION PHARMACEUTICAL REGULATIONS** — A guide for anyone engaged in marketing human medicinal products within the ever-changing European Union (EU). The guide was written by Gordon Blackwell and published by Drug & Market Development Publications. The guide reviews the national and pan-European regulatory mechanisms within the European Union, as well as the processes for effecting change. Further, it describes the prevailing trends in the management of EU healthcare and the particular problems facing the pharmaceutical sector. For more information, visit drugandmarket.com.
- ▶ **A REFERENCE SOURCE FOR QUALITY MANAGEMENT** — A book for anyone charged with improving quality management and GMP compliance. The book was written by Robert A. Rhoades of The Weinberg Group and published by FDAnews. The book discusses how to develop standard operating procedures, how to capitalize on current state-of-the-art quality assurance practices, and much more. For more information, visit fdanews.com.

Windhover Information Acquires MEDTECH INSIGHT



The merger of the two companies will allow for the launch of a host of new products focused on but not limited to the medical-device industry, says David Cassak, Managing Partner of Windhover.

form for expansion of our core competencies beyond medical devices and into the pharma and biotech industry," she says.

For Windhover, the addition of Medtech Insight's portfolio of leading products provides the opportunity to both broaden and intensify its product line.

"The merger of the two companies allows for the launch of a host of new products focused on but not limited to the medical device industry," says David Cassak, managing partner of Windhover.

Windhover Information Inc., a provider of information products and services to senior executives in the pharmaceutical, biotechnology, and medical device industries, has acquired Medtech Insight LLC, a provider of business information on new trends, technologies, and emerging companies in the medical device industry. Windhover Information publishes three journals, *IN VIVO: The Business & Medicine Report*, *Start-UP: Windhover's Review of Emerging Technologies*, and *IN VIVO EuropeRx*, and has a large conference and electronic products business, mainly targeted to biopharmaceutical executives.

Medtech Insight, in addition to publishing Medtech Insight monthly newsletter, hosts the popular Investment In Innovation (In3) medical device conference series and has a large library of syndicated market and technology reports analyzing all aspects of the medical technology marketplace. Together, say company officials, Windhover and Medtech Insight create a company unparalleled in its ability to offer business intelligence and insight to the life-sciences industry.

According to Sharon O'Reilly, president and CEO of Medtech Insight, joining forces with Windhover further strengthens the company's position and reach in the life-sciences industry.

"Together with Windhover's outstanding reputation among senior executives of major healthcare and investment firms, the move provides a plat-

B&Y LAUNCHES NONPROFIT UNIT

B&Y Communications, a public-relations firm serving corporate and nonprofit clients, has launched the B&Y Nonprofit Division. The division represents an expansion of the firm's services within the philanthropic arena.

"B&Y executives understand that nonprofit organizations, just like our corporate clients, have a mission to fulfill and a business to run," says Susan W. Youdovin, president of B&Y. "We want to share our values, experience, and Thinking Partner service-format approach to help these organizations' representatives tell their story in ways that help achieve their goals."

The B&Y Nonprofit Division supports the nonprofit sector with strategic communications, counseling and planning, reputation management, media relations, crisis communications, and publicity for events and services.



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Integrated Clinical Trial Services ANNOUNCES INTEGRATED SUPPORT SERVICE



"With less than 10% of a study coordinator's time spent on patient-recruitment activities, Integrated Support offers sponsors an efficient and affordable way to enhance the essential activities that a coordinator must perform for the success of every trial," says Tom Sturgis.

Integrated Clinical Trial Services (ICTS) has initiated a new service that offers enhanced information flow from the investigational site. This, in turn, offers investigators study support to identify potential patients in practice and to develop outreach awareness, which will increase new patient flow and prospective study volunteers.

The support service is designed to minimize time and effort in clinical-trial enrollment, while maximizing the use of all clinical resources.

"What makes the Integrated Support service unique is that we use study coordinators and registered nurses to perform our in-site and community-outreach functions, providing true peer communications with study coordinators," says Tom Sturgis, president of ICTS. "This involvement allows the site's study coordinators to focus more on the details of the protocol, thereby enhancing patient participation and flow through."

MAGI CREATED TO SPEED TRIALS

The Model Agreement Group Initiative (MAGI), a life-sciences association, has recently been launched to accelerate the clinical-trial site contracting process. MAGI membership is open to all who share its goal of accelerating clinical trials and speeding new medical products to market. The new group is using IntraLinks' online service to facilitate development of standard site contracts. This standardization is expected to shorten the contract negotiation process by at least two weeks.

"Today, the contract approval process is extremely tedious and slow because each sponsor uses a different contract form," says Norman Goldfarb, chairman of MAGI and CEO of First Clinical Research, a multispecialty clinical-research site. "Creating a standardized contract template will dramatically cut the time and cost associated with getting clinical trials started."

MAGI has tapped people from more than 100 life-sciences organizations, including Duke Clinical Research Institute, ICON Clinical Research, ImClone Systems, ISIS Pharmaceuticals, Quintiles Transnational, Stanford University, and the Veteran's Administration to collaborate on a flexible, "multiple-choice" agreement template. MAGI members will be able to distribute, exchange, and track information online with greater efficiency and ease.

"MAGI significantly minimizes the time it takes to bring efforts to fruition, while members experience first-hand the value of being part of the clinical community," says Richard Jenkins, general manager for life sciences at IntraLinks.



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Follow up

B&Y COMMUNICATIONS, Montclair, N.J., is a public-relations firm providing counsel to clients in pharmaceuticals, medical technology, health-related education, women's initiatives, the nonprofit sector, and other areas. For more information, visit bycommunications.com.

CORBETT ACCEL HEALTHCARE GROUP, New York, is a healthcare communications company and a member of the Omnicom Group Inc., a leading global marketing and corporate communications company. For more information, visit corbettaccel.com.

CRITERIUM INC., Saratoga Springs, New York, is a global technology-based contract research organization that provides innovative clinical research solutions to the biopharmaceutical, pharmaceutical, medical-device, and CRO industries. For more information, visit criteriuminc.com.

CUTTING EDGE INFORMATION, Durham, N.C., is a pharmaceutical business

intelligence firm specializing in marketing, spending, and resource allocation; salesforce optimization and management; thought-leader program development; pharmaceutical commercialization; and business development, alliance, and licensing. For more information, visit cuttingedgeinfo.com.

INTEGRATED CLINICAL TRIAL SERVICES, Raleigh, N.C., is a full-service patient-recruitment firm that provides clinical-trial sponsors, CROs, and site networks with a comprehensive resource for patient accrual expertise. For more information, visit integratedtrials.com.

INTEGRIUM, Tustin, Calif., is a contract research company that offers a range of product research, development, and communication services to clients in the biopharmaceutical and medical-device industries. For more information, visit integrium.com.

INTRALINKS, New York, is a provider of digital workspaces that connect business communities and accelerates the intelligent

flow of information and documents among participants. For more information, visit intralinks.com.

THE MODEL AGREEMENT GROUP INITIATIVE, New York, has gathered together people from more than 100 life-sciences organizations to collaborate on a flexible, multiple-choice agreement template. For more information, visit firstclinical.com/magi.

PPD INC., Wilmington, N.C., is a global provider of discovery and development services and products for pharmaceutical, biotechnology, and medical-device companies. For more information, visit ppdi.com.

WINDOVER INFORMATION INC., Norwalk, Conn., provides analysis and commentary on health care business strategy, industry deal-making, marketplace trends, and the world of medical start-ups. For more information, visit windover.com.