Society of Hospital Medicine Launches NEW MEDICAL JOURNAL

Hospitalists are rapidly changing the way physicians care for hospitalized patients by encouraging working together in teams within the hospital setting, says Dr. Laurence Wellikson, CEO of the Society of Hospital Medicine.

The Society of Hospital Medicine plans to launch a new peer-reviewed medical journal, *The Journal of Hospital Medicine*, in 2006. The journal will promote the science and practice of hospital medicine and the enhancement of in-patient care.

In addition, it will provide hospital medicine physicians with continuing education in basic and clinical science to support informed clinical decision-making. It will also offer all clinical practitioners education about the value of and processes inherent in hospital medicine, and it will foster responsible and balanced debate on medical issues or healthcare trends that affect hospital medicine and patient care. Currently the society produces only a member newsletter, *The Hospitalist*.

"It is imperative for our society to take a larger education and leadership role by publishing landmark hospitalist research and promoting industry education," says Laurence Wellikson, M.D., CEO of the Society.

The society has signed an agreement with global publisher John Wiley & Sons Inc. to publish *The Journal of Hospital Medicine*. Wiley assumed publishing responsibilities for *The Hospitalist* in January 2005.

HBA Continues Expansion WITH NEW AFFILIATE IN NORTH CAROLINA

RTP affiliate is the eighth regional group to be created by the national organization.

The Healthcare Businesswomen's Association (HBA) continues its global expansion with the formation of its Research Triangle Park, N.C., affiliate (HBA RTP Affiliate) to provide programs to members who live, work, or are visiting the North Carolina area. This is the eighth regional group to be created by the national HBA organization, and a ninth is expected to be announced by mid-year. Affiliate status is a required step to becoming a HBA chapter and is granted to regional groups that meet specific fiscal and membership criteria.

According to HBA RTP Affiliate Founder and Chair Nancy Wysenski, president of EMD Pharmaceuticals and a long-time HBA member before moving to North Carolina, "I knew the value of the organization and how important it is to offer the HBA's programs, including professional development, skill-building, networking and mentoring, to the women in the RTP area, one of the major pharmaceutical and biotech centers in the country."

I knew the value of the organization and how important it is to offer the HBA's programs, including professional development, skill-building, networking and mentoring, to the women in the RTP area, one of the major pharmaceutical and biotech centers in the country, says Nancy Wysenski, Affiliate Affiliate Founder and Chair, and President of EMD Pharmaceuticals.

The objective for the HBA RTP Affiliate is to create new opportunities for women, as well as men, to come together to advance the careers of women in healthcare.

The HBA RTP Affiliate will seek members from and provide services to the area's pharmaceutical and biotech companies, contract research organizations (CROs), local academic institutions with healthcare programs, patient advocacy groups, and service providers to the industry, such as advertising, medical-education, and public-relations agencies.

"We welcome the HBA RTP Affiliate to the growing number of HBA chapters and affiliates as our national structure has been changed to allow the association to plan strategically and implement locally," says Barbara Pritchard, president of The Pritchard Group and Intermedica Inc., and president of the HBA. "HBA members belong to an organization that stands for commitment to improving their industry knowledge and leadership skills. It provides a support system for career advice and networking, and a place to share challenges and opportunities."

The founding board of directors for the new affiliate includes: Chair: Ms. Wysenski; Treasurer: Cheryl Koepke, EMD Pharmaceuticals; Secretary: Barbara Koch, director organization and people development, GlaxoSmithKline; Codirectors of Programs: Meara Kirsh, manager data sourcing, GlaxoSmithKline, Mary-Margaret Armstrong, director of business development, PMPN, and Deena Wegner, director of business development, Integrated Safety Systems Inc.; Director of Membership: Pam Higdon, CEO, Express Personnel; and Director of Publicity/Marketing: Patrice Ferriola, Ph.D., president, KZE PharmAssociates.

PPD Expands ASIAN OPERATIONS

PPD Inc. has expanded its presence in Asia and has geographically realigned its regional management team. These changes are intended to optimize access for clients to treatment-naive populations in the region and effectively navigate country-specific regulatory processes.

In addition to PPD's established locations in Singapore, Thailand, China, Hong Kong, and Taiwan, the company is opening a new office in Seoul, South Korea.

This office provides patient recruitment and clinical monitoring services for Phase II through Phase IV studies in key therapeutic areas.

We have assembled a management team with a thorough understanding of the nuances of varying regulatory processes and systems within respective Asian nations, says Fred Eshelman, CEO of PPD.

In conjunction with the realignment, Edmund C.W. Leong, Ph.D., has been named director of strategic development for Asia. K.C. Lau, Ph.D., director of clinical operations, directs the company's operations in northeast Asia, including the new Seoul location.

"We have assembled a management team with a thorough understanding of the nuances of varying regulatory processes and systems within respective Asian nations," says Fred Eshelman, CEO of PPD. "This strategy enables us to conduct efficient global clinical studies for our clients in these emerging markets."

PharMed EXPANDS SERVICES

In recent years, the medical communications industry — advertising and medical-education companies — has found the use of freelance personnel indispensable to the development and implementation of its client projects, says Gregg Berkowitz, Principal and President of PharMed.

PharMed Staffing LLC has launched two new service offerings. Building on its freelance science writing capabilities, PharMed has developed a regulatory writing services arm to assist clients in the preparation of concise and timely regulatory documents. Additionally, it has launched a sister company, PharMed Placement LLC, which specializes in meeting clients' full-time placement needs.

"The medical communications industry has found the use of freelance personnel indispensable to the development and implementation of its client projects," says Gregg Berkowitz, principal and president of PharMed.

PharMetrics Establishes MID-ATLANTIC HUB

PharMetrics President and CEO Michael Weintraub says the Mid-Atlantic hub fufills multiple objectives for the company.

PharMetrics Inc. has opened a Mid-Atlantic hub in the greater Philadelphia area. In keeping with the company's customer-driven strategy, the new office allows PharMetrics to be even closer to many of its key customers. The office is staffed by a team of scientists, clinicians, and analysts with substantive experience in the healthcare research and market intelligence area.

In addition to bringing PharMetrics closer to key customers, the Mid-Atlantic hub serves to further the company's recruitment and research and development goals.

"Establishing a Mid-Atlantic hub fulfills a three-part objective for us," says Michael Weintraub, president and CEO of PharMetrics. "First, it brings us closer to many of our key customers. Second, it allows for the infusion of additional talent, consistent with our rapid growth as a company. Third, it allows us to further our strategy of customer-driven innovation, in that it enables us to work side by side with key customers to develop our next-generation of products."

WHAT'S NEW ON THE SHELVES

- **STRATEGIC CLINICAL DEVELOPMENT PLANNING: DESIGNING PROGRAMS FOR WINNING PRODUCTS** is a new book from William K. Sietsema, Ph.D., a 21-year veteran of successful clinical trials. Dr. Sietsema is VP of clinical and regulatory strategic planning at Kendle, a global CRO delivering innovative and robust clinical development solutions to help the world's biopharmaceutical companies maximize product life cycles and grow market share.

  Published by **FDAnews**, this is an essential guide for drugmakers looking to streamline the trials process for faster FDA approvals and major cost savings. Only 20% of drugs that begin Phase I human trials are eventually approved for marketing and more than 50% of clinical trials fall behind schedule. This guide, for drugmakers who are looking to streamline the trials process for faster FDA approvals and realize major cost savings, discusses how to: cut waste, by striking the right balance between number of trials, size of trials, and sequence of trials; know which trials are must-do's and which can be delayed; choose the most powerful clinical endpoints that will optimize a product's use; build a project team with the right skill sets and adjust team membership as the trial process evolves; register products worldwide; manage patient safety and protect patient rights; and more.

  For more information, visit fdanews.com.

- **UNDERSTANDING FDA DRUG AND BIOLOGIC ADVERSE EVENT REGULATIONS 2005 EDITION**; a guidance document that is related to the electronic submission of postmarketing periodic adverse drug experience reports.

  Published by **FDAnews**, the reference outlines the key facts for reporting adverse events, including: four core elements to include in a 15-day report; when and how to submit follow-up, periodic, and distribution reports; who's responsible for adverse event reporting; how to handle 483s and EIRs; definitions of types of events and standards for expedited reporting; how to handle electronic submissions of postmarketing expedited safety reports; five key factors to consider when implementing a MedDRA system; how to maintain quality in recording adverse events using MedDRA; and a sample periodic safety update report and what it includes.

  For more information, visit fdanews.com.

- **NAVIGATING GOOD CLINICAL PRACTICES: FDA'S GUIDELINES FOR CLINICAL TRIALS, VOLUMES I AND II**, provides FDA guidances and guidelines that executives need to better manage their clinical trials. The two-volume set provides information on how to select appropriate monitors, monitor clinical investigations, prepare for pre-investigation visits, conduct research in emergency settings, handle clinical holds and combination products, collect race and ethnicity information, document and manage subject records, identify and select control groups, conduct safety assessments of medical imaging agents, and submit correctly formatted data.

  For more information, visit fdanews.com.

Millipore Forms BIOSCIENCE DIVISION

Millipore Corp. has formed a bioscience division focused on life-sciences research and general laboratory applications for Millipore products and services.

The new division combines Millipore's life-sciences and laboratory water divisions, which essentially served the same customer base.

The merger of the two entities provides more organizational clarity, improves sales effectiveness, better serves customers, and focuses R&D investments in the laboratory area.

The new organization is headed by Dominique Baly, who previously served as president of the laboratory water division.

Pharm-Olam Expands CAPABILITIES IN LATIN AMERICA

Federico Argüelles, M.D., (pictured), and Adriana Chávez-Blanco, D.V.M., are steering Pharm-Olam's new development program in Mexico City.

Recognizing Mexico as a key clinical-trial sector in Latin America, Pharm-Olam International Ltd. has added a new office in Mexico City. The CRO has been conducting studies in Mexico since 2001.

This facility enables Pharm-Olam to meet the accelerated growth in clinical research, regulatory affairs, drug storage, and archiving requirements for its clients. The firm currently performs Phase I through III studies for various therapeutic areas, including cancer, women's health, and cardiovascular diseases.

Pharm-Olam de Mexico has added an early-phase, clinical-development program for proof-of-concept studies using a network of Phase I units.

IntraLinks and ePharmaLearning Partner to STREAMLINE SITE QUALIFICATION, ACTIVATION, AND TRAINING FOR CLINICAL TRIALS

Richard Jenkins, VP of Business Development for IntraLinks, (left) and Lance Converse, CEO and Founder of ePharmaLearning, (right) are teaming up to provide an end-to-end online solution for study sites and sponsors that will enable trial sponsors to consolidate tasks, training, and document exchange in a single workspace to accelerate drug-development timelines.

IntraLinks has partnered with ePharmaLearning to accelerate and improve site qualification, activation, and protocol training. The partnership helps pharmaceutical and medical-device companies launch clinical drug trials faster, less expensively, and with a greater chance for success than traditional methods.

ePharmaLearning is integrating IntraLinks' 21 CFR Part 11-capable secure document exchange service with its Investigator Portal Solution to provide study sites and sponsors with a single hub for clinical-trial launches. In addition to the integrated service offering, ePharmaLearning is providing clinical-support services to facilitate site qualification, site activation, and training to accelerate and improve study launch.

"We have supported the qualification and training of more than 25,000 clinical researchers in more than 40 countries over the last four years," says Lance Converse, CEO and founder of ePharmaLearning. "IntraLinks' secure electronic document exchange technology is a powerful complement to our Investigator Portal. Together, we can provide an end-to-end online solution for study sites and sponsors."

Under the partnership, IntraLinks is coordinating its services with ePharmaLearning's SiteActivater, which consolidates the qualification, activation, training, and trial management tools used by study sites. Sites are provided with single, secure, study-specific workspaces for 24/7 access to feasibility surveys, study documents, self-paced e-learning modules, online meetings, and trial-management tools. The system time-stamps, tracks, and reports on all user activity to support clinical-project management and tracking needs.

"ePharmaLearning's expertise in site recruitment, qualification, and training is the perfect complement to our secure document exchange service," says Richard Jenkins, VP of business development for IntraLinks. "The combination of IntraLinks' and ePharmaLearning's systems enables trial sponsors to consolidate tasks, training, and document exchange in a single workspace to accelerate drug-development timelines."

NEW CALL CENTER for Patient-Recruitment Firms

We understand that clinical research professionals require flexibility, and our approach is to work with our clients as partners, producing the best result, says Claire Driscoll, President of Claire Driscoll & Associates.

Claire Driscoll & Associates Inc. has opened a call center focused on providing services to patient-recruitment firms, pharmaceutical companies, CROs, and investigators. Its services include answering incoming calls resulting from media; handling protocol specific prescreening; performing appointment reminders; and other related services.

"We understand that clinical-research professionals require flexibility, and Claire Driscoll & Associates' approach is to work with our clients as partners, producing the best result," says Claire Driscoll, president. "Basing our operations in accent-neutral Canada, with a trained and educated workforce, allows us to offer the best in call-center services."

MedTrials Bolsters BIOINFORMATICS OFFERINGS

To bolster its existing bioinformatics offerings to the pharmaceutical, medical-device, and biologics industries, MedTrials Inc. has acquired the data-management and biostatistics capabilities of DataMedix Corp.

DataMedix, which was established in 1987, has operated as a full-service clinical research support organization specializing in data management and biostatistics.

The acquisition strengthens MedTrials' existing bioinformatics offerings, while helping to fuel growth in 2005 and beyond.

"We are enthusiastic about the enhanced capabilities that result from this and are looking forward to our increased ability to compete for larger bioinformatics projects in the future," says Brian Morgan, chief operating officer of MedTrials.

MedTrials and DataMedix have successfully partnered on clinical studies for years. This acquisition creates a powerful combination of expertise and enables MedTrials to build on DataMedix's technology and success.

Along with the company's existing data-management and statistical information systems, MedTrials has acquired all of DataMedix's core personnel. MedTrials' headquarters remains in Dallas; an East-coast office has been established in the Philadelphia area, where DataMedix had its headquarters, to support the venture and provide capacity for additional growth.

Follow up

CLAIRE DRISCOLL & ASSOCIATES INC., New Brunswick, Canada, is a call center that provides marketing services to the clinical-research industry by integrating data collection and patient recruitment. For more information, visit claired.com.

EPHARMALEARNING, Philadelphia, is a provider of site activation and online training services for the pharmaceutical industry. For more information, visit epharmalearning.com.

THE HEALTHCARE BUSINESSWOMEN'S ASSOCIATION (HBA), Fairfield, N.J., is a national nonprofit organization that is dedicated to furthering the advancement of women in the healthcare industry. For more information, visit hbanet.org.

INTRALINKS, New York, provides digital workspaces that connect business communities and accelerate the intelligent flow of information and documents among participants. For more information, visit intralinks.com.

MEDTRIALS INC., Dallas, is a privately held, women-owned, full-service clinical research services company that offers a comprehensive portfolio of customized solutions to pharmaceutical, medical-device, and biologics clients. For more information, visit medtrials.com.

MILLIPORE CORP., Billerica, Mass., is a multinational, high-technology company that provides technologies, tools, and services for the development and production of new therapeutic drugs. For more information, visit millipore.com.

PHARMED STAFFING LLC, New York, provides freelance placement services for the pharmaceutical and medical communications industry. For more information, visit pharmedstaffing.com.

PHARMETRICS INC., Watertown, Mass., provides market intelligence solutions to the pharmaceutical, biotechnology, medical-device, and health-plan sectors, using anonymous patient-centered data. For more information, visit pharmetrics.com.

PHARM-OLAM INTERNATIONAL LTD., Houston, is a multinational contract research organization offering a wide range of comprehensive, clinical-research services to the pharmaceutical, biotechnology, and medical-device industries. For more information, visit pharm-olam.com.

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

SOCIETY OF HOSPITAL MEDICINE, Philadelphia, is a medical society representing physicians whose primary professional focus is the general medical care of hospitalized patients. For more information, visit hospitalmedicine.org.