Parexel's Solution Brings Efficiency to CLINICAL SUPPLY CHAIN

As they face ever-more-complex clinical trials, biopharma companies are looking to gain greater efficiency through consistent delivery of trial-related supplies to multiple locations worldwide, says Dr. Joe Avellone.

As part of its clinical logistics services, global CRO Parexel International has unveiled an integrated temperature recording solution for clinical-trial drug transportation.

Parexel's temperature control process saves 24 to 48 hours of time over traditional cold-chain methods in which temperature devices shipped out to investigative sites need to be transported back to a hub to be analyzed before study drugs can be released for use. With Parexel's approach, a central hub receives and disseminates confirmations of temperature data in real time, allowing clinical site investigators to quickly begin using study drugs according to trial protocols.

The packaging container for study drugs incorporates a radio-frequency identification (RFID) tag for temperature recording and a dedicated compartment for a mobile phone, providing automatic tracking and remote, high-speed transmission of the complete temperature record. The RFID tag records study drug temperature at predefined time points, while a mobile phone application and Web-based portal allow secure, controlled data transmission and access to temperature data in real time between a central hub and an investigative site.

"This key advancement in temperature control for investigational medicines represents our commitment to ensure that clinical supplies and logistics become further streamlined, enabling our clients to reduce associated time and costs," says Joe Avellone, M.D., corporate VP, clinical research services.

Epitomics Spins Out NEW BIOTECH FIRM

The new company focuses on humanized monoclonal antibodies.

Epitomics has spun out a new biotechnology company, Apexigen, focused on the development and commercialization of humanized monoclonal antibodies for the treatment of cancer and immune disorders.

Apexigen has exclusive rights to develop and commercialize therapeutic monoclonal antibodies derived from RabMAb (rabbit monoclonal antibody) technology and mutational lineage guided (MLG) humanization technology, both of which were developed by Epitomics, for the treatment of human and animal diseases.

The spinoff also assumes development and commercialization of therapeutic 'bio-better' product programs initiated by Epitomics, including humanized antibodies against VEGF and TNF.

"Epitomics developed the cutting-edge RabMAbs and MLG technologies that should enable us to develop best-in-class antibody therapeutics," says Xiaodong Yang, M.D., Ph.D., who has assumed the role of Apexigen's president and CEO.

A service agreement between Epitomics and Apexigen allows Apexigen immediate access to the antibody generation, screening infrastructure, and technical expertise of Epitomics.

We are fortunate to be starting with a robust pipeline of therapeutic candidates that had already been in place when Apexigen was formed, says Dr. Xiaodong Yang.

Epitomics will continue to focus on its core business and assist Apexigen as it develops therapeutics to treat serious diseases, says Dr. Guo-Liang Yu.

"We believe that an independent company with experience, expertise, and focused pharmaceutical product development offers the best opportunity to see technology developed at Epitomics have a direct therapeutic impact on peoples' lives," explains Epitomics President and CEO Guo-Liang Yu, Ph.D.

Best Practices Enables Optimization of KEY OPINION LEADERS

Best Practices' recent addition to its thought leader services is specifically focused on utilization and management of key opinion leaders (KOLs), enabling life-sciences executives to improve the structure and processes for working with KOLs.

KOLs possess a credibility earned through experience and their relationships in their therapeutic area. As a result, KOLs can serve as natural resources for pharmaceutical companies in terms of generating market interest and providing knowledge about specific drugs.

Through its Thought Leadership Excellent Services package, Best Practices provides its clients with access to primary research from leading pharmaceutical and biotech companies, as well as case examples of successful practices with KOLs. The service contains a variety of data in thought leader areas, from how they relate to patient advocacy to the role they play in preparing the market for new product launches. Executives can use the resource to address numerous resource-related issues, while implementation-level managers can employ the service to create roadmaps and plans for accomplishing their KOL objectives in key areas.

SEE DIGITAL EDITION FOR BONUS CONTENT WWW.PHARMAVOICE.COM

Follow up

BEST PRACTICES LLC is a research, consulting, and publishing firm focused on best-practice benchmarking for the life-sciences industries. For more information, visit best-in-class.com.

EPITOMICS INC. is a biotechnology company dedicated to developing breakthrough monoclonal antibody technology for research and diagnostic applications. For more information, visit epitomics.com.

PAREXEL INTERNATIONAL CORP. is a provider of knowledge-based contract research, consulting, and medical communications services to the worldwide pharmaceutical, biotechnology, and medical device industries. For more information, visit parexel.com.

FOURTH ANNUAL MEETING OF

The PMRG Institute

The Art and Science of Healthcare Marketing Research

NAVIGATING HEALTHCARE'S SHIFTING CURRENTS

ESSENTIAL TECHNIQUES FOR THE HEALTHCARE MARKETING RESEARCHER

THE WESTIN BOSTON WATERFRONT
October 24-26, 2010

Early bird registration ends October 2, 2010
Agenda and registration information at www.pmrg.org

The PMRG is an independent, member-based, non-profit association that advances the principles, practice and power of healthcare marketing research by creating a community that both supports individual professional development and acts as an advocate for the profession as a whole.

- Attend lively panel discussions, breakout sessions and workshops designed to give you the tools needed to navigate in today' healthcare's shifting currents
- Be there when the winners are revealed at the PMRG Annual Awards Banquet featuring:

PMRG MARKETING RESEARCHER OF THE YEAR *Award*

PMRG R.R. Fordyce AWARD

PMRG
PHARMACEUTICAL MARKETING RESEARCH GROUP

What's new

AROUND THE GLOBE

- Global publisher **ELSEVIER** has signed an agreement with King Saud University in Riyadh, Saudi Arabia, to provide access to a series of scholarly journals from Saudi Arabia, improving and accelerating the dissemination of research from this increasingly important region. The first eight journals in chemistry, health science, pharmacology, and biological sciences are now available, and additional journals will be added in the near future.

  For more information, visit elsevier.com.

- **ICON**, a global provider of outsourced development services to the pharmaceutical, biotechnology, and medical device industries, has opened a clinical pharmacology unit within the Central Manchester University Hospitals Foundation Trust campus in Manchester, United Kingdom. The two-floor, 34-bed hospital-based unit brings Icon's Phase I global bed capacity to more than 280 and includes a sample handling laboratory, 24-hour medical cover, local GMP pharmacy, contiguous access to the accident and emergency departments at the Manchester Royal Infirmary, and local bioanalytical support.

  For more information, visit iconplc.com.

- **IMS HEALTH** has expanded its IMS Oncology Analyzer to additional cities in China, enabling pharma clients to assess treatments and guide commercial decisions in the country's fast-growing $1.5 billion-plus oncology market. The market assessment tool now covers 12 Tier 1 and Tier 2 cities in China, providing a clinically comprehensive view of cancer care from first diagnosis forward and facilitating critical market research insights for areas such as product adoption, dosing and regimen compliance, and market sizing.

  For more information, visit imshealth.com.

- **MERRION PHARMACEUTICALS** has announced that its state-of-the-art development and manufacturing facility in Dublin has been licensed under the EU Clinical Directive for Investigational Medicinal Products and that inspections conducted by the Irish Medicines Board confirmed the quality, safety, and efficacy of medicines developed at the facility.

  Merrion acquired the 30,000-square-foot pharmaceutical facility in July 2009, providing the company with a much-needed additional research and development space to handle its existing workload and initiate new collaborations and products.

  Merrion is engaged in the development of oral forms of drugs that have poor absorption and are generally given by injection.

  For more information, visit merrionpharma.com.

- Biopharmaceutical services provider **QUINTILES** has expanded its data-management services into its Shanghai location, strengthening the company's capability to serve customers in China and throughout the Asia-Pacific region. In addition to its Shanghai operations, Quintiles China has offices in Beijing and Hong Kong. The company has existing data-management operations in Japan and India.

  For more information, visit quintiles.com.

- **RESEARCHPOINT GLOBAL (RPG)** has added Spain-based Pivotal S.L., a full-service CRO and medical pharmaceutical consultancy group, to its roster of clinical partners worldwide. The partnership with Pivotal strengthens RPG's presence in Western Europe.

  For more information, visit researchpoint.com.

exl pharma Presents

QUALITY OVERSIGHT OF CLINICAL VENDORS

- Identify your outsourcing risks
- Recognize your responsibilities
- Clarify your expectations
- Remain inspection ready

Strategies for Assessing and Managing Quality at CROs & other Specialty Providers

October 12-14, 2010 • Westin Arlington Gateway • Arlington, VA

KEYNOTE:

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)

Featured Presentations Addressing:

- Inspection Findings
- Recent Warning Letters
- Vendor Selection
- Quality Agreements
- Establishing Expectations at Project Kick-Off
- Protocol Complexity Risk
- Issue Escalation
- Quality-to-Quality Interaction
- Designing and Evaluating Monitoring Plans
- Oversight in Emerging Regions
- Audits to Measure Performance
- The Clinical QA/Clinical Operations Partnership
- Quality Management Case Studies
- …and more!

Conference Sponsors:

CIS Compliance Implementation Services

PHT firsthand knowledge

With Support from:

ACRO

Save 10% off your registration rate.

Simply enter **exlpvad** when registering

TO REGISTER Call **866-207-6528** or visit us at **www.exlpharma.com/qualityoversight**

exl pharma Presents

The only event designed to address GCP compliance challenges from a strategic, senior level

European Proactive GCP Compliance

Building in Quality to Meet New Requirements and Ensure Patient Safety

October 18-20, 2010 | Hilton Berlin | Berlin, Germany

Address the Shift in GCP Enforcement Priorities and Enforcement Focus by:

- Driving your business effectively in a new enforcement environment
- Preparing for a collaborative auditing experience between the FDA and EMA
- Evolving from traditional QA to a quality management culture
- Interpreting and applying the regulatory nuances and ethics of emerging regions
- Ensuring the right mechanisms are in place for effective oversight
- Avoiding over- or under-interpreting the regulations
- Committing to the best processes and smartest use of your resources
- Recognizing compliance gaps across a study or system
- Learning how to look for patterns in deviations and where more training is needed
- Sharing your experiences by actively participating in sessions as well as end-of-day roundtable discussions

With Support from:

IPI International Pharmaceutical Industry

JOURNAL FOR CLINICAL STUDIES
Your Resource for Multisite Studies & Emerging Markets

Take Advantage Of In-Depth Half-Day Workshops On:

A Organizing Your Clinical Trial Data for Better Utilization and Decision-Making

B Quality Oversight of Clinical Vendors

TO REGISTER Call **+1-212-400-6240** or visit us at **www.exlpharma.com/EuroGCP**