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September 25, 2008

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News

Study Promotes Hatch-Waxman Model for Biologics Exclusivity

Boston (Sept. 17)—A new study concludes that an approval pathway for affordable follow-on biologics should be based on the Hatch-Waxman Act of 1984.

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House Questions FDA's Priorities

Washington, DC (Sept. 25)—In a Sept. 17 letter to FDA Commissioner Andrew C. von Eschenbach, Rep. Henry Waxman (D-CA) questions the agency's priorities, specifically poking at FDA's political appointees and whether they are promoting industry at the expense of the public's health.

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FDA Outlines Rules on Genetically Engineered Animals

Rockville, MD (Sept. 25)—In an effort to clarify its policy on the use and creation of genetically engineered (GE) animals, the US Food and Drug Administration released the draft guidance *The Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs* on Sept. 18, 2008.

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Wyeth Prepares for Supreme Court Preemption Case

Washington, DC (Sept. 15)—On Nov. 3, 2008, the US Supreme Court will hear *Wyeth v. Levine*, in which the drug company challenges a Vermont Supreme Court decision to award Diana Levine \$6.8 million.

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PharmTechTalk

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Product Spotlight



Scalable conveyance system offers traceability MagneMotion's (Acton, MA) "MagneMover" transport and positioning system is based on the company's "QuickStick" linear synchronous motors (LSMs), which offer flexibility and control. The QuickStick motor modules are mounted in the MagneMover track and convey carriers using electromagnetic forces. Each carrier is controlled independently of the others. Thus, users can move

specific payloads without moving the adjacent payloads. The carriers can be moved to within a fraction of a millimeter.

Porosity Surface Area

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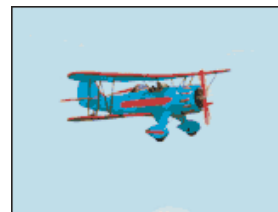
PharmTech Poll

Clinical Trial Results

Do you feel pharmaceutical companies abuse marketing with regard to clinical trial results?

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Development

- Analytical Development
- Clinical Trial Materials
- Process Development
- Scale-up
- Commercial Manufacturing



Drug Development Solutions

Events

INTERPHEX Canada 2008
September 24–25
Montréal, Canada

USP Annual Scientific Meeting 2008
September 24–26
Kansas City, MO

CPhI Worldwide 2008
September 30–October 2
Frankfurt, Germany

Prefilled Syringes and Injection Devices
October 6–7
San Diego, CA

**IVT Presents:
5th Annual Method Validation**
October 14–16
San Francisco, CA

**IVT Presents:
Computer System Validation**
October 14–16
San Francisco, CA

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**IndustryMatter
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Product Catalog**

To propel a carrier, the motor controller induces current into the motor's stator winding in the region where the vehicle is at a given time. A position-sensing system built into the motors tells the control system the precise location of all carriers at all times, thus providing traceability for pharmaceutical applications.

In addition, the conveying system is scaleable. Because it is modular, users can lengthen the MagneMover lines by adding more motors and track sections.

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Company Notes

San Francisco, CA (Sept. 17)—**Bilcare Global Clinical Supplies**, a provider of clinical trial supplies and services, completed the expansion of its warehouse and distribution facility in Phoenixville, Pennsylvania. Bilcare's facility now provides 300% more ambient storage capacity, as well as a 50% larger distribution pack-out area and a second distribution dock.

Washington, DC (Sept. 18)—Members of the **Committee on Energy and Commerce** announced they have expanded their inquiry into the FDA's dealings with **Ranbaxy Laboratories**. The committee will now investigate the safety and effectiveness of drugs manufactured by Ranbaxy for the President's Emergency Program for AIDS Relief (PEPFAR). According to a statement on the committee's website, "Allegations have been raised regarding serious irregularities in the application and production process at Ranbaxy." In July, committee members launched an inquiry into whether FDA "knowingly allowed drugs suspected of being fraudulently approved and manufactured in gross violation of Good Manufacturing Practices (GMP) to continue being sold in the United States" according to the website.

On Sept. 17, Ranbaxy announced that former New York City Mayor Rudy Giuliani and Giuliani Partners will assist the company with compliance issues related to the **warning letters and import advisory** issued by FDA last week.

Leiden, The Netherlands (Sept. 18)—The biopharmaceutical company **Crucell** signed an exclusive, commercial license agreement with **Talecris Biotherapeutics** (Research Triangle Park, NC) for an undisclosed and specific protein to be produced using Crucell's "PER.C6" cell line. Crucell will receive an upfront payment of \$2.5 million and will be eligible for milestone payments of approximately \$30 million. Further financial details of the agreement were not disclosed.

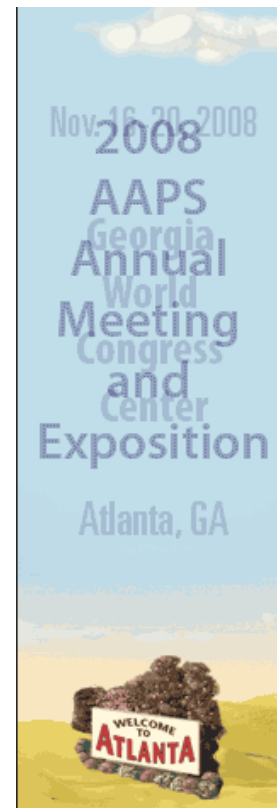
Also, Crucell announced on Sept. 23 that it received new contracts from various organizations of \$140 million for supplies of "Quinvaxem" and "Hepavax-Gene" for the period 2008–2009, bringing the total for the period 2007–2009 to \$0.5 billion.

Muenster, Germany (Sept. 11)—Pharmaceutical service provider **Diapharm** is now offering accredited shared third-party audits for active pharmaceutical ingredients (APIs). Diapharm's audit reports serve to prove whether the rules of good manufacturing practices (GMPs) are followed in the manufacture of ingredients. This proof of GMP compliance is mandatory for European manufacturers of medicinal products.

Heerlen, NL (Sept. 17)—**DSM Biomedical** and **Caliber Therapeutics** (Boston) signed a drug-delivery pact to develop a novel balloon catheter that can be used to treat vascular diseases. The partnership will combine proprietary technology from DSM on drug delivery with balloon and catheter technology from Caliber. In addition, DSM will grant Caliber a worldwide exclusive license for the use of DSM's "Trancerta" drug-delivery platform for the development of this specific application.



Cambridge, MA (Sept. 22)—**Genzyme** marked the grand opening of its Science Center in Framingham, Massachusetts. The facility serves as a central site for



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early-stage research. The company announced that the Science Center received a gold certification under the US Green Building Council's "LEED" (Leadership in Energy and Environmental Design) "Green Building Rating System." It is one of only 10 laboratories to achieve this high rating.

Princeton, NJ (Sept. 18)—**Laureate Pharma**, a biopharmaceutical development and protein production company, will increase its existing manufacturing capacity by adding two single-use bioreactors (SUBs), one 250 L and a 1000 L unit. The SUB is a single-use alternative to conventional stirred tank bioreactors.

Basel (Sept. 19)—**Novartis** announced that a new study showed that its "MF59"-adjuvanted vaccine triggered a rapid protective immune response to diverse strains of avian flu. The study showed that the investigational prepandemic vaccine "AFLUNOV" provides rapid immune response in individuals primed with MF59-adjuvanted H5 vaccine up to six years earlier. Individuals primed with the MF59 adjuvant developed immunity seven days after receiving the AFLUNOV booster. Novartis says this study supports notion of prepandemic vaccination to ensure protective antibody levels in the population, with one additional immunization in the event of a pandemic. These data were presented at the Third European Influenza Conference in Vilamoura, Portugal.

San Diego, CA (Sept. 17)—**Pharmatek**, a provider of chemistry development services, opened a cytotoxic facility in San Diego. The 18,000-ft² facility includes newly constructed analytical and formulation development laboratories and CGMP manufacturing suites dedicated to the development of highly-potent and cytotoxic drug products for early phase clinical trials.

Lowell, MA (Sept. 23)—**UMass Lowell** opened a fully automated biomanufacturing pilot plant designed to help Massachusetts biomanufacturing companies bring new biopharmaceuticals closer to commercial production and serve UMass Lowell faculty by providing a home for biomanufacturing research. The Massachusetts BioManufacturing Center facility was made possible through equipment and services donated by **Invensys Process Systems** (Plano, TX), **Wyeth Biotech** (Madison, NJ), **Dakota Systems** (Chicago, IL), and **Millipore** (Billerica, MA). The four companies' contributions are worth \$600,000, UMass Lowell officials announced.

Aliso Viejo, CA (Sept. 17)—**Valeant Pharmaceuticals International** signed a definitive agreement to acquire **Coria Laboratories** (Fort Worth, TX), a privately held specialty pharmaceutical company focused on dermatology products. Valeant will purchase all of the outstanding shares of Coria from its parent company, DFB Pharmaceuticals, and other shareholders for \$95 million. The transaction is expected to close following customary regulatory approval.

Prague (Sept. 22)—**Zentiva** and **Sanofi-Aventis** (Paris, France) agreed on the unanimous recommendation by Zentiva of a cash public offer of CZK 1,150 per share (\$69 per share), an estimated total of \$2.6 billion, by Sanofi-Aventis' wholly-owned subsidiary Sanofi-Aventis Europe to acquire all issued ordinary shares of Zentiva. Sanofi's previous bid of CZK 1050 per share (\$63 per share), or approximately \$2.39 billion, had been rejected because Zentiva felt it undervalued the company.

Do you have news to report on facility expansions, contracts, service agreements, mergers, acquisitions, or personnel appointments? Send press releases to ptpress@advanstar.com

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People Notes

Indianapolis, IN (Sept. 22)—**AIT Laboratories**, a contract analytical laboratory,

Poor Economy Affects Pharma in Many Ways: Here's One

Biotech Renewed Hope for Stem-Cell Research

named Ronald Shoup executive director of its Pharma Services division. Shoup is a former cofounder and chief scientific officer of Bioanalytical Systems (West Lafayette, IN).

Redwood City, CA (Sept. 23)—**Codexis**, a biotechnology company, appointed Lynn Marcus-Wyner vice-president of intellectual property. She will be responsible for managing the company's intellectual property strategy and will report to Douglas Sheehy, vice-president, general counsel and secretary.

Rye, NY (Sept. 23)—**Curemark**, a biotechnology company, appointed Elisa J. Zinberg vice-president of operations and member of Curemark's management team, effective immediately. Zinberg will be responsible for the day-to-day management of Curemark as well as for the implementation of Curemark's strategic plan.

Wilmington, DE (Sept. 24)—The **DuPont** board of directors elected Ellen Kullman president and a director of the company effective Oct. 1, 2008 and chief executive officer (CEO) effective Jan. 1, 2009. DuPont Chairman and CEO Chad Holliday will serve as chairman of DuPont and as a member of the board until Kullman's expected succession as chairman.

Indianapolis, IN (Sept. 18)—**Eli Lilly and Company's** board of directors appointed John C. Lechleiter chairman of the board, effective January 1, 2009. Lechleiter, Lilly's president and CEO, will succeed outgoing chairman Sidney Taurel, who had previously announced his retirement from the company and the board effective December 31, 2008. Taurel will be designated chairman emeritus in recognition of his contributions to the company during his tenure as chairman and CEO.

Research Triangle Park, NC (Sept. 23)—**Oriel Therapeutics**, a specialty pharmaceutical company focused on respiratory care, appointed Richard Fuller CEO, effective immediately. Fuller is a former executive at **GlaxoSmithKline**.

Lebanon, PA (Sept. 17)—**SCHOTT North America**, a producer of pharmaceutical packaging components, named Renard Jackson as the company's vice-president and general manager for its Pharmaceutical Systems business. Jackson will be based in SCHOTT's flagship North America Pharmaceutical Systems facility in Lebanon, Pennsylvania.

Basel, Switzerland (Sept. 23)—The pharmaceutical company **Vivendy Therapeutics** announced that CEO Roland Toder will step down, effective September 30, 2008. Toder cited personal reasons for his decision. The board of directors nominated Gosse B. Bruinsma to the board, and Bruinsma will also assume an executive function that will encompass the activities of the CEO.



Pharmaceutical Technology, the magazine



Featured Peer-Reviewed Article: Criticality Management of a Drug Product and its Manufacturing Process

By Filip Vanhoutte, Guy Smans, Luc Janssens, Marc Vanstockem

Criticality management combines pharmaceutical product, process, and material knowledge and risk management in one approach, which is reflected in a single document.

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