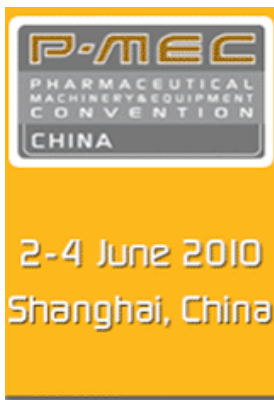


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May 6, 2010

News

FDA Advises Stakeholders about Preventing Cargo Theft

The US Food and Drug Administration sent a letter to trade associations of manufacturers, wholesalers, and pharmacies to recommend procedures for preventing and responding to the theft of regulated products. [Read More](#)

J&J Voluntarily Recalls Certain OTC Products Because of Manufacturing Problems

McNeil Consumer Healthcare, part of Johnson & Johnson, is voluntarily recalling all lots that have not yet expired of certain over-the-counter children's and infants' liquid products. [Read More](#)

US, European, Canadian, and Australian Biotechnology Markets Reach Aggregate Profitability in 2009

The biotechnology markets in the United States, Europe, Canada, and Australia reached aggregate profitability in 2009, according to Ernst & Young. [Read More](#)

Who Will Be Pharma's Top Dog in 2016?

The year 2016 will see Pfizer barely continue to cling to first place on the Top 10 pharma list, with Merck & Co. and Novartis not far behind, according to analysis from EvaluatePharma. [Read More](#)



Product Spotlight



Transport system enables track-and-trace capability
The MagneMover LITE transport system from MagneMotion (Devens, MA) uses the company's Linear Synchronous Motor (LSM) technology to move and track loads as heavy as 2 kg at speeds as high as 2 m/s. Loads are moved on individual pucks that are assigned unique identifiers upon startup. The system's software uses built-in position sensors to track each puck as it moves through the system. The software provides complete reporting for audit trails and allows users to prioritize the routing of individual pucks. Puck identifiers can be cross-referenced with radio-frequency identification or barcode information. The system positions pucks rapidly with an accuracy of ±0.5 mm.

The MagneMover LITE system is made of standard track components, and operators can customize and expand its layout according to their needs. The stainless-steel system comprises completely sealed units and is appropriate for washdown applications. The track components do not use grease or lubricants and generate few particulates, thus the system is appropriate for some cleanroom applications.

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PharmTech Poll

Tablet Manufacture
During tablet manufacture, what is the most common problem encountered by your company?
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 Poor content uniformity
 Poor formulation design
 Inadequate equipment maintenance
 Incorrect equipment operation
 Other

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Podcast: Pfizer's Maddaluna on Integrating Wyeth's Manufacturing Organization

Events

Basics of Tablet Manufacturing and Troubleshooting
May 18–19
St. Charles, MO

12th Annual C21 BioVentures
May 25–27
Nape, CA

Chemspec Europe 2010
June 9–10
Berlin, Germany

Pharmaceutical Tablet Technology
August 9–11
St. Charles, MO

CPhI Worldwide 2010
October 5–7
Paris

BIO-Europe
November 15–17
Munich, Germany

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Company Notes

The European Patent Office issued the RNAi therapeutics company **Alnylam Pharmaceuticals** (Cambridge, MA) a notice of intent to grant the company's "Manoharan II" patent series. The new patent includes 16 claims covering compositions and methods, including pharmaceutical compositions, for chemically modified small interfering RNA (siRNAs) containing phosphorothioate and 2'-O-alkyl modifications without any siRNA length restrictions. These chemical modifications are broadly used to achieve potency, stability, and selectivity of siRNAs.

Althea Technologies (San Diego, CA), a provider of services for biopharmaceutical development and manufacturing, acquired the assets and intellectual property (IP) portfolio of **Altus Pharmaceuticals** (Cambridge, MA), a developer of protein therapeutics. The IP portfolio includes Altus' cross-linked enzyme crystal and controlled-release injectable technologies. Financial terms were not disclosed.

Anacor Pharmaceuticals (Palo Alto, CA) entered a research agreement with the nonprofit organization **Medicines for Malaria Venture** (MMV, Geneva, Switzerland) to explore Anacor's boron chemistry platform for developing new therapeutics for the treatment of malaria. Under the agreement, Anacor will be responsible for leading the research effort and MMV will contribute its extensive malaria drug research expertise as well as financial support.

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The US Food and Drug Administration approved **AstraZeneca's** (London) and the pharmaceutical company **Pozen's** (Chapel Hill, NC) Vimovo (naproxen and esomeprazole magnesium) delayed-release tablets for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of developing gastric ulcers in patients at risk of developing nonsteroidal anti-inflammatory drug-associated gastric ulcers. Vimovo, codeveloped by Pozen and AstraZeneca, is a fixed-dose combination of delayed-release enteric-coated naproxen, a pain-relieving NSAID, and immediate-release esomeprazole, a proton pump inhibitor (PPI).

Biotage AB (Uppsala, Sweden), a provider of tools and technology for medicinal and analytical chemistry, agreed to acquire all outstanding shares in **MIP Technologies** (Lund, Sweden), a privately held developer of molecularly imprinted polymers and other novel polymers. Under the terms of the agreement, an upfront payment corresponding to an enterprise value for MIP Technologies will be made. In addition, further payments based on sales performance will be made until the end of 2015.

FDA issued a complete response letter to **Bristol-Myers Squibb** (Princeton, NJ) regarding its the biologics license application for belatacept in kidney transplantation. The letter requests the 36-month data from the ongoing Phase III studies to further evaluate the long-term effect of belatacept. The company said it will work with the FDA to provide the data as soon as it is available.

FDA approved the biotechnology company **Dendreon's** (Seattle) Provenge (sipuleucel-T), an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic metastatic, castrate-resistant (hormone-refractory) prostate cancer. Provenge is designed to induce an immune response against prostatic acid phosphatase, an antigen expressed in most prostate cancers. Dendreon intends to make Provenge available through approximately 50 centers,

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all of which were approved Provenge clinical trial sites, and expects to increase capacity over the next year. The increased capacity will be a result of the anticipated licensures of its expanded facilities in New Jersey, Atlanta, and Orange County, California in mid-2011.

DSM Biologics, a division of **DSM Pharmaceutical Products** (Parsippany, NJ) signed preliminary agreements with the Australian government to design, build, and operate a mammalian biopharmaceutical manufacturing facility in Brisbane. The facility, scheduled to be operational in 2010, will offer mammalian process development and current good manufacturing practices clinical and commercial manufacturing services. The Australian government will provide the funding for the facility. In other news, DSM Biologics announced the acquisition of the assets and associated business of the Rhobust technology from **Upfront Chromatography A/S** (Denmark) for pharmaceutical and other applications. Financial terms were not disclosed.

EyeGate Pharma (Waltham, MA), a provider of noninvasive ocular-drug delivery, established a research collaboration with **GlaxoSmithKline** (GSK, London) to evaluate the delivery of several GSK therapies to the anterior and posterior tissues of the eye using the EyeGate II delivery system. Specific terms of the agreement were not disclosed.

The contract manufacturing company **Goodwin Biotechnology** (Plantation, FL) and **Hyprocell** (Branford, CT), a developer of clinical cell-line development, agreed to a collaboration designed to streamline current good manufacturing practices manufacturing services.

The contract manufacturer **Norwich Pharmaceuticals** (Norwich, NY) announced the formation of **Norwich Clinical Services** to provide clinical testing capabilities that will further expand the company's third-party services. The new division will offer a complete range of clinical research capabilities, bioanalytical studies, and pharmacovigilance monitoring services.

Purdue Research Park (West Lafayette, IN) announced that its **Chao Center for Industrial Pharmacy and Contract Manufacturing** will discontinue operations in the coming months. The Chao Center is a pharmaceutical manufacturing facility that produces and distributes legacy and small-volume drugs.

Vetter (Ravensburg Germany), a provider of aseptically prefilled injection systems, and **Sentry BioPharma Services** (Indianapolis, IN), a provider of supply chain management and clinical packaging services, signed a partnership agreement. Vetter will fill early-stage, high-value biopharmaceuticals at its Chicago facility. Sentry will label, package, and ship the clinical supplies from its site in Indiana. Financial terms were not disclosed.

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

Regulatory Roundup

Pharmaceutical Technology reported on the USP Convention in last week's **ePT**. More information is now available on the **USP** website, including a list of all nine adopted resolutions. Some of the topics included grandfathering constitutionally named organizations, expanding harmonization efforts as well as collaboration efforts with US Food and Drug Administration, and exploring the development of quality standards of value to practitioners and the public.

The proposals on falsified medicines and pharmacovigilance, part of a three-part codecision package proposed by the European Commission in December 2008, were approved by the Environment, Public Health, and Food Safety Committee of the European Parliament on Apr. 27, 2010. The third part, on patient information on prescription medicines, is likely to be debated by the committee in June 2010, according to a **press release** by the European Parliament. Under the proposal approved by the committee, Internet sites that sell pharmaceuticals in European Union member states would have to obtain special authorization. These sites would be required to bear an EU logo to help the public confirm that the site is linked to an authorized pharmacy. All authorized Internet pharmacies would be linked to a central website at a member-state level and listed in an European database. Citizens also would be informed about the risks involved in buying medicinal

products on the Internet.

The European Parliament's Environment Committee also introduced measures to require mandatory safety features, such as seals or serial numbers, for certain medicines. These features would be required for prescription medicines, but the requirement could be waived (e.g., for generic medicines) following an assessment by the European Commission. The committee also wants the European Commission to assess, after four years, whether this requirement should be extended to nonprescription medicines. The measure is intended to counter the growing number of medicinal products that are "falsified in relation to their identity, history or source," according to the press release. In December 2008, the European Commission customs officials seized more than 34 million illegal pills across the EU.

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People Notes

The pharmaceutical company **Celgene** (Summit, NJ) announced its senior-management succession plan. As of June 16, 2010, CEO Sol Barer will be appointed executive chairman of the board of directors through December 31, 2010. Robert J. Hugin, president and COO, will become CEO.

Merck & Co. (Whitehouse Station, NJ) announced changes in responsibilities for three of its top leaders. Richard Clark, chairman, CEO, and president, will continue as chairman and CEO. Kenneth Frazier, president of the company's global human health worldwide sales and marketing division, was elected company president. Adam Schechter, who leads the company's pharmaceutical business in the United States, was elected to succeed Mr. Frazier as president of global human health.

The **European Medicines Agency** appointed Alexis Nolte as its head of quality of medicines sector, effective May 3, 2010. He replaces the former head of sector, John Purves, who retired after 14 years of service. EMA appointed Jean-Claude Brival as head of its product data management sector, effective May 3.

Pharmaceutical Technology, the magazine



Report from Asia

By Jane Wan

As demand for global vaccine development and production grows, all eyes are turning to Asia. [Read More](#)

Coming Soon: The May 2010 supplement provides a look into the newly created IPEC Federation and the newly ANSI-accredited IPEA excipient qualification program

Sourcing and Management



The Changing Business Models for Innovator-Drug and Generic Drug Companies

By Patricia Van Arnum

The traditional lines of demarcation between innovator-drug and generic-drug companies are blurring as each sector responds to changing industry fundamentals.

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