

## Pharmaceutical Technology Sourcing and Management

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### CPhI Exhibitors Announce Expansions

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Exhibitors announce capacity expansions, service enhancements, and new products at CPhI Worldwide, the large pharmaceutical ingredients and contract services trade show, held in Madrid last month.

The 2009 installment of CPhI Worldwide, the large pharmaceutical ingredients and contract services trade show, held in Madrid last month, showed strong attendance as exhibitors reported on new capacity expansions, service offerings, and products. In speaking with exhibitors and attendees, the general consensus was that business conditions have improved since last fall, but have not yet returned to levels post the economic downturn. Companies remain cautious about the return of the emerging pharmaceutical and biotechnology sector in wake of tightening credit and financing, although they said they have seen some improvement. As for Big Pharma, contract manufacturers said they have observed increased receptivity in outsourcing by some players although cost-consciousness remains very much a factor.

#### Show numbers

Despite some uncertainty in the market, show attendance was on a par with last year's event in Frankfurt, with 25,450 attendees in Madrid, only 300 attendees below last year's show, according to UBM International Media, the organizers of the show. The combined number of exhibitors from all events, CPhI (pharmaceutical ingredients), ISCE (contract services), P-MEC (pharmaceutical machinery and equipment), BioPh (biopharmaceutical ingredients) was 1808, an increase of 100 from last year. First-year exhibitors also increased, with 114 companies making their debut at the show.

#### Expansions

At the show or through recent announcements, several companies reported capacity expansions, service enhancements, or new products. Some highlights are outlined below.

Arch Pharmed Labs, a provider of contract small-molecule process research and development (R&D) and custom-manufacturing services, has entered into a strategic partnership with Orochem Technologies to manufacturing an active pharmaceutical ingredient (API) that is in late-stage development of a US-based innovator drug company using simulated moving bed (SMB) chromatography. Orochem manufacturers SMB equipment and stationary chromatography phases for bioanalytical, solid-phase extraction, flash, and preparative applications.

**Ash Stevens** (Detroit, MI), a contract drug-development and current good manufacturing practices (CGMP) manufacturer, is planning a \$6-million expansion project to upgrade its API manufacturing facility in Riverview, Michigan. The plan's initial phase includes an isolated new reactor bay, which will house two 100-gallon glass-lined reactors and a 50-gallon hydrogenation vessel. The new reactor bay will provide redundant capacity to a similarly designed existing bay that holds three 100-gallon reactors, while providing additional plant capacity and plant-scale hydrogenation capabilities. The company expects the initial phase to be operational in January 2010.

BASF (Ludwigshafen, Germany) debuted a new developed solubilizer, Soluplus at CPhI. The excipient forms solid solutions with poorly water-soluble drug substances and was developed specially for pharmaceuticals produced by hot-melt extrusion.

Cambridge Major Laboratories (CML, Germantown, WI) dedicated a new 125,000-ft.<sup>2</sup> large-scale API manufacturing facility in Germantown, Wisconsin, in late July. The facility is designed with six GMP suites capable of producing multiton quantities of APIs and advanced intermediates. The installed capacity is 70 m<sup>3</sup> with an expansion capability for an additional 120 m<sup>3</sup>. The new facility follows recent multimillion dollar investments at the company's development facilities in Europe, which includes new R&D and analytical laboratories and additional pilot-plant capacity. Those investments will add more than 40% to CML-Europe's capacity and enable the facility to produce up to hundreds of kilograms and APIs and intermediates

Capsugel (Strasbourg, France), a provider of dosage-form solutions, has received authorization from the Agence française de sécurité sanitaire des produits de santé (Afssaps) to produce clinical batches at its product development center in Strasbourg, France. The company says this allow it to better serve pharmaceutical and biotechnology companies that require small-scale batches of encapsulated compounds for use in clinical trials. The company also has a product development center in Boston.

Hovione (Lourdes, Portugal) reported that its API plant in Loures, Portugal, successfully passed a preapproval inspection by the US Food and Drug Administration. The inspection covered five abbreviated new drug applications and one new drug application. The Loures plant produces both generic products as well as APIs and bulk formulated products for clinical-trial materials and commercial scale. Early this year, Hovione opened a new API manufacturing site in Cork, Ireland after acquiring the facility from Pfizer (New York). The company also reported in September that its TwinCaps inhaler licensees, Daiichi Sankyo (Tokyo) and Biota Holdings (Victoria, Australia), have both announced successful Phase III trials for CS-8958, a neuraminidase inhibitor for treating influenza. TwinCaps is a dry-powder inhaler. Hovione is planning for large-scale manufacturing of the TwinCaps devices. Daiichi Sanyko is intending to submit its market authorization application for Japan by March 2010. Biota is advancing its clinical development program to support registration in the US and UK.

ISP Pharmaceuticals (Wayne, NJ) launched a drug-solubility initiative in support of pharmaceutical companies that work with APIs that exhibit poor solubility. The multifaceted initiative will include R&D aimed at advancing the state of solubilization technology, the development and application of a broad portfolio of ingredients for use in solubilization as well as formulation services designed to enhance solubility using different processing approaches to a broad range of actives. ISP says it will expand its facilities and personnel dedicated to solubilization efforts, establish alliances with companies involved in developing technologies for solubilization, and outreach to the industry. ISP has a contract-services business that focuses on solid-dispersion technology and offers both spray drying and hot-melt extrusion to develop solid forms.

As part of the initiative, ISP is expanding its R&D facilities in Hyderabad, India, to create a Solubility Center of Excellence, which will serve as a focus point for R&D. Activities at the center will center on the use of polymers, disintegrants, and cyclodextrin chemistry and tools to improve drug solubility and bioavailability of oral and parenteral drugs. The company also has R&D and technical support facilities in Colombia, Maryland; Istanbul, Turkey; Sao Paulo, Brazil, Columbus, Ohio; and Wayne, New Jersey. ISP is also forming an alliance with Coperion (Stuttgart, Germany) with the goal of advancing hot-melt extrusion for the pharmaceutical market. Coperion provides equipment and testing and expertise in the physical systems used for extrusion. ISP will bring its expertise in ingredient technology such as polymers and disintegrants. ISP will also hold a series of drug solubility and bioavailability in Europe and the US in first half of 2010, called Solubility Twenty Ten. The day-long programs will be open to

pharmaceutical scientists and students and will be held in Cork, Ireland; Duesseldorf, Germany; Basel, Switzerland; and Wayne, New Jersey.

Phyton Biotech (San Antonio, TX) has purchased the assets of Natural Pharmaceuticals, a manufacturer of APIs for oncology drugs. Phyton will acquire intellectual property and patents for the production of taxane-based APIs, a manufacturing facility in Delta, British Columbia, Canada, and an API manufacturing subsidiary in Shanghai, China, Syntax Biotechnology.

Piramal Healthcare (Mumbai) announced a further investment in its high-potency substances production facility in Grangemouth, Scotland. The two-year, £1 million (\$1.67-million) investment will prepare and validate one of its six production suites for commercial-scale production of antibody drug conjugates. The latest expansion follows a \$270,000 investment in 2008 to commission a sixth CGMP suite and a \$500,000 investment in 2006, which added clinical-trial-material manufacturing.

Piramal also reported that Pfizer (New York) has renewed key supply contracts at Piramal's production facility in Morpeth, United Kingdom. Piramal had acquired the facility from Pfizer in 2006. Under the supply-contract renewal, Morpeth will continue to produce APIs, bulk formulated products, and finished dosages for Pfizer.

In other news, Piramal's clinical-trial-services business has been granted a manufacturing license for producing clinical-trial materials by the UK Medicines and Healthcare Products Regulatory Agency. In September, Piramal relocated its UK biocatalysis division to custom-laboratory facilities in Wilton, Teesside, United Kingdom, to allow for further flexibility for expansion. Piramal also commissioned a new formulation and development and clinical-trial-materials supply center in Ahmedabad, India. The center has a footprint of 50,000 ft<sup>2</sup>. Thirty-four formulators and 48 analytical chemists are based at the center with plans to increase to a total of 180 over two phases.

Piramal also recently completed a near \$40-million merger with Minrad International, which provides the company with additional inhalation anesthetics manufacturing capacity and access to the US market. The company says the move puts it at third in market share in the global inhalation anesthetics sector. The move was complemented by a recent acquisition of the US inhalation anesthetics gas distribution business, RxElite Holdings.

SAFC (St. Louis, MO) reported that its Pharmorphix solid-state research laboratories in Cambridge, UK, have installed a new single crystal X-ray diffraction system. The company says the installation of the Oxford Diffraction SuperNova system, which is capable of performing single crystal X-ray analyses on small microcrystalline fragments with dimensions as low as 30 to 50 microns, is the first industrial installation of the instrumentation in the world.

SAFC also reported that it has completed the \$12-million expansion of its Carlsbad, California, viral-product manufacturing facility. The expansion added 8000 ft<sup>2</sup> of manufacturing space to the existing 44,000 ft<sup>2</sup>. The addition enables both 100-L batch production in stirred-tank bioreactors and 1000-L batch manufacturing in disposable bioreactors. The facility is Biosafety Level 2-compliant, thereby allows manipulation of human pathogens.

Also, SAFC's parent company, Sigma Aldrich (St. Louis, MO) and Sangamo BioSciences (Richmond, CA) expanded their existing license agreement to include the exclusive rights to develop and distribute zinc finger DNA binding protein (ZFP)-modified cell lines for commercial production of protein pharmaceuticals. Additionally, Sigma-Aldrich licensed rights to certain ZFP-engineered transgenic animals for commercial applications.