

Informex Report: Contract Manufacturers Expand

By Patricia Van Arnum

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Almac Sciences (Craigavon, Northern Ireland) has expanded its GMP (good manufacturing practices) and non-GMP radiolabeling services with plans to double its capacity over the next several months, according to a company press release. The company also launched its solid-state chemistry capabilities for the North American market. Almac Sciences is the contract manufacturing arm of the Almac Group. The company is investing \$100 million in new North American headquarters, which are scheduled to be completed by 2010.

Ash Stevens (Detroit), a contract manufacturer, added parallel synthesis and calorimetry instrumentation at its Riverview, Michigan, active pharmaceutical ingredient (API) development and manufacturing site. The new equipment gives the company the ability to assess heats of reaction for the safe scale-up of processes. The news system allows up to four experiments to be conducted simultaneously using a broad range of reaction conditions. The new safety enhancements also include a thermal screening unit to evaluate the onset of thermal decomposition of reaction components.

Ash Stevens will also bring on line a new three-reactor processing suite designed for hydrogenation and additional manufacturing capacity. It is scheduled to come on line in the third quarter of 2009. The new suite will house a 50-gallon glass-lined steel hydrogenation reaction vessel and a pair of 100-gallon vessels.

The company also reports that it has completed the program requirements for and is now certified as compliant with the Synthetic Organic Chemical Manufacturers Association's "ChemStewards" program. The program incorporates and evaluates continuous performance improvement in environmental, health, safety, and security measures.

CiVentiChem (Carey, NC) expanded its research and development laboratory in Carey, North Carolina with the launch of CiVentiAnalytical, an analytical laboratory operating under good laboratory practices and current good manufacturing practices. In addition to the analytical laboratory, the company is adding a new active pharmaceutical ingredient and intermediates pilot plant in Hyderabad, India, to manufacture large-volume products.

DSM Pharmaceutical Products (Parsippany, NJ) joined the Green Chemistry Institute Pharmaceutical Roundtable of the American Chemical Society (ACS) as an associate member. The Pharmaceutical Roundtable is a partnership between the ACS Green Chemistry Institute and pharmaceutical companies. It was formed in 2005 to promote sustainable manufacturing of active pharmaceutical ingredients.

Dishman Group (Ahmedabad, India), a contract manufacturer, announced capital investments of more than \$33 million: \$20 million in the current financial year and \$13 million planned for fiscal year 2009, which begins in April. Investments include the addition of a high-potency facility near Dishman's headquarters in the district of Ahmedabad in India and a new plant in Shanghai.

The 4300-m² facility in India caters to cytotoxic and non-cytotoxic highly active substances. The plant in Bavla, India, will be managed and operated by the Dishman subsidiary, Switzerland-based Carbogen Amcis, and is scheduled to be operational in mid-2009.

The facility in Shanghai will include a production plant, a warehouse, dedicated on-site utilities, and administrative/quality control offices. Construction of the facility is underway and is expected to be fully staffed and operational by the second quarter of 2009.

Excelsyn (Holywell, England), a contract manufacturer of active pharmaceutical ingredients (APIs) and intermediates, has completed the initial phase of a three-year expansion and upgrade program at its Holywell, England, facilities. The full investment program includes a new API finishing suite, reactor train alignment, and increased product isolation capacity. The company also appointed Peter Chinigo, formerly with DSM's emerging pharma division, to lead business development in the United States, and the consultant Jim Bruno as an US agent.

Piramal Pharma Solutions (Mumbai), the contract development and manufacturing division of Piramal Healthcare, India's fourth largest pharmaceutical company, is on schedule to commission a formulation-development and clinical trial materials (CTM) supply center in Ahmedabad, India. The center will have GMP (good manufacturing practices) supply capabilities beginning in March 2009. The center has a total footprint of 50,000-ft², of which only half will be built on in Phase I of the project. The center will initially be staffed with 34 formulators and 48 analytical chemists with plans to increase this staffing to a total of 180 over two phases.

Reaxa (Manchester, England), a pharmaceutical catalyst technology provider, recently received a third round of financing from international investors to enable more focus on bulk-scale operations. The company's bulk "QuadraPure" and "QuadraSil" scavengers are available in hundreds of kilograms, and production of metric ton lots are scheduled to be on line later this year. These products are used for metal extraction and purification technology for pharmaceutical manufacturing. Reaxa is also planning to establish low-cost production of its leading products with partners in India, according to a company press release.

SAFC Pharma (St. Louis, MO), a business segment of SAFC, which is part of Sigma-Aldrich (St. Louis), started operations at its 7000-ft² laboratory complex in Carlsbad, California, adjacent to the company's existing viral-substance production facility. The new complex includes a dedicated polymerase-chain-reaction (PCR) facility and a tissue-culture laboratory and stability suite supported by microbiology and regular testing laboratories. The new PCR facility consists of separate suites with uni-directional personnel flow for sample processing, reaction assembly, and PCR amplification. In addition to PCR assays, the unit is capable of performing cell-based, molecular, and immunological assays as well as analytical assays using high-performance liquid chromatography.

The commissioning of the new laboratories follows SAFC's 2008 announcement of a \$12-million expansion at the site to construct two fully segregated manufacturing suites, which are scheduled to be operational by the end of 2009. These suites will add 8000-ft² of manufacturing space to enable 100-L batch production in stirred tank bioreactors and 500–1000-L batch manufacturing in disposable reactors. The expansion adds commercial manufacturing capacity within the current 44,000-ft² site and is planned to be Biosafety Level 2 compliant, which allows for manipulation of human pathogens.

Wuxi AppTec (Shanghai), a contract research and manufacturing organization, began validation at its new 350,000-ft² commercial manufacturing plant, located at the company's research and commercial manufacturing site in the Jinshan area of Shanghai. The addition of the new plant quadruples the manufacturing capacity at the Jinshan site, which also includes a 220,000-ft² CGMP (current good manufacturing practices) process-development and manufacturing plant. The plant features 18 reactors with capacities ranging from 8000 to 20,000 L. It also has cryogenic capability as low as 78 degrees Celsius with 10,000-L scale. Annual capacity of the plant is projected at 50 to 100 metric tons. Other plant features include two isolated API finishing areas, each classified at 100,000; high-temperature capability; GMP kilo laboratories (classified at 100,000 for handling production of active pharmaceutical ingredients), and high-pressure reaction capability.

Wuxi AppTech introduced a new global procurement services (GPS), which will assist customers in navigating the challenges of purchasing low-cost commercial reagents from qualified vendors in China. The GPS services also include quality control testing, certificates of analysis, repacking, relabeling, and export services.

The company also launched rapid microbial testing services through use of the "BacT/Alert" 3-D microbial detection system. The system detects microbial growth based on the production of carbon dioxide by microorganisms rather than visual turbidity as in conventional methods, so there is no need for extended incubation to measure sample matrix interference.