

## Specialty Chemical News

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### New Capabilities for Ash Stevens

Ash Stevens, a Detroit-based cGMP contract manufacturer of high potency APIs, revealed at CPhI Worldwide in Milan that it has added high containment capacity and a low-temperature pilot plant to the capabilities of its development and manufacturing site in Riverview, Michigan.

The new additions include a 0.3 m<sup>3</sup> Rosenmund filter-dryer with glove-box technology to facilitate the handling of air-sensitive materials and safe handling of Category 3 and 4 potent materials at plant scale. A smaller, 0.03 m<sup>3</sup> filter-dryer is to be used with the cryogenic pilot plant system, which can operate at down to -80 C and up to +200 C.

The new systems are modeled on the company's process laboratories, with pocket filters and vessels using the same geometries as those in the plant. This will facilitate the rapid scale-up of processes to support product requirements throughout clinical development and post-launch. The total investment was over 1 million, according to president and CEO Dr Stephen Munk.

Ash Stevens was originally founded in 1962 to supply chemical research services to the US federal government, which supplied 90% of its work in the 1960s and 1970s. Now, Munk said, because of a mixture of falling government demand and increasing outside work, this proportion is down to 15%, though the government is still the largest single customer.

In December 2006, Ash Stevens won two multi-year contracts from the National Cancer Institute, with which it has worked for over 30 years. One of E7.4 million was on 'Manufacture of Bulk Chemicals & Bulk Pharmaceutical ingredients', while another of E1.25 million covers 'Synthesis of New GMP Small Molecules'. Turnover has been growing by S- 10%/year for the last six years and there are now over 50 employees and 11 FDA-approved drugs in the portfolio, according to Munk. The non-governmental customer base is now spread between Big Pharma and biotechs.

Of late, Ash Stevens has had a very high success rate in its projects. "Since January 2003, the FDA has approved 85 NME-based drugs, of which we were involved in three as the API manufacturer.

Our contribution in terms of the total volume is obviously insignificant but to have been involved in 4% of the world's approved drugs may be unique," Munk said.

The three approvals – Millennium Pharmaceuticals' oncology drug Velcade, Pharmian's orphan drug Vidaxa for myelodysplastic syndrome (on which Ash

Stevens worked in its early stages at the NCI) and Genzyme's Clolar for the treatment of relapsed or refractory acute lymphoblastic leukaemia in patients from the ages of one 21 - all came within the space of 18 months.

"Unlike many chemicals companies who come at it from a chemistry perspective, we came from Big Pharma and tend to see things more from a pharma perspective," said Munk, who was himself a medicinal chemist at Allergan.

"We are not at the cheap end of the market and all our products will eventually go generic. We want to be in the part of the market where being in the same time zone is valued and a good regulatory record and nimbleness are key."

Traditionally Ash Stevens had a low profile but it recognizes the need to raise this. For this reason, it took part at Informex for the first time in 2007.

"With our new plant and plans for continued investment, we are looking for growth and we need people to know who we are," Munk said.