

Pharma not concerned enough about environment when outsourcing; CEO

By Nick Taylor

<http://www.outsourcing-pharma.com/Contract-Manufacturing/Pharma-not-concerned-enough-about-environment-when-outsourcing-CEO>

Environmental and safety matters concern pharma “less than they should” when outsourcing to Asia, according to the CEO of Ash Stevens who believes there are long term benefits of using US-based companies.

Speaking to Outsourcing-Pharma at CPhI 2009 Stephen Munk, CEO and president of Ash Stevens, said he expects standards to improve in Asia in coming years, noting that the US used to lack tight regulations, but has concerns about incidents such as Lake Tai, China.

In 2007 the lake, which provides water for 30m people, suffered from a significant algal bloom, believed to be caused by pollution. This was a major environmental event, which China is working to clean up, but Munk believes cost takes precedent over the environment at some companies.

However, James Hamby, vice president, business development at Ash, added that, although the initial costs are lower, outsourcing active pharmaceutical ingredient (API) production to Asia can prove costly long term.

Hamby believes Ash has the technical competence, attention to detail, vigilance and understanding of regulatory compliance to ensure that a client’s chemistry, manufacturing and controls (CMC) are done properly.

This all increases costs, with Munk describing Ash as “not cheap but cost-effective”. However, Munk acknowledged that convincing small biotechs, which often have little knowledge of regulations or CMC, is a hard task and requires Ash to educate the client.

Consequently Asia took some business from Ash in the middle of the decade but Hamby believes biotechs are returning to the US. Hamby explained that biotechs’ tight budgets mean they “cannot afford to fail” and this has made them cautious about outsourcing CMC to Asia.

Furthermore, outsourcing CMC requires a lot of interaction between the client and contract manufacturing organisation (CMO), resulting in significant travel to and from Asia, according to Hamby.

He added that a “lot of people are getting tired of hopping on planes” and spending time away from their families. Cultural differences between the US and Asia also play a role in companies choosing to outsource to local CMOs.

Growth at Ash

Despite commenting that small biotechs are increasingly considering the US as an outsourcing location, Munk and Hamby said business from these companies is currently flat, which they attribute to the current lack of funding.

However, Ash’s clients are a mixture of small biotechs and larger pharma companies and this has ensured that the business has continued to grow, according to Munk. He added that 2008 was a record year and sales were up in 2009. Ash’s fiscal year closes in September.

This growth has helped underpin a period of expansion at Ash. The company borrowed money to began the expansion in 2000 when \$13.5m (€9m) was invested over three years and since

then it has used its own funds for additional improvements. Further work is planned in coming years.