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**ASH STEVENS PRESENTS ADVANTAGES OF BARRIER ISOLATION  
TECHNOLOGY FOR HANDLING HIGHLY POTENT ACTIVE  
PHARMACEUTICAL INGREDIENTS AT PHARMA ED CONFERENCE**

**Philadelphia—May 29, 2008**– Rebecca Ahn, an industry expert with Ash Stevens Inc. (ASI), today will present the advantages of barrier isolation technology over cleanroom suites in the safe and efficient manufacture of Busulfex<sup>®</sup> at PharmaEd’s “Containment of Potent Compounds Conference” in Philadelphia. ASI is a full-service cGMP contractor that provides low-volume, high-value API (active pharmaceutical ingredients) to the pharmaceutical industry.

Busulfex<sup>®</sup>, the intravenous version of the drug Busulfan, is a highly potent drug, used as a pre-treatment regimen for bone marrow transplant patients with chronic myelogenous leukemia. The challenges with handling Busulfex<sup>®</sup> are two-fold. Human contact can easily introduce contaminants during processing. Moreover, without proper safeguards, Busulfex<sup>®</sup> can impair the immune system if accidentally inhaled. ASI is currently the only FDA approved supplier of the Busulfex<sup>®</sup> API.

Barrier isolation technology offers the best solution since the work area consists of a self-contained glove box to protect the worker from potentially dangerous compounds and to ensure that the compounds are protected from the environment. The isolator permits the entire range of tasks necessary to move the product from synthesis through filtration, washing, drying, sampling, packaging and product transfer.

“The glove box provides an enclosed setting that protects the operator from the product as much as it protects the product from the operator and the rest of the environment,” said Ahn, an ASI Senior Engineer.

A cleanroom environment does not afford the operator or the compound the same degree of protection. There is also no assurance that a person entering the cleanroom is wearing the necessary protective equipment, i.e. a Level C isolator suit. Of particular concern in large scale manufacturing processes, productivity in the isolator suits may be hindered due to limited mobility.

“Handling these compounds involves a great deal of manual dexterity. This is much harder to do and takes a lot longer if one is covered from head to toe – including fingertips – in an isolator suit,” said Ahn.

In addition to discussing the differences between barrier isolation and cleanroom technology, Ahn’s presentation will focus on the following:

- Design of a chemical process and options for the manufacture of potent compounds using barrier isolation technology
- Isolator design and cleaning requirements
- Managing FDA regulatory requirements

#### **About Rebecca Ahn**

Rebecca Ahn has been a Manager of Engineering and Operations with Ash Stevens Inc. for seven years. She has experience in process engineering, scale-up and manufacturing, both as a scientist and as a manager. She directs capital spending projects for the company’s manufacturing operation, including the installation of a low-temperature reactor suite and filter-dryer equipment with barrier isolation. She also manages production of ASI’s FDA-approved drugs. She received her Bachelor of Science degree in Chemical Engineering from the Georgia Institute of Technology.

#### **About Ash Stevens Inc.**

Founded in 1962 and headquartered in Detroit, Ash Stevens Inc., is a one of the premier chemical manufacturing organizations in the country and a leading provider of low-volume, complex Active Pharmaceutical Ingredients to the federal government and to the commercial pharmaceutical industry. Moreover, the company is well known for its expertise in the area of high-potency compounds. Today, Ash Stevens has more than 50 employees and holds a variety of patents covering topics from medicinal chemistry to process chemistry. The company maintains a state-of-the art manufacturing plant in Riverview, Mich., including reaction vessels with capacities up to 500 gallons. For more information, visit the company's website at [www.ashstevens.com](http://www.ashstevens.com).

### **About PharmaEd**

Located in the United Kingdom, PharmaEd is a specialist medical education company, focusing on the information needs of clinical development and pharmaceutical strategic marketing staff. PharmaEd's conference – *Containment of Potent Compounds: Implementing Risked-Based Approaches and Ensure Safety through Strategic Containment Operations and Processes* – will take place in Philadelphia at the Radisson-Plaza Warwick Hotel and will bring together experts in the field of potent compound containment. For more information, visit the organization's website at [www.pharmaedresources.com](http://www.pharmaedresources.com).

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