

ASI ChemStewards® Case Study


Ash Stevens™
2010

Company Profile

Ash Stevens, Inc. (ASI) is an established full-service contract pharmaceutical manufacturer (CMO) servicing the research needs of the US federal government and commercial clients in the life sciences industry, developing innovator small-molecule therapeutics.

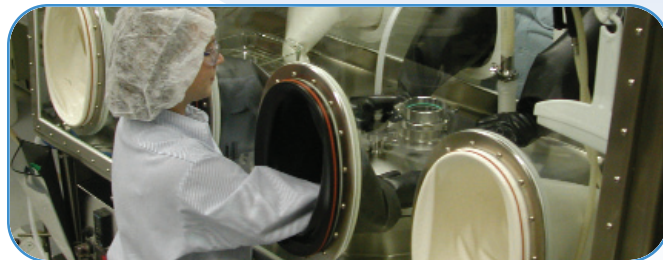
ASI was founded in 1962 to provide contract research services to the US government, mainly the National Institutes of Health (NIH) and the National Cancer Institute (NCI). Over the years, ASI worked on many of the drugs developed through these government agencies. Today, ASI's government contract work constitutes only about 10% of its overall business and is conducted at the company's 8,500 sq. ft. research facility in Detroit, Michigan, which also serves as Ash Stevens' headquarters.

ASI's primary business (90%) is providing comprehensive contract drug development and manufacturing services to commercial clients in the life sciences sector ranging from virtual Biotechs to Large Pharma. The company provides drug development and cGMP (current good manufacturing practices) services spanning early-stage development through commercial API (active pharmaceutical ingredient) manufacturing. ASI supports all facets of chemistry and manufacturing controls related to the development of small-molecule APIs. Services offered by ASI include:

- Process research, development, optimization, and scale-up
- cGMP manufacture of clinical trial API
- Commercial API manufacturing
- Development and cGMP manufacture of highly potent APIs using Glovebox technology
- Comprehensive analytical and regulatory services to support early-stage development through registration and commercial manufacturing.

ASI serves the following markets:

- US government - Contract research service provider of medicinal chemistry, non-GMP scale-up, process development, and the manufacture of drug substance for toxicology studies and clinical trials.
- Life science companies – Contract provider of innovator small-molecule drug development and cGMP manufacturing services for virtual Biotechs through Large Pharma.



EHS&S Background

Throughout its 48+ year history, ASI has always maintained a strong focus on Environmental, Health, Safety and Security (EHS&S). As a long time developer and manufacturer of high potency APIs, ASI very early on in the company's tenure recognized the need for a rigorous approach to environmental, health and safety practices. Over the years, ASI has maintained an excellent EHS&S track record, as well as recognized the need for continuous improvement as a critical component to an effective EHS&S program.

Soon after joining SOCMA, it became evident that the ChemStewards® program would be a valuable enhancement to the company's existing EHS&S program. The ChemStewards program is unique in the industry and specifically designed to meet the EHS&S needs of small batch manufactures like Ash Stevens. With SOCMA's help, ASI was able to implement the ChemStewards program very quickly and became one of the earlier contract manufacturers to be certified in the program.

"The SOCMA staff was very responsive to our needs, providing training and seminars on the audit process which greatly assisted our work" said Sheryl Goddard, EHS Manager for Ash Stevens, Inc.

ChemStewards brought a number of important benefits to the existing Ash Stevens EHS&S program. Chief among these benefits was the formalization of a continuous EHS&S improvement program reviewed by outside auditors that help to ensure regulatory compliance and the continuous improvement of best practices. Other benefits of the ChemStewards program include the conveyance to Ash Stevens clients that the company is seriously committed to keeping its employees, the community, the environment, and client's investments safe. Participation in ChemStewards also serves to raise the safety awareness of ASI's employees, which is reinforced by regular safety discussions in meetings and company addresses by Ash Stevens CEO and President, Dr. Stephen A. Munk. Dr. Munk's addresses resonate with the staff, and every employee understands that safety is of the upmost importance.

[Continued on following page...]

ASI ChemStewards® Case Study



Ash Stevens™
2010

[Continued from previous page]

Pollution Prevention

ASI has an extensive waste management plan developed for the collection of all process waste materials. The plan calls for the assessment of waste stream content as chemical processes are developed. Environmental risk is managed through the evaluation of each waste stream generated to determine the most appropriate disposal or recycling method. Engineering controls are implemented as required to capture potential emissions. ASI employs QbD (Quality by Design) to maximize the volume efficiencies and product concentrations for every process, which in turn minimizes the amount of waste generated on site. The company is in compliance with all local and federal environmental regulations and guidelines. In 2009, ASI was awarded two Silver Awards by SOCMA for performance improvement in the areas of Employee Training and Engagement and EHS&S Planning and Operations.

Community Outreach

ASI has a very good relationship and a positive image within the local community. State and local public officials, including members of the city council and governor's office, attended a recent groundbreaking ceremony at ASI to celebrate the company's expansion of its facility in Riverview. In addition, a fair number of ASI employees live and work in the surrounding communities.

ASI maintains an excellent relationship with its community emergency responders. Material Safety Data Sheets (MSDS) for materials on site are regularly shared with the local fire department. At least annually, the site's emergency procedures are rigorously reviewed and a formal safety inspection is conducted by the local fire department.

Cost Benefits

The ChemStewards program is an attractive attribute to retaining and attracting new business at Ash Stevens. ASI's clients are very cognizant of the company's commitment to EHS&S excellence and the fact that the company is ChemStewards certified. As Ash Stevens' clients walk through the company's lobby, the ChemStewards program certification and awards on display often attracts attention and positive remarks. ASI's commitment to EHS&S and ChemStewards certification provides clients with an additional level of confidence – that their investments are safe with Ash Stevens. The biggest cost benefit of the ChemStewards program, however, is ensuring the safety of all stakeholders: employees, clients and the community at large.

Other Benefits

The ultimate benefit of the ChemStewards program is having a state-of-the-art EHS&S program in place that mandates continuous improvement to ensure that ASI is doing everything in its power to maintain a safe, environmentally responsible, and secure facility. As a SOCMA member and ChemStewards participant, ASI's clients and peers in the industry recognize that the company's commitment to EHS&S extends beyond compliance. Ash Stevens is committed to the continuous review, training, and improvement of its EHS&S program to ensure current best practices are the standard of operation. Regular client feedback from small and large life science companies have been very positive. Additionally, as a member of SOCMA, ASI has been able to leverage a network of associates to share EHS&S best practices and to have input into important legislative issues that impact the industry.

Contact Information

Sheryl Goddard
Ash Stevens, Inc.
18655 Krause Street
Riverview, MI 48193
734.282.3370 x1107
sgoddard@ashstevens.com
www.ashstevens.com

SOCMA Contact Society of Chemical Manufacturers and Affiliates

SOCMA ChemStewards
1850 M Street, NW, Suite 700
Washington, DC 20036
202.721.4162
chemstewards@socma.com
www.socma.com/chemstewards