Siemens

Siemens Meets Major GHS Compliance Requirement to Ensure Access to US/EU Markets, Gain Competitive Edge

Siemens is one of the world's top suppliers of systems for power generation and transmission as well as medical diagnosis technologies. As a Global Fortune 500 company, Siemens and its subsidiaries employ nearly 345,000 people and sell products in more than 200 countries.[1]

"To achieve excellence, to capture leading positions in the markets of tomorrow, to develop innovative technologies that help ensure the future viability of modern civilization – this has always been our vision and our challenge," says the "Sustainability at Siemens" webpage.[2]

Every day, the Laboratory and Point of Care Diagnostics business areas of Siemens Healthcare strive to achieve important goals. Among these goals, the company works to meet all regulations and standards required for Siemens products to access target markets worldwide. Consistent also with the company's vision, Siemens works to extend its position as an industry leader in environmental and social sustainability by producing products and designing processes that are safe and eco-friendly.

Implementing GHS in the EU and US is Major Regulatory Challenge

With the confluence of two major regulatory changes becoming effective on the same date, Siemens faced a major business challenge. The U.S. OSHA adoption of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) framework as its standard for hazard communication combined with the enforcement of the EU GHS regulation on mixtures meant Siemens had to reassess and reclassify over thirty-five hundred products by the June 1, 2015 regulatory deadline.

"GHS was a core compliance requirement and a high-visibility project that was critical to our operation," said Kevin Johnson, Director of Global Environmental, Health & Safety (EHS) Systems at Siemens. "Non-compliance would have created an extreme business disruption since we would have been unable to sell our products in several markets."

Siemens' GHS implementation project formally began in 2014 and leveraged sofware, content and expertise from Sphera to help them facilitate the transition. Sphera had been a trusted partner to Siemens for nearly a decade. In 2008, while merging three acquired companies into one, executives benchmarked best practices in terms of EHS systems. As it related to authoring and automation of safety data sheets, Sphera Intelligent Authoring™ was chosen to support Siemens' global operations.

Recognizing the complexity of this task, a major business-wide team effort was established for the GHS Project, and the project was managed by Frank (Chuck) Fives, Vice President, Manufacturing, and Maria (Elisa) Bowling, Project Management Specialist. It took the partnership of over 17 cross-functional teams to execute the GHS implementations from end-to-end. Important operational partners included: Commodity Management, Communications, Demand Planning, Document Control, Engineering, Environmental Health & Safety, Information Technology, Labeling, Logistics, Manufacturing, Procurement, Project Management, Quality, Regulatory Affairs, and Technical Operations. Team members worked across 10 manufacturing sites and with outside manufacturing partners

---

CHALLENGE

- Meet U.S. OSHA and EU GHS compliance deadlines and maintain access to key markets
- Train product stewardship managers about complex GHS requirements
- Identify substances of concern in their products to create safer, more sustainable products and respond to customer inquiries

SOLUTION

Product Stewardship
- SDS Authoring
- Managed Regulatory Content
- Product Compliance Analysis

RESULTS

- Reassessed 3,500 reagents according to new GHS classifications and updated 70,000 Safety Data Sheets prior to 2015 GHS deadline
- Created GHS-compliant SDSs in 20 unique language formats
- Avoided product interruption to customers in key GHS-affected markets
- Effectively analyzed product portfolio to identify substances of concern and respond effectively to customer requests

Siemens Ensures GHS Compliance, Gains Competitive Edge

to ensure the regulatory deadlines were met, changing over 14,500 labeling files and coordinating the changes into finished goods without disruption to customers.

As part of this team, Maureen Gillis, Senior Manager, EHS, and her team took on the complex task of analyzing the chemical composition of their product portfolio to determine their new classifications under both the U.S. and EU implementations of the model UN regulation. This was no easy undertaking as thousands of individual reagents required reassessment, according to Gillis. "We had to implement the classification across all of our products. We met the challenge by leveraging Sphera data as our department evaluated the chemical make-up of each product, including a great deal of toxicity data."

"Fortunately, we were able to use the information to support the classification process," she explained. The scope and complexity of this project also prompted Siemens to take advantage of the GHS training opportunities and task force meetings managed by Sphera, giving the EHS department a better understanding of the intricacies of each of the GHS implementations and some of the best practices being adopted by industry peers.

Making a Critical Impact to Save Lives

Transitioning labels and Safety Data Sheets (SDSs) to the GHS standard was challenging from the start and without the Sphera delivered software; this would have been even more difficult. The Sphera updates were delivered early in the process so Siemens had sufficient time to perform the required analysis, preview the results and make further modifications as necessary for each SDS. As a result, Siemens was able to deliver GHS-compliant labeling and SDSs in 20 language formats to meet its customer requirements.

"EHS was able to communicate the new GHS classifications to the GHS Project Team well in advance of the deadline. "Our products are regulated as medical devices. As such, labeling changes are subject to regulatory approval and oversight. The process was made simpler because we were able to leverage the classification and toxicity data that had been generated by Intelligent Authoring." Gillis explained. The GHS Compliance Project ensured that appropriate changes were made to our product finished goods labeling and implemented in a highly coordinated and cost-effective manner.

Overall, the GHS Project was considered a major success because Siemens was able to avoid interruptions to product delivery schedules. "Our core products help save people's lives", said Johnson. "And they're critical to the functionality of some countries' healthcare systems. You remove our products

from the marketplace, and that puts a significant dent in the ability of healthcare providers to run needed diagnostic tests.

Going Beyond Compliance to Drive Growth

Today, executives have expanded their vision for compliance far beyond its legal requirements. "We want to be proactive, by developing our own chemicals-of-concern list. This is a broad approach towards creating products that are safer and more environmentally responsible than some of our older versions, as well as those that are available from our competitors," Johnson said.

"To find out where the chemicals of concern are being used, we are leveraging the search functionality of Sphera Intelligent Authoring to scan our products for their presence," continued Johnson. "If you're managing 3,500 products, you don't want to be hunting and pecking through a spreadsheet, or batch documents to figure out where those substances are present. Intelligent Authoring is an important part of the equation because it helps us find where substances are, and at what levels they are present."

Siemens can now more easily address and respond to customer or prospective customer queries. Gillis' group periodically receives inquiries from Siemens' Proposal Services Group where potential or existing clients will ask specific questions about the substances contained in Siemens products or if they have certain hazards. Her team is then able to quickly glean that information using the software.

> "We had to implement the classification across all of our 3,500 reagents. Sphera met the challenge by enabling our Siemens team members to evaluate the chemical make-up of each product, including a great deal of toxicity data. Fortunately, we were able to use the information that was available in SPHERA to simplify the classification process."
>
> Maureen Gillis
> Senior Manager, EHS,
> Siemens Healthcare

Earning Visibility with Executive Leadership

The GHS Project and its cross-functional team membership were recognized by Siemens executive management for a key business-wide initiative. Johnson reported, "The project had so many moving parts and a short implementation period, yet it was completed with very few issues. Our sales, manufacturing, and logistics teams appreciated how well this critical project was executed, managed and implemented."

1   http://www.siemens.com/about/en/
2   http://www.siemens.com/about/sustainability/en/sustainability-at-siemens/our-understanding.htm