Manufacturers of high-tech electronics who market their products globally face looming deadlines in a race against the calendar to ensure their manufacturing processes and products are free of hazardous materials that might have a negative impact on end users and/or the environment. AB SCIEX, a manufacturer of scientific instrumentation, software, and services for the life sciences, clinical research and industrial markets, is taking a proactive approach and aggressively working to beat those deadlines.

Meeting environmental compliance throughout the product development process is especially important for companies like AB SCIEX who must meet the European Union’s (EU) Restriction of the use of certain Hazardous Substances (RoHS) for electrical and electronic equipment directive, the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation and other similar directives emerging in Asia and North America.

George Valaitis, RoHS program manager at AB SCIEX, took a highly personal interest in the new restrictions. In fact, his concern was so strong that Valaitis left his job as a mechanical engineer manager to become the RoHS program manager in order to drive the implementation of AB SCIEX’s entire environmental compliance program.

“The major issue I see with companies that wait too long is they have to pull all of their people out of R&D or engineering and push them into environmental compliance for six months,” Valaitis says. “Then they stop developing new products and the business suffers. I didn’t want to see AB SCIEX in that kind of position.”

Proactively meeting regulatory challenges
Rather than view RoHS as a looming regulatory nightmare, Valaitis saw tremendous potential in meeting this new challenge head on. In 2016 all of AB SCIEX’s medical device products will be subject to RoHS regulatory restrictions and in 2017, most of its other products will follow. However, Valaitis has proactively structured a material compliance program to ensure that the company’s products would remain globally marketable without any hazardous materials quagmire.

Valaitis points out that while RoHS remains targeted at only six chemical substances classifications, REACH covers a broader spectrum of substances and continuously adds new substances. As of June 20, 2013, there were 154 substances or substance families and the list is expanding at the rate of 20 to 50 substances per year.

“It’s a gradual step process that the EU has put into place,” Valaitis says. “We’ve gone forward with our program to really drive environmental compliance and restrict the use of those substances today in our products. Then we will be ready for when the laws do come into effect.”

Ease of staying with the 3DEXPERIENCE Platform
Once Valaitis became the RoHS program manager, it didn’t take long to recommend Dassault Systèmes’ 3DEXPERIENCE Platform with ENOVIA’s Materials Compliance Central (MCC) product to his senior management team as he had prior experience with the 3DEXPERIENCE Platform.

“[I] really wanted a solution that would minimize the amount of effort it would take me to get an integrated enterprise solution,” Valaitis
Life Sciences Case Study: AB SCIEX

says. “By already using ENOVIA, CATIA and some of the other 3DEXPERIENCE Platform applications in-house, implementing MCC would save us time and provide immediate benefits.”

Built on the 3DEXPERIENCE Platform, the MCC capabilities of the ENOVIA application give AB SCIEX a single collaborative platform for managing engineering and design data so that users around the world can collaborate effectively in real time. AB SCIEX uses ENOVIA across its entire enterprise in 12 separate locations, supporting hundreds of users.

“I looked at how it compared with some of the other high-end products, and I didn’t find anything that MCC did not do that the others were able to do,” says Valaitis.

ENOVIA incorporates best-in-class industry-standard business processes for everything from contract and requirements management to configuration, workflow and bill of materials management, helping AB SCIEX get up and running faster and more efficiently with fewer challenges.

“The beauty of the 3DEXPERIENCE Platform and ENOVIA is that it allows us to manage environmental compliance by region through multiple compliance definitions,” Valaitis continues. “I can analyze data within my products and offerings globally by having a RoHS-based compliance definition, or a specific Korean-based or a Japanese-based definition, once I have the data loaded. It offers a lot of flexibility.”

Staying current with materials compliance

The 3DEXPERIENCE Platform allows AB SCIEX to proactively prepare for and react to where the global market is heading in terms of regulatory compliance. It provides the company with a vehicle that will allow AB SCIEX to remain current in the way it conducts a materials compliance assessment. Valaitis explained that one of the biggest challenges is gaining the necessary data to import into ENOVIA.
“After talking to several consultants and service providers, we felt comfortable asking third-party data providers for full material disclosure information of all our electronics and as many mechanical and cable components as we could,” Valaitis says. “We worked with Dassault Systèmes to create an upload routine from our third-party data provider, so that we could then take XML files from the data provider and automatically import the files into ENOVIA.”

With the upload routines and the bill of materials (BOM) management automation tools, AB SCIEX was able to turn these around, import the data into ENOVIA, and start looking at which components were or weren’t compliant. “With full material disclosure,” Valaitis says, “you create a compliance definition that says ‘I want to restrict certain substances,’ and then MCC will quickly tell you what components contain these substances and which do not.”

This was especially true in August 2012 when the Securities and Exchange Commission passed the Conflict Minerals Resolution. At the time, Valaitis asked his compliance engineer to tell him which components were going to be impacted by the resolution.

With about 8,000 to 10,000 material components loaded into ENOVIA, the compliance engineer responded in ten minutes with a list of suppliers that AB SCIEX needed to contact to ensure that they would not source conflict minerals from restricted areas. “For a company that doesn’t have a tool such as ENOVIA, it would literally take them hours to get the information they need after contacting and tracking down all of their suppliers and distributors, if they can get it at all,” Valaitis says. “I was able to get that answer in ten minutes.”

Handling of intellectual property
In some cases, suppliers will not divulge what’s in their products because they consider it their intellectual property (IP). In those cases, AB SCIEX has to work with a third-party data service provider to access materials declarations.

Manufacturers requiring that their suppliers report material declarations via the BOMcheck system can access a download action in ENOVIA to download supplier submissions directly from BOMcheck for specific suppliers, part lists, or date ranges. “We can upload full material disclosure data from the customer or supplier through BOMcheck into ENOVIA, so we are protected from their IP concerns,” says Valaitis.

Valaitis points out yet another ENOVIA advantage. “When our suppliers build something to our BOM specifications, I have all the data in place and ENOVIA is able to analyze and report that we are in compliance.” When environmental regulators want to know if AB SCIEX meets certain specifications, the comparison between how long it would have taken to compile the necessary data prior to implementing ENOVIA versus now is dramatic.

“Before implementing ENOVIA, on average, it would have taken us several months to collect the information required to respond to a specific regulatory requests, and now that same request may take only ten minutes,” Valaitis explains.

Review leads to redesign
As a result of the company’s proactive approach, Valaitis believes that AB SCIEX is gaining an unexpected bonus: efficiencies in its development cycle.

“Our compliance implementation program is giving us the opportunity to tidy up existing designs, really enhance our product development processes and attain environmental compliance all at the same time,” Valaitis points out.

Until recently, most impacted companies have been reactive to environmental regulations by conducting compliance reporting and analysis late in the product development cycle. Such an approach requires significant resources and is not integrated into the overall product lifecycle.

By integrating their compliance processes and analysis into their product lifecycle, AB SCIEX has gained a cost advantage of 10 to 20 percent by leveraging enhancements for a more robust overall design.
As an example of his company’s approach, Valaitis says that when AB SCIEX redesigned its circuit boards, the company gained a cost advantage of 10 to 20 percent by leveraging enhancements and cleanups for a more robust overall design. “As the deadlines approach, there are going to be more questions about what’s in our products and what’s not, and we’ll be in a better position to let our customers know.”

Better communication, better relationships

In an effort to better manage today’s environmental compliance issues, AB SCIEX is striving to improve communication with its customers and suppliers. This, in turn, is providing AB SCIEX distinct advantages.

One of those advantages is having the right answers when the company receives a request for a quote. “It’s becoming more and more advantageous to be able to communicate to our customers the types of tools and approaches that we have in place to manage our environmental compliance today,” says Valaitis.

As materials compliance deadlines approach even closer, AB SCIEX anticipates that its products will experience increased visibility. In addition, the company will field more and more questions about which materials its products contain or do not contain.

“We’re developing relationships with companies that can supply us this data, and who are implementing processes that are often much more efficient in the general development cycle than they were before we came on board,” says Valaitis. “To document what we’ve done, and to demonstrate very quickly to customers the compliance level of a product, is invaluable, and will increase in value as we move forward. AB SCIEX now has a proactive program in place that, while not perfect yet, will place us in a very good position to let our customers know.”

3DS Industry Services

From the start of the ENOVIA implementation process, the 3DS Industry Services team provided AB SCIEX with ongoing guidance and help. To jump start the project, the 3DS Industry Services team and AB SCIEX organized a project launch meeting led by a project manager to set up the integration plan.

The team then provided the necessary training to help AB SCIEX navigate through what needed to be accomplished first, what to watch out for as well as defining proper roles and responsibilities. AB SCIEX held meetings once a week for 16 weeks to ensure follow through on the implementation plan.

“There were times when it took us three months to solve an issue, but we simply tabled it, tracked it or did other things in the meantime,” Valaitis explains. “The key has been 3DS’ support and collaboration to make sure we were on the right track. Without their team’s capabilities, we would not have accomplished everything in the time we did.”

Generating peace of mind

AB SCIEX’s ENOVIA implementation has had a direct positive impact on several materials compliance program stakeholders. Valaitis points out that senior management feels confident that a process is now in place with the right tools and approaches that will mitigate RoHS and REACH noncompliance risk.

“One significant advantage is that everything is available up front,” Valaitis says. “ENOVIA allows us to generate the exact type of report we need based on any compliance definition we’ve entered into the application. It’s a very clear communication tool for our product managers and senior management team, as well as for each of the project leads that are running a subsystem or trying to achieve compliance.”

In addition, Valaitis says, “the component engineering people are happy because we have now put into place all the documentation and processes that they need to drive compliance. And in many cases, it speeds up their entire development process.”

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