Opportunities arise for biopharma companies throughout the global marketplace. But keeping up to speed with the ever-changing global regulatory environment is vital to professionals involved in the development of drugs, biologics, medical devices or IVDs across the product lifecycle. Whether a company is seeking a development partner, a distributor, or a clinical trial site, local regulatory rules constantly come into play.

Rules vary from country to country and region to region in both profound and subtle ways. One of the biggest challenges, as Biosidus S.A. of Argentina has found, is that rules and regulations are often in native languages on local government websites – and difficult to access and understand. Moreover, working with vendors across the globe, Biosidus found that it could not always rely on all of its local partners to keep up with changing regulations. It needed access to a single tool that would help the company stay on top of the shifts in regulations in every market in which it does business.

About Biosidus S.A.
- Based in Argentina, Biosidus is a pharmaceutical and biotechnology company with more than 500 employees and three decades of experience
- Focused on biosimilars, generics, niche products and new technologies
- Works with licensees in Africa, Asia-Pacific, Latin America, the Middle East and Eastern Europe
- Regulatory team consists of a director and 10 employees – four chiefs and six analysts
"Biosidus needed access to comparisons of specific regulatory issues between regions. A cross-checking system was required to work in regulatory strategy in countries where commercial markets exist with no defined partners."

Talia Gaeta
Senior Regulatory Affairs Analyst, Biosidus

The challenge
Biosidus focuses on biosimilars, generics, niche products and new technologies. It works with licensees – not subsidiaries – in many different countries in Africa, Asia-Pacific, Latin America, the Middle East and Eastern Europe. Some licensees work distributing other products in addition to those from Biosidus.

Biosidus found that sometimes these partners did not pay close enough attention to regulatory issues and delayed informing the company of changes in local rules that impacted ongoing procedures. This presented a danger to Biosidus – and put the company at risk of non-compliance, jeopardizing its business operations.

Staying up-to-date
Biosidus found the content in Cortellis Regulatory Intelligence™ to be an indispensable tool for efficiently accessing information relating to the local regulations using comprehensive regulatory summaries in English, backed-up with English translations for the key regulations. Biosidus also gets timely alerts when new regulations are announced or go into effect.

The company heavily relies on regulatory summaries that are comprehensive, continuously updated, available in English, and also provide hyperlinks to the relevant reference documents. “I work with countries whose native language is different from English,” Viceconte notes. The language difference can make compliance with the local regulations incredibly difficult. “But these summaries are in English and provide current and thorough information about their local regulations,” she says. The team also finds the global regulatory comparison tables and the searches and alerts extremely valuable.

As companies like Biosidus sift through the many different sources of information, finding and analyzing exactly what is needed for submissions and beyond is a time-consuming task. To make the right decisions, fast access to trusted, accurate information can make all the difference.
Reaching global markets

Biosidus has found Cortellis Regulatory Intelligence to be a key contributor to the company’s growth strategy via global market expansion. “Since I have Cortellis, I can find out the updates faster than waiting for the licensee notices,” says Talia Gaeta, who is also a senior regulatory affairs analyst. “The global regulatory comparisons are very useful to compare specific issues between regions.” She adds that Cortellis allows the company to have a cross-checking system in place and “to work in regulatory strategy in countries where commercial markets exist with no defined partners.”

The Biosidus regulatory team use Cortellis every week – it’s part of their standard workflow. The tool is intuitive and becoming comfortable and confident using the solution took little time. The company said it has also received plenty of support and training from Clarivate Analytics in getting the most out of the tool.

The company has found that the Cortellis team members are helpful and respond quickly to its queries, “looking for creative solutions to the dynamic and changing issues we face daily,” Gaeta says.

Biosidus found what it was looking for in Cortellis – a centralized tool to access current and updated worldwide regulations despite language barriers, an efficient way to track regulatory changes and to share information across the organization, and ensure continuous compliance for their products in multiple markets, says Myrna Miani Cosentino, the head of regulatory affairs at Biosidus. “It is an easy tool to use and met the expectations of the regulatory team,” she adds.

For more information on how Cortellis Regulatory Intelligence can help you navigate the global landscape, visit our website at: clarivate.com/cortellis

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