

Case Study | Global regulatory intelligence

Streamline regulatory requirements monitoring and distribution

Enable faster and better-informed compliance and policy-shaping decisions across regions

The regulatory intelligence team at a medium-sized pharmaceutical company was challenged to stay on top of on-going legislative changes across a variety of regions and disease areas, to support teams making decisions in safety, manufacturing, clinical trials, regulatory strategy and various disease programs. This is often an unsurmountable task for small teams, but if the company is not up to date with the

latest changes, it can mean wasted time, repetition of work and ultimately failure to comply resulting in potential fines, damaged reputation, and drug development delays.

The company worked with Clarivate regional regulatory experts and regulatory intelligence solutions to keep on top of fast-moving, nuanced changes globally.



The challenge: Keeping up to date with constant regulatory changes

The pharma regulatory team is tasked with keeping abreast of all regulatory changes across a variety of regions and disease areas. It supports colleagues across the GxP space, and this provision expands to teams working in safety, manufacturing, clinical trials, regulatory strategy and various disease programs.

"A lot of the issues lie around keeping abreast and up to date with all the regulatory changes in a wide variety of areas because we support colleagues across the drug development lifecycle," said the manager of the regulatory intelligence function.

The regulatory team also provides ongoing global regulatory surveillance workflows. In the past, they manually updated metadata sourced from regulatory documents from international health authorities to a SharePoint system and used a patchwork of email, SharePoint and many types of large, unstructured documents. This process needed to change. The data gathered could not be tailored to fit each business function and needed a digital transformation to achieve automation under a systematic set of business rules. One such need involved streamlining data for efficient use in marketing applications.

They are also responsible for producing recurring reports on various topics around the world.

The team had noted a growing number of queries from colleagues about pricing and reimbursement factors in specific countries. Without procuring and managing dozens of localized consultants, finding information in a timely manner – especially when English is not the first language – can be troublesome and frustrating.

"A lot of the issues lie around keeping abreast and up to date with all the regulatory changes across the globe in a wide variety of areas because we support colleagues across the GxP space."

**Associate Manager,
Regulatory Intelligence**



The solution: Boots on the ground with regulatory experts and intelligence

By partnering with Clarivate regulatory experts, and specifically using its Cortellis Regulatory Intelligence™ solution, the team is now able to view valuable information from a wide variety of countries that enables the company to drive strategic decisions around marketing applications.

Cortellis Regulatory Intelligence provides comprehensive global, expertly analyzed information that spans all regulatory functions across the R&D lifecycle in one central location.

"Having the 'boots on the ground' has really helped," the manager said. Instead of relying solely on guidance from individual countries, the Cortellis team goes a step further by partnering with local consultants physically present in the country, who have that deeper expertise you may not get from regulation alone. This allows the company to contextualize that information and make business-critical decisions."

"We get a lot of very valuable information from a wide variety of countries where I don't think we'd be able to access that information, especially as we don't have affiliates in all of these different countries like large pharma has," explained the regulatory intelligence team member.

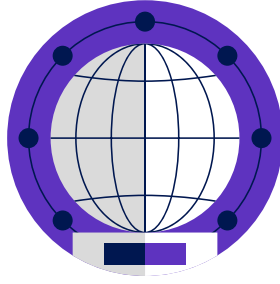
While the pharma company embraced Cortellis Regulatory Intelligence, it needed to go further still. To meet its customized needs, the Clarivate team built a customized electronic impact assessment platform, which the regulatory intelligence team has found incredibly helpful.

The tool streamlined the regulatory policy information and lessened the burden of work on the intelligence team. The team also noted the stability of the system, saying that "the customized platform is really a significant step forward."

"Cortellis helps immensely in sourcing the right information. Not only in the breadth of information, but the challenge is the fact that we are a global regulatory intelligence team, so we need to know what is happening across the world."

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Outcomes: Streamlined global regulatory intel to support decision-making

The regulatory intelligence team continues to partner with Cortellis to save time and resources in getting internal partners the insights needed to optimize marketing applications, plan clinical trial requirements and support other regulation-impacting decisions.

As an example, one of its programs needed information on a manufacturing strategy dependent on a country's guidance. The regulatory intelligence team sourced much of the information from Clarivate, and "essentially it helped us determine where it was going to be most feasible to submit a marketing application," explains the team.

The regulatory intelligence team leader says she believes that Clarivate is aware not just of its clients' current needs, but what they may need in the future. The integration of former Decision

Resources Group means that marketing and reimbursement information will be broader. The team has started to field a lot more queries in the pricing and reimbursement space so being able to access that information has been extremely helpful in making real-world decisions.

"Clarivate excels at taking client feedback and needs on board to make the processes and reports better."

Manager, Regulatory Intelligence

To learn more about how Clarivate can help you navigate the regulatory landscape and drive strategic decisions, please visit: clarivate.com/cortellis/solutions/regulatory-intelligence-solutions

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