

Global platform-and-hub regulatory outsourcing service from ProductLife Group targets affiliates and small in-country operations

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- Reduced compliance risk at a time of accelerating change
- Global resources + local knowledge = superior economies of scale
- Improved consistency and transparency across all markets
- Local teams freed to focus on commercial goals

Paris — 26 July, 2016 — ProductLife Group (<http://www.productlifegroup.com/>), which offers outsourcing and consulting services for life sciences companies, is continuing to expand the firm's global platform-and-hub-based regulatory outsourcing service so as to relieve teams and affiliates in smaller markets from soaring administrative burdens. The platform-and-hub-based service offers to relieve local operations from all regulatory information preparation and processing and from dealing directly with national authorities, which will free up in-country teams to focus on strategic and commercial roles.

All life sciences companies face a growing need to improve the ways they update and share regulatory information on a global scale. They're also under increasing pressure to streamline processes and improve the performances of in-country operations and partners. "The cost of maintaining head count for regulatory activities in smaller, less-strategic markets has become unsustainable," says Adam Sherlock, ProductLife Group's CEO. "If you're using affiliates, the picture becomes even more complicated, making it difficult to gain the scalability, transparency, and standardisation companies now need."

Until now, companies have had only limited options because outsourced services have been patchy—something ProductLife Group has set out to change. Earlier this year, a major industry debate the firm hosted on the subject confirmed that attitudes towards outsourcing are changing based on rising pressures. Britain's decision to exit the European Union has only served to increase companies' concerns about managing all of their obligations in a global market that is in a constant state of flux.

ProductLife Group's comprehensive outsourced regulatory affairs services take a platform-and-hub approach that blends international resources with vital in-country knowledge and contacts. Platforms span regulatory strategy consulting, regulatory intelligence, planning and coordination of registrations, and marketing authorisations in more than 80 countries worldwide. Local hubs provide expertise and local advice involving country-specific procedures, regulatory activities, and local regulatory intelligence. Hubs also have in place the tools, training, and standard operating procedures to enable rapid scale-up.

Qualified local regulatory affairs resources are available in markets across Europe, the Middle East, Asia Pacific, Africa, Latin America, and North America; and ProductLife Group's geographic reach continues to lengthen. Support for each country is provided either through ProductLife Group's own people or through local, vetted partners. "We're offering life sciences companies the best of both worlds: global scope and economies of scale, complemented by in-country expertise," Sherlock says. "Effectively, we can act as the operational back office for all regulatory maintenance activities at

the local-affiliate-company level—worldwide. This framework enables companies to streamline their processes and to consolidate and better deploy strategic resources in major markets.

"As the global regulatory environment becomes more and more complex and as margins get squeezed even further, the need for a partner with both the expertise and the global leverage to manage the product life cycle becomes imperative," Sherlock adds. "By engaging ProductLife Group, companies are assured of much-needed flexibility, process harmonisation, and across-the-board compliance with ever-changing regulatory requirements. For a lot of companies, such an arrangement will come as a huge relief."

Getting Started

ProductLife Group advises that a company starts with a pilot as a way of first ensuring that processes are aligned properly. Experts can talk through the options and help companies prioritise.

Find out more here

(http://productlifegroup.com/wp-content/uploads/2016/07/PLG_Brochure_Global-Markets_FINAL_20160715.pdf)

About ProductLife Group

ProductLife Group specialises in helping international life sciences organisations more effectively get their products and therapies to market by providing those clients with functional support across all of the regulated stages of the product life cycle—from development to launch, to postmarketing.

Performing successfully for more than 20 years, ProductLife Group has an established global presence in Europe, the Middle East, Asia Pacific, Africa, Latin America, and North America. We deliver services via an innovative, platform-and-hub operating model, enabling our clients to achieve continuous improvement, increased quality, enhanced performance, reduced risk, better compliance, and overall cost benefit. That approach, combined with our collaborative, partnership-oriented culture, empowers life sciences organisations to realise the commercial potential of their own international operations.

See more at productlifegroup.com or follow us on Twitter at @ProductLife_EU.

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