

2016 Life Sciences World Class Regulatory Information Management Industry survey confirms accelerating pace of transformation and investment

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- 88% of survey participants now undergoing or planning some type of transformational change
- Those with a common RIM capability are 3.5 times more likely to realise business benefits and are 18% more efficient
- 20% may achieve 'World Class' standard within 2-3 years

Paris, France – May 24th, 2016 – The 2016 study entitled, Pursuing World Class RIM: Strategy, Measures and Priorities surveyed 52 of the top 150 life sciences organisations globally. This research is the third global RIM survey conducted by Gens & Associates (<http://www.gens-associates.com/>) in partnership with ProductLife Group (<http://productlifegroup.com/>) (PLG), and the 30th study it has done in the life sciences industry. This year for the first time respondents were able to assess themselves against a comprehensive RIM World Class baseline to provide a best practice reference point against peers and this performance baseline.

RIM efforts are intensifying, compared to 2014,” commented Steve Gens, founder of Gens & Associates. “After a gradual increase in investment activity, we’ve seen a dramatic leap in the last two years.” Regulatory organisations are transforming how they work globally in an increasingly complex regulatory environment while trying to gain significant efficiency and cost reduction. This survey found 52% of the participants currently changing at least 70% of their global regulatory information capabilities, with 88% having many areas of transformational change.

The highest degree of change indicated was in the areas of data standards, dossier management, product registration, reporting & analytics, and submission forecasting. Respondents named labelling, submission forecasting and dossier management as particular priorities.

It also found that the more holistic organisations’ approach to regulatory information management, the greater the business benefits. 26 companies that reported a common RIM capability were 3.5 times more likely to gain from process integration, reduced time to submission, and higher user productivity. The survey measured the type of and degree of change, process and organisation work, and the evolving solution provider community (innovation index, satisfaction, and market share).

“We developed the World Class baseline with direct input from 18 leading companies internationally,” Gens explains. “For the first time, organisations can visualise and quantify what a world-class RIM capability looks like, giving them something to aim for. Think of it as a gold standard for regulatory information management.”

Measuring current progress against the baseline, Gens estimates that around 20% of the participants may achieve the world class standard within 2-3 years, becoming significantly more efficient and productive

as well as compliance-confident. Others, currently behind the curve, could take 3-5 years to achieve parity, he suggests.

“What surprised us is the difference between achieved and projected business benefit realisation. The data clearly shows many are just starting or in transformation mode and delivering tangible business benefits are 2 – 3 year out for the majority of companies,” says Gens. “One reason for this is that the regulatory function was historically just focused on effective compliance and information quality where the switch is gaining efficiency and productivity that enhances compliance and the confidence in data quality. We advise companies to bring in the manufacturing people where waste reduction, efficiency improvements and faster turn times are part of their organisational DNA.”

As well as providing the strongest idea yet of what World Class looks like, the 2016 survey is the broadest yet in its scope. The 50+ participants span all sizes of organisation, and include a robust sample of medical device manufacturers alongside smaller biopharma organisations. Participants spanned Europe, North America and the Asia Pacific region.

A white paper containing highlights of the findings will be published in July 2016.

Commenting on the results, Adam Sherlock, CEO at ProductLife Group, said, “We’re greatly encouraged to see progress in RIM accelerating across the life sciences sector. With the added ability for organisations to plot their performance against similar organisations, the value of this research is immense.”

About ProductLife Group

ProductLife Group is a trusted partner that helps clients stay ahead of the changing R&D landscape. We provide support across all stages of the product life cycle and have experience in working with companies in every segment of the life sciences industry. With an established presence across Europe, North America, and Asia Pacific; with extensive capabilities in key markets; and with more than two decades of serving the industry, ProductLife Group has a solid platform from which to provide clients a range of services, consulting, and outsourcing solutions. PLG empowers clients to focus on innovation and business growth strategies and to make strong, informed decisions every step of the way. What’s more, we wrap it all up with partnership flexibility, for a truly customised experience that helps clients scale their initiatives cost-effectively. By taking advantage of the power of deep domain expertise, established relationships, intelligent collaborations, and a flexible delivery framework, ProductLife Group delivers exceptional service to clients. Our goal is to develop long-term relationships by being responsive and relevant and by consistently delivering value. We cultivate a trusting, consultative environment and are positioned to operate as an extension of clients’ businesses, with a shared interest in their long-term success. More at productlifegroup.com or follow us on Twitter at @ProductLife_EU

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Gens & Associates is a leading independent boutique management and organisational consultancy

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