Point of View

GENPACT
GENERATING IMPACT℠

GENERATING TECHNOLOGY IMPACT

Transforming regulatory and compliance processes in life sciences through advanced technologies: Systems of Engagement™

Over the last 20 years, life sciences companies have spent millions of dollars in regulatory and R&D IT systems of record to control and manage their regulatory information. For a variety of reasons, these investments have failed to deliver. Users are frustrated at the lack of an end-to-end view, and management is dissatisfied with frequent compliance failures and a lack of quality data and analytics. The current regulatory and R&D IT technology environment is dominated by large-scale system of record consolidation projects, yet the user and process perspectives remain under-served.

Systems of Engagement™ form an agile solutions layer to complement systems of record, offering a viable option for addressing these gaps.

Regulatory IT systems of record are failing the business

Traditional regulatory IT systems have focused on individual systems of record, such as content management, change management, publishing, or registration management. These multi-million-dollar investments in regulatory IT have not fulfilled their potential in delivering enterprise-standard regulatory information, which is the desired business benefit for most life sciences companies.[1] There are a number of contributing factors to this:

Siloed systems lead to compliance challenges

Regulatory IT systems rarely interact with manufacturing, supply chain, or commercial systems, despite these functions being heavily reliant on regulatory information for critical activities, such as batch release, change assessment, and promotional materials approval. Failing to align these systems of record with critical business processes in R&D, manufacturing, supply chain, and commercial has resulted in these functions building their own "source of the truth," rather than relying on regulatory systems directly. This has led to a proliferation of duplicate, unsynchronized local systems and spreadsheets, plus required individual knowledge holding the regulatory and compliance business processes together. With no clear data governance and cumbersome, manual reconciliation processes, these data silos quickly become out of date, leaving organizations potentially out of compliance.

Diverse regulatory structures lead to governance challenges

They are expensive to extend to regional or in-country colleagues, who control much of the regulatory information essential to the compliance these regulatory systems were planned to deliver. Further, local operating companies (LOCs) and infrequent users face complicated, global regulatory systems that are difficult to learn and provide little benefit to anyone outside the central corporate functions. Yet regulatory compliance is largely reliant on LOCs having timely and effective access to maintain company data in regulatory databases, often with small, local staffing levels. Again, this results in off-line local systems, spreadsheets, and tribal knowledge filling the process gaps that the global regulatory systems of record do not cover.

Disjointed vendor landscapes limit native integration

Regulatory IT and wider R&D IT is a disjointed system and vendor landscape. It is common to see standalone applications across and within the clinical, safety, and regulatory functions, where users need to "dip in and out" of several systems every day in order to perform their roles. These standalone systems lack underlying R&D master data, resulting in poor process-based reporting and analytics capabilities.

Heightened M&A activity needs an enabling IT strategy

The relentless cycle of mergers and acquisitions and the evolution of therapeutic area operating models have acted as a barrier to R&D IT system integration. Quite often within the same organization, the different business units will each run separate systems. When companies merge, the problem multiplies exponentially as the acquired entity is also likely to have a similarly disjointed R&D IT system landscape.

With regulatory affairs functions facing unprecedented demands from increasing global legislation, the growing burden of product lifecycle maintenance activities and CFO scrutiny of their growing cost base[2], this sub-optimal technology foundation is severely hampering life sciences companies wanting to transform

[1] http://gens-associates.com/2014/10/13/2014-enterprise-rim-building-the-business-case
[2] http://www.cuttingedgeinfo.com/research/regulatory/pharmaceutical-regulatory-affairs

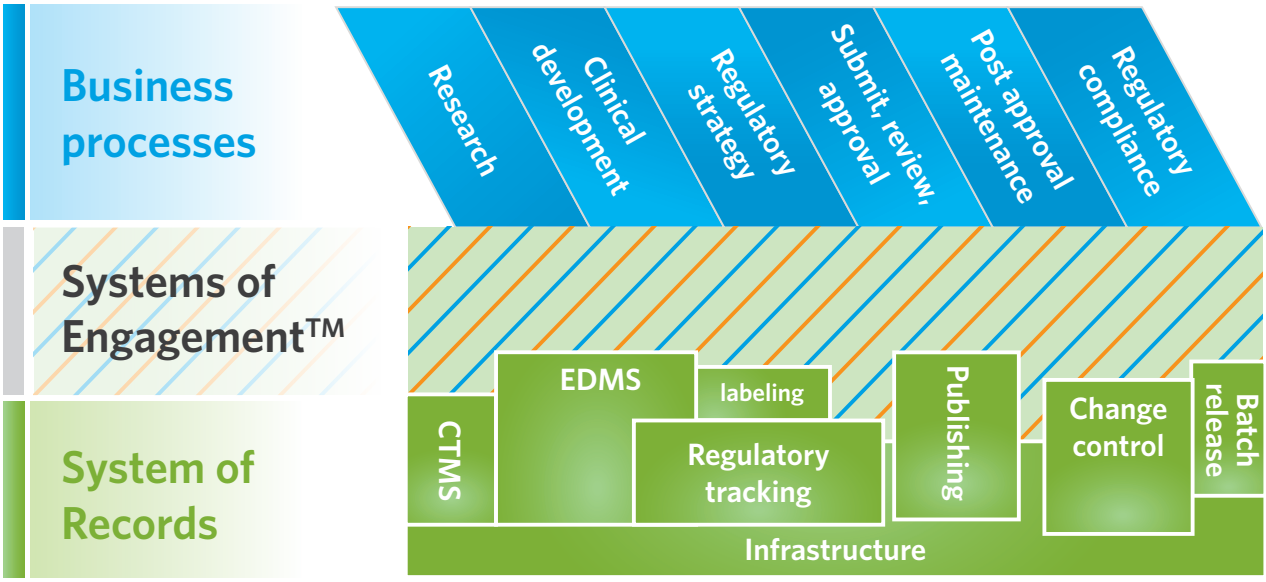

Figure 1: *End-to-end processes spanning multiple applications and "white spaces" between them*

their regulatory affairs operating models. These pressures have resulted in a significant wave of global regulatory system consolidation projects, combining multiple regional and local systems into a single global system that provides one version of the truth. However, the lack of an over-arching user- and process-centric technology approach will likely limit the return from these significant investments.

An agile technology layer that complements existing systems of record can accelerate benefit realization

Systems of Engagement™ are a thin layer of technology that orchestrate business processes while sitting on top of, and interacting with, the underlying systems of record (Figure 1). They take a process-based view, enhancing the user experience, embedding workflow, automation, reporting, and analytics. They allow rapid data integration across multiple sources while maintaining the integrity and validation status of the underlying systems of record. This technology approach can bring huge benefits to regulatory affairs, and has been proven in areas with equally complicated data and systems, such as finance and accounting.

> ***"Systems of Engagement™ dramatically improve process efficiency and compliance, KPI reporting, and metrics."***

Systems of Engagement™ accelerate the standardization and simplification of processes by eliminating the Excel spreadsheet culture and codifying tacit institutional knowledge that currently holds many business processes together. This dramatically improves process efficiency and compliance, transparency, user acceptance, and the reporting of KPIs and metrics. They can be flexibly deployed in the cloud or in an on-premises data center.

Example use-cases for Systems of Engagement™ in regulatory and R&D are as follows:

- End-to-end management of chemistry, manufacturing, and controls change control – connecting content management, registration tracking, change control, and manufacturing systems
- Capturing and assessing new global regulations and managing all related follow-up actions – connecting submission planning, registration tracking, and content management, for example
- Making ancillary documents (critical process parameters, good manufacturing practices certificates, etc.) into an automated service, a black-box for LOCs, and emerging market regulatory affairs groups

Systems of Engagement™ can be developed and deployed in-house, purchased as a service, or a combination of both. Organizations can start small, tackling simple use-cases to test the concept and develop a suite of offerings based on their unique needs. Systems of Engagement™ can evolve through iterations and ensure that the organization starts generating immediate impact even as large and time-consuming system of records consolidation projects are being executed.

Conclusion

Sub-optimal regulatory technology serving unreliable regulatory information is hampering the efficiency and effectiveness of regulatory and compliance processes. Systems of Engagement™ can enable transformation of regulatory operating models by orchestrating business and compliance processes across departmental boundaries into other parts of R&D, supply chain, manufacturing, and commercial, as well as across regions, simplifying the user experience and providing reliable data and insights for smart and timely decision-making. Systems of Engagement™ support today's regulatory affairs' need for efficiency and immediate return on investment, allowing life sciences organizations to mitigate risks, reduce costs, gather actionable intelligence, and be more flexible in order to stay competitive.

This paper was authored by John Cogan, Chief Technology Officer, Genpact Pharmalink. Author's email:john.cogan@genpact.com

Genpact Pharmalink is the global regulatory affairs organization of Genpact.

About Genpact

Genpact (NYSE: G) stands for "generating business impact." We design, transform, and run intelligent business operations including those that are complex and specific to a set of chosen industries. The result is advanced operating models that support growth and manage cost, risk, and compliance across a range of functions such as finance and procurement, financial services account servicing, claims management, regulatory affairs, and industrial asset optimization. Our Smart Enterprise Processes (SEP℠) proprietary framework helps companies reimagine how they operate by integrating effective Systems of Engagement™, core IT, and Data-to-Action Analytics℠. Our hundreds of long-term clients include more than one-fourth of the Fortune Global 500. We have grown to over 70,000 people in 25 countries with key management and a corporate office in New York City. Behind our passion for process and operational excellence is the Lean and Six Sigma heritage of a former General Electric division that has served GE businesses for more than 16 years.

For more information, contact, technology@genpact.com and visit www.genpact.com/home/solutions/systems-of-engagement

Follow us on Twitter, Facebook, LinkedIn, and YouTube.