genpact

POINT OF VIEW

Transforming regulatory affairs with robotic process automation

Spreadsheets were great in the '90s...

Life sciences organizations are used to dealing with a myriad of variables. Whether it be global supply chains, changing regulations, or introducing additional data sources, the complexity across regulatory affairs demands new solutions. With the introduction of emerging technologies, such as robotic process automation (RPA) and artificial intelligence, regulatory organizations now have access to cutting-edge, business-altering solutions.

At pharmaceutical companies around the world, regulatory affairs (RA) departments are feeling the pressures of a world that is going digital while still relying on spreadsheets to maintain data and make decisions. Spreadsheets represented a computer-assisted mechanical evolution – and that was fantastic in the '90s. But this technology is no longer meeting needs. Many of the processes are still manual in nature – and gathering documents across disparate functional areas for inclusion in regulatory submissions or determining whether these documents adhere to regulatory standards are not value-added functions.

In life sciences, global supply chains, changing laws, and expanding data sources add complexity to RA that demand new solutions. Today, the function can get help from advanced technologies such as robotic process automation and artificial intelligence.

Is your company's approach to RA still stuck in the two-dimensional spreadsheet, manual-processes era? Or is your function digitally enabled, agile, and ready for growth?

The high cost of non-compliance

Consider the following incidents:

- The FDA requires drug label changes for commonly prescribed antibiotics, including warnings for mental health side effects, after a university student on one such an antibiotic passed away unexpectedly
- A company that makes an anti-psychotic drug is facing a class-action lawsuit because its prescribing information failed to mention that compulsive gambling was a possible side effect, even though scientific literature had confirmed the connection for years
- A popular blood-pressure drug has been recalled after a lot of the firm's products were found to be mislabeled

The companies involved not only face the prospect of huge fines; they risk losing the trust they've worked hard to build with consumers.

These examples are extraordinary. However, less dramatic problems with RA processes occur regularly. When the EudraVigilance Medicinal Product Dictionary (EVMPD) first came into effect, for example, companies struggled with their initial electronic submissions. Many still do. And there are scores of other challenges. Terminology from agency to agency isn't uniform. Labeling and Chemistry, Manufacturing & Controls (CMC) changes don't reach affiliate countries. And some regulators are now pressing for detailed supply-chain tracking and in-depth monitoring of raw materials and contract manufacturers. Every day, RA teams are expected to standardize more and to meet new norms, as is the case with identification of medicinal products (IDMP) norms.

Regulatory teams don't lack the will or desire to do better – they lack the right resources and tools. And while leaders sometimes succumb to the temptation to hire consultants to patch the holes in the process, that solution isn't sustainable. Engagement in new ways of working needs to be examined. Taking advantage of technology and an assessment of outdated processes must take place.

Job one: changing the traditional mindset

In the fast-moving world of life sciences – a world of exciting, new therapies and devices racing to get to market – the labor-intensive work of RA may seem like a necessary evil. Leaders know that RA eliminates the roadblocks and can speed the approval of a product hitting pharmacy shelves. But they also think of RA workers as foot soldiers fighting from the bureaucratic trenches – the people they need to complete tasks that satisfy demanding authorities but add little to no value to the business.

Regulatory departments typically focus on new discoveries in late clinical trials and those in the approval stage. That focus worked more or less effectively in the past, when parameters were narrower. When legislation wasn't changing at the speed of light. When connected devices didn't pose security threats and businesses could keep track of what entered their supply chains at every step. When data wasn't amassing exponentially. And when the risk of non-compliance didn't mean huge fines, lawsuits, and extensive, costly remediation plans.

Today's RA must keep on top of an intricate network of laws and guidelines across the globe. After R&D and other

divisions of the enterprise have moved on, it falls to RA to monitor drugs and device dossiers, including those no longer under patent, wherever they are in the world. RA is always on duty to update files for manufacturing and labeling changes and is looking for omissions and gaps that can result in non-compliance. And when it doesn't have the best tools and the right resources to help them negotiate this territory, trouble occurs that can cause both financial and reputational harm to a firm.

Regulatory teams that recognize this understand they must manage their own change, too. If they want to stay relevant, they must seek out, adopt, and own the technologies that can make them true partners in the business.

Job two: finding the right digital technologies for RA

Technology has come a long way since companies first started using spreadsheets. Today, developments in robotic process automation, artificial intelligence (AI), machine learning (ML), and natural language processing are revolutionizing industries in every sector. They're poised to have a true impact on RA, too. As regulators place more focus than ever on standardization, increasingly stringent data management becomes critical. While new laws are driving this push, a beneficial side effect for competitive pharma companies is improved productivity.

One technology that has already proven itself useful to RA, for example, is RPA. Many activities in RA lend themselves to this kind of automation because they're repetitive and rules based. Case in point: RPA can gather information from documents like summaries of product characteristics (SmPCs) for use in EVMPDs, or it can identify and extract updated 1572 forms for investigator submissions.

Meanwhile, AI and its subset, ML, are coming into their own in the RA realm as well. ML is the perfect tool for identifying the data you need from legitimate and up-to-date sources. It then extracts the appropriate material to help RA create items like a Module 3 baseline file of the most currently registered information.

The point is this: new technologies are disrupting traditional means of doing business. Not every new technology is appropriate for the RA function. But if practitioners keep an open mind about its possibilities, they can move out of the bureaucratic trenches and into their rightful place as full partners in the business.

With the right technology in place, a company can improve productivity and make its devices and medicines safer. It can hasten the time it takes to get new drugs to market. And it can spur growth by enhancing consumer trust and confidence.

And you have to admit: no spreadsheet can do any of that.

This point of view was co-authored by Rajiv Naidu, Vice President, Regulatory Affairs - Service Line Leader; Teresa Booth Genthe, Vice President, Regulatory Affairs - Transformation Services; Jake Doran, Chief Technology Officer, Regulatory Affairs; and Amit Sarkar, Assistant Vice President, Regulatory Affairs - Transformation Services, at Genpact.

About Genpact

Genpact (NYSE: G) is a global professional services firm that makes business transformation real. We drive digital-led innovation and digitally-enabled intelligent operations for our clients, guided by our experience running thousands of processes primarily for Global Fortune 500 companies. From New York to New Delhi and more than 25 countries in between, we connect every dot, reimagine every process, and reinvent companies' ways of working. Transformation happens here.

For additional information visit https://www.genpact.com/risk-compliance/regulatory-affairs

Get to know us at Genpact.com and on LinkedIn, Twitter, YouTube, and Facebook.

genpact
Transformation Happens Here