Automation: What Regulatory Team Needs to Know Before Investing

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In recent years, Automaton has become more powerful and its applications to business have increased dramatically. As a result, companies and business functions, including Regulatory, that hadn't seriously considered using Automation, are taking a fresh look. The appeal is obvious: different forms of automation can enhance performance and save costs while increasing the capacity of existing teams / investments.

Where Regulatory Organizations often struggle is in knowing where to invest in an Automation project that will really pay off. But if Automation hasn't been a part of your company before, it can be hard to know where the real potential and risks lie.

If you are thinking about adopting, you should consider how it might create value, what good first projects might be, what tools/vendors to partner with, and whether you have the right talent on staff for your efforts to succeed in the long run. A first Automation project can be daunting, but knowing which factors to focus on will bring the project down to earth and clarify whether it's worth the investment at all.

Will Automation create value for you?

"Why do we think this investment will be worth it?" is one of the first questions you'll need to answer. That means knowing which source of operational pain (e.g., redundancy in particular tasks or freeing up teams time or bottlenecks in operational flow) you're trying to address or where you're aiming to improve efficiency. Automation projects should address processes that significantly impact cost or resource allocations, where the ultimate result can be a noteworthy impact to the bottom line.

Good candidates for Automation to provide value include:

- Activities that are very time consuming and labor intensive (e.g., Authoring, documents QC of documents/dossiers, Formatting, Submission readiness, and Reviews)

- Work flow activities that require data verification across systems (and sometimes verifying from documents)

- Regulatory impact assessments & change control (considering high volume requests coming in both from internal sources and external agencies)

- Processes that can be augmented with document/data analysis

- Data extraction from documents like CMC, Labeling

Pick a task, not a project, as your entry point. Automaton is generally task oriented.

Know what data and complementary systems you need

Good data or documents are the lifeblood of a

successful Automaton project. Before committing to a project, you need to formally investigate the types and amount of data required to do it well, whether there are any restrictions on using that data (such as privacy regulations), and whether it's in a reasonable accessible format. This investigation is not limited to internal data to an organization but data that may exist in external sources.

Once you've identified that adequate data is available for Automation to process, you'll need to ensure that it's possible to integrate an Automation's output into the target task.

Adjust your expectations of accuracy

Automation is a powerful, but it's not magic. The type of Automation tools you're deploying, the data you have available, and task you are looking to focus on can all dictate the rate of accuracy and the return on investment. Understanding what affects accuracy and why can help you set reasonable expectations for what the success of the project looks like.

Simply put, it's key to understand the type of Automation you are deploying and what the outcomes will be used for in order to estimate the impact on your bottom line.

Don't rush to deploy enterprise-wide

Just because Automation works well for one task doesn't mean it will for others. In other words, consider the task of deploying Automation to enhance compliance issues in your organization. Models/Tools will be effective in identifying red flags according to a particular functional area. However, that model/tool "as-is" will not be a plug and play to other areas to address compliance. Automation projects will have to be conducted according to functional procedures and corresponding data that drive them.

Be realistic about whether you have the skills to maintain Automation

Larger companies already have the infrastructure (e.g. IT and data engineers). The addition of practicing data scientists may be enough to maintain internal projects. Of course the option to engage outside vendors is always a viable play and may be a good way to break into Automation deployment and learn.

One notion to keep in mind: if you believe your company has the characteristics that will benefit from Automation deployment, it may be worth investing in the personnel to make it an ongoing integral part of your operations.

The results of starting Automation the "right way"

The key to successful implementation of any new strategic technology is due diligence. In the case of Automation,

companies need to know the capabilities of Automation scope and consider its deployment to the right processes, ones where it can make a difference. More specifically, due diligence with Automation requires collaborative brainstorming among data engineers, Regulatory SMEs, internal process SMEs and executives. A few days of focused deliberation can enhance the likelihood of successful roll-outs that optimize resources, or can avoid the painful purgatory scenario of new technologies remaining in the perpetual state of pilots and testing.

If Automation is a fit, companies can let the technology do the heavy lifting of routine based processes. But in order to get there, you need to find the approach that works for your function. Once you do, you may see new opportunities opening up all around you.

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