



PIONEERING ROBOTIC PROCESS AUTOMATION (RPA) IN LIFE SCIENCES

How we introduced robotic process automation (RPA) at a major life sciences company, improving efficiency, consistency and quality.

Life sciences companies have many regulatory responsibilities, including the obligation to document and maintain consumer feedback on the safety and efficacy of their products. A major life sciences company saw that obligation increasing exponentially, with the volume of Individual Case Safety Reports (ICSR) doubling year over year.

The company asked us to examine its largely manual process and design an automated solution. We saw an opportunity to introduce RPA, which is proving to be extremely effective in environments that rely on manual, rule-based processes. Essentially, RPA allows automation to take over manual tasks, enabling people to shift their attention to higher-value activities.

In developing the RPA solution, we saw it as a first step in introducing automation that can be utilized in other areas of the organization. We started with an important but relatively simple part of the ICSR process involving the electronic

AT A GLANCE

A major life sciences company wanted to automate a highly manual process that was becoming a quality-control risk and a regulatory burden. We built a robotic process automation (RPA) solution that addressed the immediate issues and will be leveraged in other parts of the organization. Our solution is a first in the area of “pharmacovigilance” processes.

Outcomes:

- 30 percent reduction in end-to-end cycle time.
- Improvement in first-time accuracy from 85 percent to 99 percent.
- Improvement in regulatory compliance from 95.7 percent to 96.12 percent.
- Improved turnaround time compliance from 88.6 percent to 91.9 percent.

transfer of data, known as E2B transmissions. Our team designed and implemented BOTs that automate the sorting and data-entry stages of the E2B transmission.

The solution is delivering numerous benefits including faster processing with greater consistency and fewer errors. More important, its modular design can be customized and scaled for future needs for other types of documents and transmission modes.

A forward-thinking solution

The immediate goal of the project was to replace and automate repetitive manual activities with a “O-touch” RPA solution for the processing of Individual Case Study Reports submitted by consumers and monitored by pharmaceutical industry regulators.

Longer-term, however, our goal was more far-reaching, and that required careful planning. First, we had to ensure that the solution would stand up to regulatory scrutiny. If and when regulators wanted to inspect the reports, would

the company be able to make them available immediately in the form the regulators required?

Second, we needed to ensure that it was scalable, so we could expand process automation to other areas of the organization.

To ensure inspection readiness, we adopted a rigorous approach, testing, documenting and validating the BOTs in three phases comprising 300+ test cases.

Building a scalable solution meant a modular approach, which can be customized as needed. The modular approach also enables faster deployment, which will allow the company to respond rapidly to change in the always-evolving life sciences industry.

The RPA solution was completed and went live in just seven months. New automation efforts are in development to incorporate areas where more complex processing is needed along with certain cognitive elements including Artificial Intelligence and Machine Learning.

ABOUT COGNIZANT

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