

Process Automation Project

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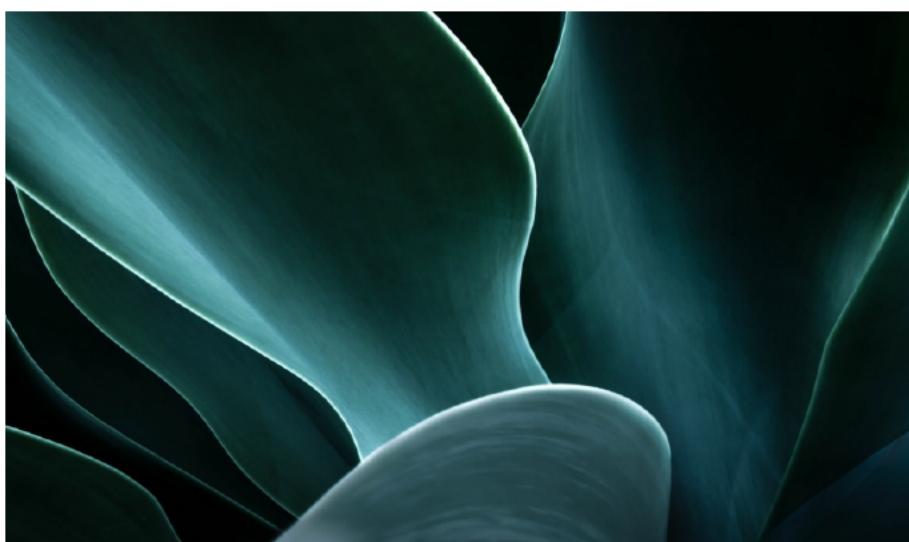
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Innovation through Technology (MIS540)

Mack Jackson

Abstract

Building a culture of innovation enables businesses to adapt and keep up with change. Leaders and employees across an organization are responsible for supporting and leading that innovative change. The organizational leaders who incorporate and implement automation, machine learning, and artificial intelligence (AI) technologies are revolutionizing business processes. Embracing these technologies can enable an organization to experience increased productivity, improved quality, reduction of repetitive, time-consuming tasks, and enhanced return on investment. Over the last several years, Health Authorities have focused on reducing their paper footprint by adding mandates for electronic submissions within their instructional/guidance documents. Consequently, the Regulatory Operations and Regulatory Submissions landscape has had a significant rise in the use of and need for technology. Utilizing automation tools allows work processes and team communication become more self-serving for a company's local and/or global workforce and management.



Introduction

According to Gartner, a leading research and advisory company, organizations who “fully embrace digital acceleration” and “continually strive for digital operation excellence and resiliency” will likely encounter a 30% decrease in their operation costs by the year 2024 (Gartner, 2021). [REDACTED] itself, is committed to big-picture thinking, targeted problem-solving, and innovative solutions as well as understanding the importance of key collaborations, all assist in attaining such a significant goal.

Over the last several years, health authorities have converted from guidance/recommendation wording within their instructional documents to mandates and requirements for electronic drug application submissions. As a result, the Regulatory Operations (RegOps) and Regulatory Submissions (RegSubm) landscape experienced a significant rise in technology. The COVID-19 pandemic further accelerated the use of and need for technology since companies had to speed up their digital footprint to, quite frankly, stay afloat. As a result of these events, [REDACTED] now has a critical need for a liaison between RegOps and the Information Technology (IT) department. To be successful in this liaison role, an extensive understanding of the regulatory operations business, a strong technological aptitude, a successful project management track record, and data analytics background are needed for leading/implementing process automation within the department on a global scale.

Background

[REDACTED] is a specialized provider within the pharmaceutical, biotech and medical device industries who offers services such as clinical development, monitoring on-going drug safety, managing regulatory operations and submissions as well as facilitating interactions with health authorities. [REDACTED] has a team of professionals with offices in 22 countries representing 40 nationalities who bring an extraordinary amount of education, training, and real-life experience to the table. With the extraordinary support of [REDACTED] companies can reduce their product(s) time to market, maximize their development process, and accelerate their ability to make more effective business decisions ([REDACTED] 2021).

Currently, users are spending time on repeatable, time-intensive tasks and are more likely to encounter rework/confusion as work is shared across time zones. In addition, the groups work/life balance is deteriorating due to increase in volume of work. Figure 1 depicts the manual steps involved in the submission process and covers receiving/processing files from a client, creating/updating a Submission File Plan (SFP), and communication steps needed with users/clients. Please note this is just one example as there are other manual processes that can be reviewed for automation usefulness.

Utilizing automation tools will allow communication to become more self-serving for local and global workers (and management), decrease time zone delays, likely minimize rework, and produce more real-time data for better quality data analyses. As shown in Figure 2, machine-to-machine (M2M) processes with no human intervention will be used to produce the previously discussed efficiencies/benefits.

Innovation Opportunity

The Objective:

Work with users, management, and IT to utilize the company's existing technology in coordination with their in-house applications and processes to increase workforce productivity and decrease the need for rework within [REDACTED]

The Problem:

Missing a liaison with extensive understanding of the RegOps/RegSubm business and strong technological aptitude for leading/implementing process automation on a global scale. As a result, too much time is spent on repeatable, time-intensive tasks and existing automation technology is unused.

Need #1. Spend less time on repeatable, time-intensive tasks

Need #2. Utilize automation technology, coordinating with document/submission management & ERP apps

Need #3. Enable internal/external customers to become more self-serving (locally & across time zones)

Need #4. Increase visibility of project statuses and/or collected data

Need #5. Produce standardized visualizations/dashboards with real-time updates

Need #6. Rapid training for staff on new/revised processes

The Opportunity

This solution will...provide ability to use existing applications/processes to decrease operation costs and increase efficiencies, increase real-time/self-service capabilities, fully utilize the company's global landscape and expertise, provide

Innovation Opportunity

management and clients with real-time updates as documents travel through the RegOps and RegSubm processes, capture additional data to provide further data-driven insights, and will increase management and executive's visibility of project statuses (Microsoft, 2020). [REDACTED] will see many benefits from this project with the goal of providing the best in-class customer service and savings for new and existing clients.

- Goal #1. Interview user base, prioritizing and finalizing wants/needs list within 2 weeks of project start date
- Goal #2. Involve local & global subject matter experts in design and testing of solution, including documentation
- Goal #3. Interview management, IT, and users, discussing key performance indicators (KPIs) for solution
- Goal #4. Train local RegOps/RegSubm users on solution before production roll-out
- Goal #5. Train remaining RegOps/RegSubm users within 4 weeks after roll-out
- Goal #6. Work with IT regarding SP landing page and information needed for creation of Teams site
- Goal #7. Produce standardized visualizations/dashboards
- Goal #8. Integrate sales training with functional training on solution
- Goal #9. Monitor agreed-upon KPIs for 6 weeks following initial roll-out and last training session
- Goal #10. Complete phased approach to solution
- Goal #11. Implement monthly updates for 6 weeks then transition to quarterly updates
- Goal #12. Train company admin/super user(s) to own, manage, or update solution

Technology Integration

For this project, several existing technologies will be utilized. [REDACTED] uses the Microsoft 365 (MS365) application suite (i.e., MS Word, MS Excel, MS PowerPoint, MS Outlook, Planner, Teams, etc.) and are currently implementing Dynamics 365 for tracking opportunities/sales as well as resources and schedules. In addition, [REDACTED] created a proprietary software application for global management and tracking of documents/submissions which is utilized by the Regulatory Submissions (RegSubm) and RegOps departments in addition to business administrators and management. SharePoint with use of metadata and network file shares are the company's document repositories; although, network file shares will eventually be phased out. SharePoint sites are also being used for collaboration with external clients. For internal publishing projects, documents are directly assigned from SP to their publishing tool and then output is viewed by internal and external clients through a second proprietary software application. Please note there are several additional software's and/or plug-ins utilized by [REDACTED] for pre-processing of reports and section documents; however, those are not covered in this project.

When building the automation aspects of this project, Microsoft's Power Platform will be used since it provides non-technical users the ability to create, automate, and analyze data themselves...all without coding knowledge. In the past, to accomplish any of those items, an IT request would need initiated that included requirements and then a person could wait weeks or possibly months for a solution (Microsoft, 2020).

Technology Integration

The Power Platform consists of three MS technologies covering a variety of process-agnostic software such as robotic process automation (RPA), low-code application platforms (LCAP), artificial intelligence (AI) and virtual assistant tools. The three technologies within the Power Platform are...Power BI (insights on data or business), PowerApps (interface between user and data), and Power Automate (handles task automation) and each will be incorporated into the project when and where needed.

To ensure a successful project, several team representatives will need to be selected and involved with this project. It will be important to have representatives from various IT groups, RegOps, RegSubm, SP, Power Platform, MS365 Administrators, Data Governance and/or Policies, Sales/ERP, Learning Academy, Project Management and Finance. Team members/representatives need to include local and global users. Due to the complexities and depth of this project, a phased approach will be utilized for deployment purposes. Phases will be determined by core project team and based on user, management, and client needs.

Operational Environment

In the beginning phases of this project, the existing operational environment encompassing the needed technology, permissions, and licensing will be utilized for this solution. An expert user/liaison will need access to a test and development environment, test users/groups created covering various permission levels, and an IT resource for any questions on most efficient way to generalize the needed Power Automate process flows so they can apply to various clients and projects. In addition, project team members (from Finance, Management, MS365 Admins/Licensing, etc.) will determine if the company needs to invest in Power BI licenses or server setup to ensure the sharing of interactive visualizations/dashboards are possible.

At first the automation processes will be focused on low hanging fruit within the RegOps/RegSubm groups then will expand to include external groups such as Sales/ERP and proprietary in-house software. The various departments will need to become involved when reaching next phases of project to ensure data compliance, security, and that existing infrastructure technologies will handle the volume of data calls/processing. The Power Automate process flow files will be stored within the existing cloud storage area with IT determining best placement for efficiencies and appropriate access.

Why Embrace and/or Fund

[REDACTED] and leading technological innovation just go together. Implementing automated processes utilizing already existing technology will have a significant effect on operation costs and efficiencies as well as better utilize the company's resources and expertise. Managers, executive leaders, workers, and clients will all benefit from this automation project, from accurate project statuses to dashboards powered by real-time data. With the experience and knowledge gained from this process automation project, [REDACTED] will have an additional technology-enabled tool that will not only benefit their own operations but will also provide a new service/tool offering for their clients. Early phases will require minimal funding due to use of internal systems and resources. Later phases will need additional funding, but those numbers can be included within ITs upcoming development budget with the understanding that this will be an opportunity for the company to create a new revenue stream, ultimately, enhancing their return on investment.

Summary

As discussed in this report, [REDACTED] has a strong commitment to big-picture thinking, targeted problem-solving, collaborative technologies, and innovative solutions. With the Health Authorities focus on digital transformation, electronic submissions are now more of a mandate versus a recommendation thus increasing the use and need for technology within RegOps and RegSubm. As a result, [REDACTED] has reached a critical need for a RegOps/RegSubm and IT liaison to further drive the adoption of automation, machine learning, and AI technologies throughout the company. The liaison's first project would have an initial focus on the RegOps and RegSubm work processes then will move onto interactions with external groups (i.e., Sales, ERP, Regulatory Affairs, etc.) and proprietary in-house software. Utilizing the company's existing technology-enabled applications and systems will enable [REDACTED] to experience increased productivity, improved quality, reduction of repetitive, time-consuming tasks, and enhanced return on investment.

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