BAXTER'S LLC
PROCESS AUTOMATION PROJECT

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OVERVIEW

Baxter's LLC is pleased to submit this proposal for services to support [redacted] in their commitment to big-picture thinking, targeted problem-solving, and innovative solutions. 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 lower their operation costs by 30% by the year 2024 (Gartner, 2021).

Over the last several years, health authorities have been adding mandates for electronic drug application submissions so there was already a rise in technology within the Regulatory Operations (RegOps) landscape. Then the COVID-19 pandemic accelerated the use of 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 the Regulatory Operations group and the Information Technology (IT) department. To be successful in this liaison role, an extensive understanding of the regulatory operations business as well as a strong technological aptitude is needed for leading/implementing process automation within the department on a global scale.

Baxter's LLC is equipped to fulfill this liaison role with a Business Technology/Process Consultant who is an accomplished Regulatory Operations and Information Management professional with over 25 years' experience supporting regulatory submission operations across pharmaceutical and contract research operation environments. This consultant spent most of her time in a role where being a liaison between users, consultants, IT, and management was one of her main job responsibilities. She has a Bachelor of Science degree in Computer Information Systems and has one more class to complete before receiving a Graduate Certificate for Big Data and Analytics. She will then continue schooling and is on-track for receiving a Master of Business Administration degree with a Business Intelligence and Analytics Management concentration in July of 2022 (Baxter, 2021).

The Organization

[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. These are just a few services that make this global-reaching organization essential to companies. [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. [redacted] also designs and improves technology-enabled services to meet the ever-increasing demands of this world. 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).

The Objective:

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

The Problem:

Missing liaison with extensive understanding of the RegOps 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 management and clients with real-time updates as documents travel through the RegOps 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 users on solution prior to production roll-out
- Goal #5: Train remaining RegOps users within 4 weeks following roll-out
- Goal #6: Work with IT regarding SharePoint 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

Technical/Project Approach

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, 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 SharePoint 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-publishing 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. 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 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 needed.

The Solution

Here is a simpler example of the proposed solution in action:

1. Susan in the sales department just received the client's signed proposal in a group mailbox
2. Using AI and what they call machine-to-machine (M2M) communication (no human involvement), the client email was automatically found then processed
3. The found/gathered data initiated a notification to Susan then placed the signed contract into repository
4. Susan, the sales representative, reviewed the email then initiated an event by setting the contract's status field to closed/won
5. That status change was considered an event trigger
6. Once the event trigger was completed, another automated process started
7. In this instance, the automated process sent an email to the Project Lead and created a project plan

Please note there are many touchpoints in the current process where users need to manually copy/upload files from one location to another, create a new submission record, or update an existing record's lifecycle state. Each of these items are perfect examples for process automation functionality within the Power Platform tools.

For a more involved automation scenario…

1. A client uploads files to their respective SharePoint site, the system can locate the specific Planner task card under the 'Not Received' bucket (or column) for that application, set the end date to current date, and set progress to complete

2. The next automated step would be to create a Planner task card within the PrePublish bucket, setting the start date to current date and sending a notification to the appropriate person (i.e., Publishing Lead, Publisher, or even the Manager of the assigned Pre-Publishing group). This notification or task card creation signifies to the pre-publish teams that the file is ready to prepublish

3. An available or assigned prepublisher locates the task card by a quick search, assigns themselves to the card, changes Start date to current date and sets Progress to In progress.

4. When the prepublish step is completed, the prepublisher will open the task card and do the following: set End date to current date, change Progress from In-process to Complete. This file will continue moving onto the next step in the publishing process until it reaches the end of the process.

In addition to these automation steps, the document and submission management/tracking application can be updated along the way as well. Once the application has been submitted to the Health Authority, the Publisher/Publishing Lead can export the Planner through the Planners web application which produces an Excel file containing start/stop dates and times for each file within a bucket as well as any questions/problems that may have arisen for that file. This Excel file can be added to an organization wide data warehouse which will enable data-driven insights to answer questions like…how long it really took for this file to go from start to finish, what types of files take longer to process or to review, what clients provide clean, publishing-ready files and which ones do not…so many, many possibilities with this information.

REFERENCES

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