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A REVIEW ON ROBOTIC PROCESS AUTOMATION IN PHARMACEUTICAL INDUSTRY

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ABSTRACT

Robotic Process Automation (RPA) is a technology that uses software robots or "bots" to automate repetitive and rule-based tasks within business processes. RPA is a software-based automation service that utilizes the concept of revolutionary AI technology. Robotic Process Automation, as the name suggests, relies on robots or the software for performing mundane tasks and certain business processes with higher accuracy and speed. RPA services can replace humans from repetitive jobs to bring automation in the process. The biggest advantage of robotic process automation is it can work on a 24/7 basis.

KEYWORDS: RPA services can replace humans from repetitive jobs to bring automation in the process.

RPA follows the operating procedure and involves a series of interconnected steps performed by robots to achieve a specific goal. It is a highly efficient and cost-effective technique and enables users to monitor and review the process. In the context of the pharmaceutical industry, RPA can offer several benefits by streamlining various operations and improving efficiency. Here's how RPA can be applied in pharmaceutical industries.

It throws up a new vista of research to the research community and lot many types of research are going on in this domain. It is not Robotics but is different technology altogether. RPA is a recent and fast-growing sub-domain of Robotics. The healthcare and pharmaceutics domain generate a lot of data, or we may call it medical big data, and it is all the more pertinent to analyse & evaluate such data coming from varied sources. New drug discovery, drug formulation process, drug delivery mechanisms or in-patient and out-patient activities are some of the key processes in the Healthcare and Pharmaceutical industries generating a

tremendous amount of data. Therefore, data science and RPA provides handy tools to work with such huge data volumes. RPA is proving to be the technology of future and its goal is to provide a sustainable solution that reduces costs and delivery time, improves quality, speed and operational efficiency of a business process. The application of Machine Learning (ML) technologies in the healthcare domain are proving to be beneficial and effective in gaining new insights.

The pharmaceutical sector processes large volumes of paperwork on a daily basis, dispensing over 1 million prescriptions every year. Pharmaceutical professionals must ensure full legal compliance across all activities including inventory control, clinical trial information and manufacturing.

How Can RPA Help In Pharmaceuticals?

Robotic process automation can tackle many manual processes and Robocloud aims to support your human workforce, enabling them to focus on ensuring patients receive the care they need and meeting the standards set by the General Pharmaceutical Council.

Here's a few examples

Administration

- Sort and update records – every pharmacy record is important, containing patients' confidential information including medication, treatment and medical history. RPA can sort incoming documents accurately, improving documentation and processes. Other records include.
- Orders and delivery notes
- Quality control documents
- Clinical trials information
- Dispensing labels
- Ward pharmacy requests
- Laboratory notebook data
- As part of Clear data RPA offer document storage and scanning services, enabling pharmaceutical documents to be scanned, OCR'd and sorted quickly and efficiently.
- Data validation – RPA can validate documents and compare the information to a database e.g., the comparison of delivery notes with a purchase order database.

IT

- System integration and data migration – The robots can integrate data between your various business systems. Acting as a bridge between new cloud-based systems and older legacy systems. For example, integrating data from a cloud-based CRM system into an ERP system. Allowing a seamless integration and saving time for your staff.

HR

- Employee onboarding is an opportunity for process improvement. The digital workforce can automate onboarding activities including reference checks, documentation requests and order work wear.

Finance

- Accounts statement reconciliation – the bots can automatically work through your bank statement and carry out reconciliation tasks for you such as matching receipts and checking loans.
- Automated credit checking – the digital workforce can carry out credit checks at the point you usually complete it manually. This process improvement saves time and helps protect your company when onboarding both new customers and new suppliers.

Sales

- CRM management – RPA can perform automatic updates in your CRM system in accordance with the stages of your sales process and provide the team with automated reminders to send follow up emails.
- Thanks to the digital workforce integrating systems, and storing and updating necessary information, the sales team can have easy, flexible access to accurate sales data. They can use this to identify potential opportunities and use the records to better prepare for sales meetings.

Supply and inventory management

- Supplier onboarding – The bots can onboard suppliers to ensure compliance with your standards, carrying out supplier checks and requesting third party references. Have a look at the supplier onboarding page to learn more.
- Inventory management – RPA can use demand and previous order level data to establish acceptable order quantities when stock levels of medications reach a minimum threshold, as set by your rules.

Automated Reminders

The digital workforce can send automated reminders to both pharmaceutical professionals and customers regarding various activities.

- Prescription pick ups
- Supply chain management – keeping suppliers and customers aware of the various stages that an order is progressing through and when, from order placement to shipment and delivery.
- RPA can track legislative sites and alert you of any changes or updates to legislation to help ensure that you remain compliant and implement any necessary procedures.

RPA Benefits in Pharmaceuticals

- Proof of compliance and fewer prescription errors
- Confidentiality
- Enhanced patient care
- Reduced costs
- Improve speed and accuracy.
- Built in scalability.
- Quick ROI
- Flexibility for approved persons
- Full audit trail
- Boost job satisfaction and performance

Pharma is a large industry with market size of $1.3B. And the pharmaceuticals industry has been gaining more attention with the rise of COVID-19 and the need to quickly and safely develop vaccines for the public. However, according to PwC, pharma is facing difficult challenges regarding stretched budgets, increasing restrictions and policy changes, and the large size of data that needs to be collected and analysed.

In this article, we explore RPA use cases in pharma to show how RPA can help pharma industry leaders automate mundane and error-prone tasks, generate better analyses, and improve the productivity of employees and scientists.

1. Manage clinical trial processes

Drug clinical trials involve numerous repetitive processes such as patient data entry, trial data validation, and regulatory submissions to compliance teams and auditors.

RPA can automate many processes to facilitate clinical trial management, including.

- Patient data entry
- Cross checking patient records against EHR
- Patient matching to relevant trials based on their provided data.
- Appointment scheduling and notification
- Trial File Master (TFM) management (e.g., data entry and updates, file transfers)
- Clinical trial reports generation

Trial master file management with RPA software

All activities related to clinical trials have to be registered and stored in TMF, and in many cases, those data are entered manually. With proper use of RPA, all of that information can be uploaded automatically, and with proper data structure, bots can be also used to verify which data are missing.

The list of information that should be gathered in TMF is extensive, including trial documents, details of the laboratories, shipment records, storage records, monitoring visit reports, and much more. By combining RPA software (for example UiPath) with optical character recognition (OCR), which allows converting print or handwritten text into machine-encoded text, most of the data in those documents can be easily digitized and effectively used.

Automatization in processing pharmacovigilance cases

According to an Ernst & Young report, a large pharma company processes approximately 700,000 adverse events (AE) cases annually.

It's worth noting that.

- 50% of PV resources are currently spent on managing cases that require integration of data that vary in quality, structure, and format,
- by Ernst & Young estimations by automating such manual steps the typical top biopharma company can reduce time spent on PV by 45%, with potential multimillion-dollar annual savings.

By implementing RPA software data collection and management can be radically improved, increasing effectiveness and guaranteeing significant cost reduction. We went in more detail

on this subject in our article about clinical trials automation - Automating clinical trials with RPA - step by step guide to success.

Meeting compliance and regulatory requirements with RPA

Regulatory affairs (RA) departments in pharmaceutical companies have to deal with many processes that are still manual in nature. Gathering documents, verifying if they are compatible with regulatory standards, and including them in regulatory submissions is time-consuming and error prone. In many cases, RA employees are still using spreadsheets to maintain data, which is not helping them to effectively gather and use that information.

Amount of data that have to be gathered and used to comply with regulations will only increase, a good example proving how much, can be a case described by pharma manufacturing.com, related to data that have to be created and stored, resulting from unit-level serialization required in Drug Supply Chain Security Act (DSCSA).

When employees have to compile reports for regulatory purposes, they should be able to access the documents and information quickly. It's in many cases difficult with companies using legacy IT systems that lack the ability to integrate with newer software.

RPA tools allow not only to gather data in faster and more reliable ways but also to access and compile them faster when they are needed the most.

2. Automate compliance processes

Legal frameworks governing drug production are significantly important to follow and keep up to date as they have a direct impact on the health and safety of the community. With the emergence of COVID-19, Deloitte reported that regulators have continuously been modifying their compliance regulations and approaches to tackle the pandemic.

RPA solutions can help pharma businesses achieve transparent and insightful compliance by.

- Scraping regulation websites to keep up with policy modifications.
- Validating if internal documentations comply with policies and regulations.
- Automating regulatory submissions to auditing authorities.

Additionally, all processes completed by RPA bots create audit trails that can be analysed by audit teams to generate transparency reports.

3. Enhance inventory management

Pharma inventory suffers from important challenges such as lack of planning for peak seasons (e.g., cold and flu seasons, EoY) or difficulty tracking drug shipments from origin to consumer.

RPA bots can improve inventory management by.

- Automating shipment tracking and recording delays and discrepancies.
- Automating order management processes (e.g. source-to-pay, order-to-cash).
- Automating invoices.
- Managing warehouse and storage temperatures by detecting changes from the data collected by IoT devices.
- Collecting drug expiration dates and notifying warehouse managers.

4. Automate supplier onboarding

Supplier onboarding is the processing of collecting supplier data, performing due diligence to assess their compliance measures and risks, creating, and signing a contract, and implementing the data into the company's vendor management platform. Having an accurate onboarding process in pharma reduces the risks of facing future lawsuits relevant to the vendor's compliance and ensures better data quality.

RPA bots can complete repetitive tasks in supplier onboarding to reduce data errors and ensure compliance. Some of these tasks include.

- Collecting and entering data from vendor's records (e.g. PDFs, emails, contract details)
- Cross-checking vendor data with different resources.
- Identifying mismatches between processes and regulations in vendor's records.
- Updating supplier data in the vendor management databases and software
- Sending notifications and emails to suppliers when contract is approved or when RPA in pharmaceutical industries.

Robotic Process Automation (RPA) is a technology that uses software robots or "bots" to automate repetitive and rule-based tasks within business processes. In the context of the pharmaceutical industry, RPA can offer several benefits by streamlining various operations and improving efficiency. Here's how RPA can be applied in pharmaceutical industries.

1. **Data Entry and Validation**: RPA can be used to automate data entry tasks, such as transferring data from one system to another or inputting data from paper documents into digital systems. This can reduce errors and ensure data accuracy.
2. **Regulatory Compliance**: The pharmaceutical industry is highly regulated, and compliance with various regulations (such as FDA regulations) is crucial. RPA can help by automating tasks related to data collection, reporting, and documentation, ensuring that all necessary information is accurately recorded and reported in a timely manner.
3. **Inventory Management**: RPA can assist in managing pharmaceutical inventory by automatically tracking stock levels, generating purchase orders, and managing supplier interactions. This helps in avoiding stockouts and overstock situations.
4. **Order Processing**: RPA can automate the order-to-cash process, from receiving customer orders to generating invoices and processing payments. This not only speeds up the process but also reduces errors and improves customer satisfaction.
5. **Clinical Data Management**: RPA can aid in collecting, processing, and managing clinical trial data. It can automate data extraction from medical records, patient data entry, and even data validation processes.
6. **Drug Development and Research**: RPA can assist in data analysis and data mining tasks related to drug discovery and research. It can help gather and process data from various sources to support decision-making in drug development.
7. **Adverse Event Reporting**: RPA can automate the process of collecting and reporting adverse events related to pharmaceutical products. This ensures that all necessary information is captured accurately and reported to regulatory agencies as required.
8. **Contract Management**: RPA can automate contract creation, review, and management processes. This is particularly beneficial for handling contracts with suppliers, distributors, and other business partners.
9. **Quality Control and Assurance**: RPA can play a role in automating quality control processes, such as inspecting products and ensuring they meet regulatory standards. This can include automating checks for labeling accuracy, batch consistency, and packaging integrity.
10. **Customer Support**: RPA can be used to automate certain aspects of customer support, such as responding to common queries, processing returns, and managing product inquiries.

Pharmacovigilance

Given the huge amount of adverse event data that companies must periodically process pharmacovigilance is one of the main areas that could benefit from robotic process automation. Currently, companies tend to manually manage case reports because the data vary in quality, structure, and format and are not easily integrated. Robotic process automation could be the answer to this problem, allowing companies to process an increased caseload while maintaining the current cost base.

Furthermore, robotic process automation has the potential to aid marketing authorization holders (MAHs) in active searches of databases such as the EMA's EudraVigilance database, which tracks individual case study reports (ICSRs) of suspected drug side effects. A robotic process automation bot can access the EudraVigilance database and download ICSRs on a daily basis; then, the bot can automatically analyse all the ICSRs based on predefined rules to decide if a case is related to the MAH's products and/or to active ingredients used in the MAH's products.

Regulatory Submissions

In the regulatory submission process, RPA solutions can speed up certain required activities, such as document status tracking and creating a records dossier, thereby shortening the process timeline and the time to market. Steps to bring value with RPA include mapping the document landscape to understand compliance requirements, walking through the as-is process to identify pain points and areas for improved user experience, developing a new automated workflow enabled by RPA, and proving the technology can manage the new workflow with better compliance at a reduced cost.

Implementing RPA in the pharmaceutical industry requires careful planning, process analysis, and integration with existing systems. While RPA can bring significant benefits, it's important to choose the right processes to automate and to ensure that data security and compliance are maintained throughout the automation process. Additionally, as technology evolves, more advanced capabilities like cognitive automation and machine learning can be integrated with RPA to further enhance its capabilities in the pharmaceutical sector.

Many procedures and tasks across sectors require a significant amount of time and people to execute, which has a direct impact on productivity and resulting in reduced profit margins. Robotic Process automation can be beneficial in this circumstance. Robotic process

automation (RPA) has seen a major surge in recent years, with many firms aggressively pursuing and adopting efficient pre-programmed software bots to handle repetitive, time-consuming, and more error-prone jobs. Speaking particularly of the pharmaceutical industry, some of the primary challenges it faces include expensive drug testing expenses, regulatory fees, the availability of new treatments on the market, and many other factors. RPA digitization and automation provide pharmaceutical firms with the tools they need to thrive, from enhancing the patient experience to optimising organisational agility and assisting in the achievement and maintenance of regulatory compliance. The result of robotic process automation in supply chain management is a 43%-time reduction in billing, data administration, credit, and collections, among other things, which is a major victory for any firm. RPA in supply chain management improves productivity, costs, and other metrics for the firm.

CONCLUSION

In the highly regulated pharmaceutical sector, RPA solutions can enable organizations to comply with regulatory guidelines while taking full advantage of automation and innovation. Furthermore, RPA can decrease labour costs, reduce the time spent by employees on repetitive and noncore tasks, and reallocate users to higher value-added activities. In a nutshell, adopting RPA helps pharma companies bring safe and effective drugs to market in a shorter time and at a lower cost.

Declarations

Conflicts of interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Abbreviations

RPA: Robotic Process Automation

OCR: optical Character Recognition.

CRM: Customer Relationship Manager.

ROI: Return on Investment.

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