COMPLIANCE NEWSLETTER 09/2020

ACHIEVING BUSINESS PROCESS EXCELLENCE

Best practice: Using process mining and RPA in a regulated environment

A key metric from the Regulatory Affairs department illustrates the enormous effort involved when coordinating between pharmaceutical companies and regulatory bodies: Approximately every fifteen minutes, the Regulatory Affairs department submits a document for review to authorities such as the FDA or EMA somewhere in the world. In order to shorten the workflow associated with this process, as well as the associated data processing, one can evaluate the potential benefits of new technologies such as Process Mining, Robotic Process Automation (RPA) and Text Mining. RPA in particular proved to be an effective digital assistant that was able to take over some of the workflows completely and also increase process quality - for example, by using a corresponding RPA tool to automatically enter feedback from the authorities into the document and workflow systems.

Companies in the life science sector are familiar with the general challenge this example is based on: How can business processes be transformed so that the trade-offs between several challenges are successfully addressed? For example, when it comes to generating competitive advantages such as reducing the “time to market” of products or services while at the same time maintaining global regulatory compliance?

Business process excellence as a success factor

Business Process Excellence (BPE) provides adequate answers and solutions. This includes various areas (see figure 1) that need to be analysed and evaluated. All of these areas strictly focus on processes and their continuous improvement.

In this context, compliance and IT managers should use two approaches in particular: Firstly, an indicator-based business performance management system that helps decision-makers to identify critical developments in the company at an early stage and to take appropriate countermeasures. Here, process mining technologies provide valuable

QUALITY RISK MANAGEMENT IN GDP – TRANSPORTATION RISKS

Quality Risk Management (QRM) is a requirement of Good Distribution Practice (GDP). It provides an approach that enables the GDP quality system to be safe for patients, efficient and effective through identification of risks, and facilitates proportionality of mitigation. Quality risk management should ensure that the evaluation of the risk is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient. The level of effort, formality and documentation should be commensurate with the level of risk (EU GDP Guidelines SI 2013/C343/01).
The following common weaknesses with GDP quality risk management are identified by the MHRA:

- Risk assessments are not reviewed
- QRM is used as an excuse to avoid developing appropriate mitigation
- QRM is not understood by managers

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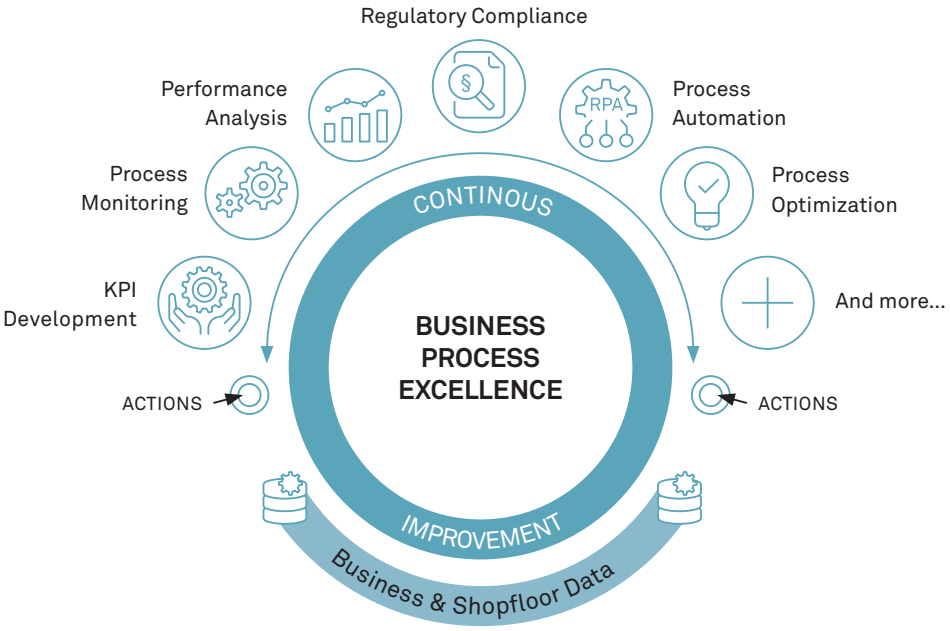

Figure 1: Business Process Excellence areas © msg advisors

support, for example by collecting and analysing existing business processes using the available log data. Key questions here include: Which process variants exist? Which process steps are carried out in which sequence and at which time intervals?

What are the differences between defined target processes and the actual daily execution of the respective process?

Secondly, attention should focus on business process management. In this area of activity, the aim is to optimise business processes. This can be successfully achieved by automating key processes, among other things. Thus, Business Process Management is the main point of entry for the application of RPA and other technologies related to digital transformation. A closer look at the process industry shows that business processes within a company are already recorded and managed at various levels via ERP and MES systems. It also reveals that there is further potential for optimisation in many areas, which can be exploited by using RPA in combination with the already existing systems. In general, the main focus is on the process requirements and the objective of making the best possible use of business & shop floor data.

RPA as a driver for excellent processes

It is precisely at this interface that RPAs provide valuable support as "technology building blocks". With robotic process automation, software robots (bots) learn to perform repetitive, manual, time-consuming tasks and carry them out automatically. In a manner comparable to human performance, the bots can even control applications.

The other main advantages of RPA tools are that they can not only be transferred to existing IT systems without much time effort, but are also inexpensive to purchase - in general, their initial cost and implementation can be recouped within one to two years. This makes

FDA TAKES ACTIONS TO RESUME ON-SITE INSPECTIONS

After a temporary break from their regular inspection cycles due to the ongoing pandemic, national health agencies such as the FDA or MHRA are planning to resume their on-site inspections. To comply with national measures to combat the spread of Covid-19, both regulatory bodies take a risk-based approach to determine the feasibility of on-site inspections. The FDA specifically released a guideline document explaining both their risk assessment process as well as the determination of "mission-critical" inspections. Comparing these guidelines with the recent statement of the MHRA declaring their return to on-site inspections, common factors in their approaches include:

- Adjusting the intensity/level/duration of on-site activities based on regional trends of infections and continuously incorporating remote assessments whenever possible
- Sending prior notice to companies to allow for arrangements concerning staff safety and availability of key personnel
- Continuation of inspections on critical areas/processes/sites relevant to overall public health or COVID-19 response specifically

the technology very popular: sales of RPA software are forecast to grow from $151 million (2016) to over $5.1 billion (2025) (1). But what are the actual benefits or the spectrum of applications of RPA in daily operations? This is illustrated by the following use cases.

Use case 1: Shortening time to market
In the case of a medical device manufacturer, RPA takes on the task of improving the process chain surrounding the applications for market approval of new products. To this end, the software collects data from various systems on the course of the clinical studies. In most cases the application process takes several years. In this case, the aim of the RPA is to shorten the time to market cycle while maintaining compliance.

Use case 2: Reducing complexity
A pharmaceutical company requires technological support in the preparation of an annual report on the payments to healthcare professionals and organizations. This involves a high degree of complexity as the payment data is scattered across different IT systems. In addition, new codes and guidelines were introduced (Sunshine Act) to ensure high integrity standards. In this case, the RPA tool can automatically compile all the required documents, with integrated rules and controls to ensure compliance. Meanwhile, the results and adherence to process compliance can be measured and monitored via process mining.

Success factors when using RPA

In the above-mentioned use cases as well as in other projects, it has repeatedly been shown that continuous monitoring and constant optimisation in response to changing conditions and the latest findings are decisive for the long-term success of an RPA deployment. In addition, there are several important key elements in the project phases for the selection, implementation and application of RPA. For example, one should not only identify potential areas for optimisation and innovation and possible solutions, but also test the performance of the RPA in practice as part of a lighthouse project. If successful, this project can serve as an ideal starting point for the creation of a company-wide roadmap for the deployment of RPA. Last but not least, appropriate governance structures should be created and competencies and capacities should be developed right from the start of the project to ensure successful deployment and daily operation of the RPA application.

About the Author

Alisa Schmidt is a consultant at msg advisors. The main focus of her consultancy work is on business process excellence and digitisation in the life science industry.

(1) Der Markt wächst ("The market is growing"). commagazin.de, 2018.

EU RELEASES A CHECKLIST ON - HOW TO PREPARE FOR THE BREXIT

The end of the Brexit transition period is getting closer and an agreement is not in sight. Having first published a notice on preparing for the Brexit for companies, governments and citizens, the European Commission has now published a suitable checklist on: How to prepare for the Brexit. This checklist is intended to help EU companies doing business in the UK and/or UK companies doing business in the EU to check in detail how good they are prepared for 1 January 2021. Some key points are: the responsibilities for import and export of goods; customs clearance and the termination of the EU regulation on the production and use of chemical substances.

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