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EMBEDDED PROCESSES – EVOLVING FACE OF QUALITY IN THE WORLD OF ROBOTIC PROCESS AUTOMATION (RPA)

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ABSTRACT:

Systems and processes have been the backbone of any emerging and existing organization in clinical domain. The password to live a disease-free life is the 'most wanted' i.e., 'drug'. In search of this 'most wanted' fugitive, drug companies are investing in their best possible detectives. Quality and compliance management is the key, ensuring subject safety and data integrity in our domain falling in line with the regulatory requirements.

Evolution from a paper-based quality system to electronic systems led to the emergence of regulations and guidelines such as 21CFR PART 11 and GxP. Evolving further towards Robotic process automation (RPA) – how will quality be perceived and implemented is the problem statement. RPA does not involve any form of physical robots instead it is the software robots which mimic human activities by interacting with applications in the same way that a person does. All will have the tools to configure their own software robots to put an end to automation challenges.

Ethics, human resources will be important along risk and change management, feedback management and root cause analysis from a compliance oversight point of view. Transparency, cybersecurity, platform resilience are the critical risk areas requiring high impact controls. Enhancing process efficiency and efficient methodologies for compliance would be important in the phases of development, testing, deployment, integration and owning the process too. The focus of regulatory bodies, employment opportunities, scope for innovation and organizational strategy to embrace the new culture of 'embedded process' will be the focus of this paper.

INTRODUCTION

RPA is not about robots. The technology is based on applications robots. Robotic process automation refers to the use of software robots that operate on top of existing IT infrastructure or systems (your APIs and existing software user interfaces) to execute specific business functions.

Unlike software in the traditional sense, these bots mimic the behavior of an end user, meaning that they interact with the front-end infrastructure that is already in place. This makes them API-agnostic, so naturally, their integration capabilities are unparallelled.

RPA's core purpose is to automate repetitive functions such as manual data entry so that workers can execute tedious tasks with much greater speed and efficiency and focus instead on the workflows and business goals that matter most to them.

RPA can be described as introducing digital labor into a governance structure in order to carry out tasks originally considered to be capable of performing only by humans.

AUTOMATION – A REAR VIEW

1776 Adam Smith writes "Wealth of Nations" where he describes the concept of "division of labour"

1760–1840 Industrial revolution gathers steam as machines take over more manufacturing processes previously done by hand. In the two centuries since the industrial revolution, the world's average per capita income has increased over 10-fold, while the world's population has increased over 6-fold.

1911 Frederick Winslow Taylor publishes "The Principles of Scientific Management" for the American Society of Mechanical Engineers. The work advocates the "enforced standardization of methods, enforced adoption of the best implements and working conditions, and enforced cooperation" in order to improve efficiency. Although hugely unpopular with workers at the time and now considered largely obsolete, Taylor's work laid the foundation for modern industrial engineering.

1913 Henry Ford introduces moving assembly belts into plants producing "Model T" cars in order to increase efficiency. By 1916, the car cost less than half of what it cost in 1908.

1920's Walter A. Shewhart at Bell Laboratories pioneers the use of Statistical Process Control (SPC). SPC focused on detecting and preventing manufacturing issues before they became problems—an advantage over methods like inspection which meant throwing out defective products.

Advances in Quality Management & Early Computing

1940s-1970s Japanese engineers Taiichi Ohno, Shigeo Shingo and Eiji Toyoda are credited with developing the Toyota Production System—sometimes called "Just in Time Manufacturing"

1941 Conrad Zuse develops the Z3, often considered the world's first digital computer. Developments in computer technology advanced rapidly in the 40s and 50s. These computers took up an entire room and could only perform basic math calculations.

1950s Dr. W. Edwards Deming, an American statistician who had worked with Shewhart, trains hundreds of Japanese engineers and businessmen in SPC and concepts of quality. Joseph Juran, a Romanian born American engineer also influenced by Shewhart's work, moves to Japan to teach quality management methods. By the 1970s Japan was considered the world leader in quality.

Advent of the era of digital process management

1980's America has crisis of confidence as Japan's economy roars ahead and American-made products are largely seen as inferior in quality. American TV network NBC runs a documentary called If Japan Can, Why Can't We? seen as the moment where the works of Dr. W. Edwards Deming was popularized in the West.

1980's FileNet develops a digital workflow management system designed to route scanned documents through a predefined process. This early system—later acquired by IBM—is often cited as the precursor to modern BPM Software.

1986 Engineers working at Motorola pioneer the use of Six Sigma, a new technique for process improvement. Six Sigma uses statistical methods to identify causes of and then reduce variation (seen as the cause of problems that can lead to defective products or services) in processes. Although similar to SPC, Six Sigma, was credited for moving quality management out of being just a bunch of statisticians in a backroom.

1990 James Womack, Daniel Roos and Daniel T. Jones publish The Machine That Changed the World about the Toyota Production System. The book looked at how the company's system of "Lean" production produced superior results to those of traditional mass manufacturing.

1993 Michael Hammer and James A. Champy publish Reengineering the Corporation: A manifesto for Business Revolution, which sparked off a fervour of Business Process Reengineering (BPR) initiatives in Fortune 500 companies. In contrast to TQM or Lean, BPR focused on radical transformation rather than iterative, continuous improvement of processes. By the late 90s BPR had largely fallen out of fashion.

1980s/1990s Advances in computer technology and processing speed means that Personal Computers (PCs) start to experience widespread adoption by both companies and individuals.

1986 Dr. W. Edwards Deming publishes "Out of the Crisis" (originally published as Quality, Productivity and Competitive Poison in 1982) where he proposes a management theory based on his famous 14 points.

1990 Analyst firm Gartner coins the acronym ERP—"Enterprise Resource Planning." By the mid-1990's ERP tools handled all sorts of back office processes and data including accounting, HR and maintenance as well as front office processes supported by CRM (Customer Relationship Management). Thus begins the digitization of enterprise data and processes.

1990's Many companies adopt Total Quality Management (TQM)—a method similar to Six Sigma but also incorporating aspects of the Japanese system of continuous improvement.

1995 Jack Welch, CEO of General Electric, makes Six Sigma a key part of managing the company. By the late 1990s, most Fortune 500 organizations had begun Six Sigma initiatives to reduce costs and improve quality.

Era of Business Process Management

2000s Analyst firm Gartner coins the term "Business Process Management Suite" to refer to a vast array of software applications that deal with processes (whether carried out by machines or people). The term "workflow" falls out of fashion in IT circles (although some argue it made a comeback in the late 00's).

2007 BusinessWeek runs an article entitled "Six Sigma: So Yesterday?" about how major companies like Home Depot, GE, and 3M, were either abandoning or reducing their Six Sigma programs.

2013 Where will the combination of process and technology take us next?

2000s Business Process Management software advances to handle a wide range of functionality from process modeling, management through to reporting and analytics.

2012 Gartner coins the term intelligent Business Process Management (iBPM) to refer to BPM Suites that include support for analytics and complex event processing. Forrester coins the term Smart Process Applications to refer to

BPM software that supports collaborative processes and incorporates data, analytics, and content.

RPA hands individual tasks over to software robots to streamline, and BPA takes an entire business process and automates it from start to finish.

BPA VS RPA

- Business Process Automation: BPA focuses on restructuring the actual core operations and workflows of a business to make day-to-day tasks more efficient
- Robotic Process Automation: RPA uses software to augment the performance of existing processes

BPA overhauls the processes with the capability to remove roadblocks and create smooth workflows. RPA, on the other hand is quicker and adaptable.

RPA –

- Boosts productivity with minimal process change. As a result, the process in place is unchanged, eliminating data integration and analysis efforts.
- Brings an easy-to-calculate ROI. The cost of an RPA robot will range from $5,000 to $10,000 annually. In some use cases, there is a one-to-one relationship between a robot and a worker. In others, a single robot replaces three to five workers.
- Savings are easy to calculate.
- Is a fresh alternative to the “big spend” of typical BPM programs. Business process management (BPM) as a technology strategy too often drives a wedge between the business and the technology management organization. BPM has a legacy of long implementations and fuzzy business cases — the opposite of RPA.

RPA – BENEFITS:

Few benefits of RPA include:

- Time and Cost Savings – An EY report on Robotic Process Automation for HR & Payroll says that RPA reduces Time to Process forms from 2 hours to 3 minutes and enables a cost reduction of 50% to 70%.
- Reduced risk – RPA can be overlaid on existing systems and does not require major system upgrades, which makes it low risk and non-invasive.
- More effective work force – With the increase in efficiency and automation brought by RPA, companies will be able to bring together smaller, more specialized and effective teams.
- Reduction of manual errors and compliance risks – With data being handled by RPA technology, human contact with sensitive and important data can be minimized. This reduces the risk of error and of information getting into wrong hands.
- Increased scope for data collection – With RPA “bots” uncovering data by interacting with legacy systems, the scope for data collection increases. High quality data that could otherwise take years to gather can be made available quickly and eiciently to the Analytic teams.

RPA – THE TECHNOLOGY:

Team RPA is the application of technology that enables a human to configure computer software or a "robot" to capture and interpret existing applications for processing a transaction, leveraging data, triggering responses and communicating with other digital systems.

Traditional IT automation relies on and leverages only programmatic interfaces, such as APIs. RPA leverages user interfaces, as well as APIs, to automate a business process from end-to-end. RPA can combine the abilities of a human user with the abilities of the software (robots) to provide a greater range of service capabilities.

RAP – THE IMPLEMENTATION:

Identifying the right process is a critical step and is the key to the success of an automation initiative. A suitable framework needs to be employed to ascertain the fitment of a process for automation and to prepare for a priority-based roadmap. The framework can view the process for different perspectives – for e.g.

1. Appropriateness: Appropriate degree of automation suiting the needs is important.
2. Value: Financial value including cost benefit ratio; strategic value including efficiencies impacting customer satisfaction
3. Risk – Benefit analysis:

A suitable RPA candidate is expected to have the following attributes:

1. Medium to Low – volume of human transactions and requirement to scale
2. Medium to High – Labour involvement and repetitiveness of tasks
3. Low to Medium – status/stage of automation required
4. Medium to High – Bottlenecks and dependencies involved
5. Medium to Low – Customer satisfaction index and alignment
6. Medium to High – Risks involved
7. Medium to Low – Change/Upgrade of the tool/process in near future
8. Medium to High – Tactical importance

Key points which deserves attention in RPA implementation is:

1. Centralization of the activity: The effectiveness of the implementation has to be tested in one of the geographies/departments before it is rolled out across the organization/geographies. There will be challenges related to maintenance, debugging, configuration and support – it is very important to consider these factors before implementation.
2. Structured vs Unstructured process: RPA is extremely well-suited for defined workflows and structured processes. However, in cases of unstructured process without a defined workflow system, implementation of RPA is a challenge. The cost-effort analysis involving such cases must be considered before implementation.
3. Process stability: Regulatory requirements or business requirements might make few processes or steps prone to frequent changes. Task of automating such process involves high risk since the cost of change management is high

To create a strong foundation, enterprises particularly focus on:

1. Integration and position of the RPA unit

2. Structuring and establishment of a Centre of Excellence

3. Organisation of RPA staff

4. Definition of strategy

Integration and position of the RPA unit:

There are many ways in which an enterprise may choose to be organized in order to get optimum effect of RPA. Where exactly to embed RPA and how to otherwise adapt the organization to incorporate RPA depend on the enterprise's strategy, structure and culture. In global enterprises that have shared service centers, RPA is often integrated in the SSC, either through an internal RPA team or through an outsourcing partner. The enterprises consider the Shared Service Centers a good choice, as the automation potential gathered in one place is typically quite substantial, and they constitute a good starting point for the establishment of an RPA service unit that can assist the entire business. The remaining enterprises that have no shared service centers, or want to keep their RPA initiatives local, either integrate RPA in a business unit or in the IT function. The location typically depends on the possibility of obtaining a sponsor in one function instead of the other or is based on a strategic choice as to ownership.

Structuring and establishment of a Centre of Excellence

Enterprises use their CoE for:

1. Managing the operation and the RPA initiative: The CoE oversees the RPA initiative, and the centre also decides how to operate the RPA initiative. Often, RPA employees located in the CoE will drive the roll-out and implementation of the RPA in their capacity as project managers, business analysts and RPA developers.

2. Ensuring quality: Through well-defined standards, procedures and guidelines, owned and developed by the CoE, the enterprises obtain high quality RPA solutions.

3. Prioritizing: The CoE helps enterprises prioritize processes with automation potential. Several of the enterprises make use of a gatekeeper function in the CoE who approves all automation procedures, before they are put into production. This also allows the CoE to assess whether RPA is the right tool for this process optimization, or whether other IT solutions would be more useful.

4. Developing talent: The CoE is responsible for RPA training and instruction of employees.

5. Communicating with stakeholders: A coordinated communication effort is often driven by the CoE.

6. Ensuring compliance: The CoE ensures that all robots and processes comply with the guidelines issued by compliance and security.

Organization of RPA staff

Enterprises organize themselves in three different ways, each of which has its advantages and disadvantages. The choice as to how they organize themselves is strongly linked to the strategy behind the initiative.

Central operation of RPA: Everything is managed from the CoE. All RPA employees work at the same location, and all RPA-related assignments are carried out and managed from the CoE. The enterprises that have chosen this approach experience that central operation ensures high quality, synergies and tight control. On the other hand, the approach is less agile, which may lead to bottlenecks and business units feeling excluded. The centralized model is the most commonly used model among the participants of the survey.

Decentralized operation of RPA: When having decentralized operations, the majority of the RPA initiative is driven in the various business units. The CoE's role is solely to make the correct settings available (RPA software, infrastructure, standards, etc.), after which the business units will have their own RPA teams, including business analysts and developers. In this case, the perception of the enterprises is that the approach is agile, and that the business has complete control and may implement processes at their own pace. On the other hand, the quality of the solutions is lower, and, on occasion, duplication of work is performed across the business units due to the less coordinated work effort. The decentralized model is the least used model among the enterprises participating in the survey.

Hybrid operation of RPA: A hybrid model mixes the elements of the centralized and decentralized models. Enterprises using this approach establish a strong central CoE, but with local RPA units capable of identifying processes, and documenting and developing simple solutions. The enterprises applying this model find that it contributes to high quality due to quality checks between the CoE and the local teams as well as a high degree of agility as a result of the local presence.

Definition of strategy

An RPA strategy can be defined as a set of instructions, which guides the RPA initiative and clarifies how RPA must be applied by the enterprise.

RPA – ROLES INVOLVED:

Central roles in the RPA unit

Enterprises typically divide their RPA specialists into business analysts, developers, controllers, and project managers. However, the roles are far from always this well-defined. Particularly in the start-up phase, where the RPA unit is still relatively small, the enterprises choose to let business analysts, developers or process owners be controllers for the solution. Often during the start-up phase, not everyone is on the RPA project full time.

RPA business analyst: A business analyst identifies the processes which are assessed to hold a potential for application of RPA. They document the processes as they are now and then re-design and transform the processes, in order to reap the largest possible benefits from the use of RPA. The business analyst works closely with those who perform the processes on a day-to-day basis and the RPA developers.

RPA developer: RPA developers configure the RPA solution in the RPA software. The development is based on the process documentation, which has been prepared by the business analyst. Concurrently with the configuration, the developer must document the RPA solution to ensure that other developers will be able to understand and maintain the solution.

RPA controller: An RPA controller's task is to monitor all the RPA solutions that are in operation through a virtual control

room. The controller must ensure that the RPA solutions run without problems, that they have been scheduled for the right times, and that there is sufficient capacity in the form of activated licences to handle the transaction volumes. In the event that an RPA solution comes to a standstill, the controller is obliged to inform relevant stakeholders.

RPA project manager: An RPA project manager's role is to coordinate the other RPA roles' assignments to ensure an effective and successful implementation of an RPA solution. The project manager has the overall responsibility for the final solution and may work on one or more RPA projects at a time.

RPA – CHANGE MANAGEMENT

There is often a certain degree of skepticism among the employees when the word "robot" is mentioned, and in the experience of the enterprises, many employees are afraid that an RPA implementation will lead to redundancies. Change management is an important aspect when a firm intends to implement RPA. RPA will free up capacity, and it is important to have a clear idea of what to use this capacity for and how it is communicated to ensure that employees do not fear RPA. By focusing on change management and good communication early on, employees will see RPA as a help in their day-to-day work and not as an enemy

(a) Investing time in defining new roles and responsibilities for the teams managing the implementation cycle, operational realignment and service governance.

(b) Ensure the target operating model (TOM) is in place. Operations should be aware of the prerequisites of RPA, what needs to be completed prior to moving into business as usual (BAU) and the controls around the automation book of work.

(c) Reframe policies and redesign the key performance indicator (KPI)/key risk indicator (KRI) model for the virtual workforce. After investing in automation, an organization cannot accept accuracy standards that are similar to those for the human workforce; they need to assess and set up new standards of quality measurement.

(d) Plan communication and the impact of the change on the existing workforce.

(e) Conduct training. The business users need to be adequately trained to enable them to interact and interface with the bots, especially in the case of changes in business processes. Reskilling of the workforce that is being freed up will be a major factor for the overall success of automation.

(f) Manage knowledge. Usually, bot creation would be done by an implementation partner or the vendor. The relevant knowledge on bot creation and maintenance has to be passed to internal staff for a seamless transition. Organizations assessing RPA applicability should develop a long-term strategy and involve key people from the strategy team, business unit and the technology team to define value drivers and owners of the RPA initiative upfront. They should focus on automating cross-functional end-to-end processes across multiple stages instead of deploying bots in pockets. Once an organization has pondered over all the said challenges and obtained leadership buy-in, they should deploy a robust change management approach to engage employees throughout the organization.

Evaluating all the vendor selection challenges optimal technology solutions to meet the long-term objectives. In order to harness the full potential of RPA, companies need to view RPA as part of their strategic goal rather than a tactical one.

RPA – STAKEHOLDER MANAGEMENT

Changes or ambiguity as to ownership will delay and complicate the implementation. Lacking or late buy-in from executive management may slow down the implementation process

RPA – ROLE OF IT

The following three reasons pose a challenge for the enterprises:

1. Unclear division of roles between the business and the IT function

2. Setting up a solid IT infrastructure, including access rights and security

3. Choice of software

Normally experienced two issues with reference to access rights and security:

1. Challenges in terms of assigning the necessary user access to the robots

2. Challenges in terms of ensuring solid governance of user access to mitigate the risk of misuse.

The enterprises' points of evaluation in terms of RPA software include:

• Functions and user interface

• Maturity and level of ambition

• Pricing and licencing structure

• Training, support and business partners

• Recommendations and references

• Ability to handle assisted and non-assisted RPAs

• Degree of necessity for involvement of IT competencies, including the possibility/need for programming of software

• Supplier's ability to prove the business case

• Opportunity to test the software for a period

• Scalability of set-up

• Administration of roles and security.

Security concerns

Organizations selecting RPA tools must evaluate on the following criteria to ensure data security and integrity:

1. Data encryption
2. Access movement through credential vault
3. Authentication and authorization
4. Version control
5. Alert/alarm system
6. Audit trail
7. Ease of integration with other applications

RPA – RISKS

To avoid the introduction of a potentially systematic risk within an organization, RPA implementation teams should:

• Expect enhanced regulatory and internal audit scrutiny — articulate and document visions, approaches, rationales and recognition of process, risk and control considerations

• Create and preserve artifacts — create document repositories and connections to existing governance, risk and control (GRC) platforms that are linked to processes, risks and controls to demonstrate framework adherence and evidence traceability

• Anticipate production disruptions following deployment — establish handling procedures for timely resolution of issues identified to minimize the impacts on connected operations

• Embed risk and control involvement — entertain the inclusion of a dedicated work stream to proactively foster risk and control consciousness, including participation in a seat-at-the-table capacity during agile development working sessions (e.g., Scrum)

• Assess consistency of control process, risk and control inventories — determine overlaps and disparities with the organization's technology risk and control inventory

• Plan accordingly for delayed deployments — recognize that stage gates (and, therefore, buffers) may need to be incorporated into timelines to manage risk and control implications during agile development efforts

• Challenge the audience and degree of progress and risk reporting — understand the desire for reporting about benefi t realization, concentration risk, control adherence and resulting people risk management

• Consider synergies of the risk and control work stream — recognize that content within a process, risk and control work stream can be pivoted to serve as an internal audit work plan to evaluate the RPA implementation

• Determine the new role of people — recognize that roles and responsibilities will be altered as a result of RPA implementations, yet oversight and monitoring are critical to foster control and sustainability

IPA – EVOLVED RPA

IPA is an emerging set of new technologies that combines fundamental process redesign with robotic process automation and machine learning. It is a suite of business-process improvements and next-generation tools that assists the knowledge worker by removing repetitive, replicable, and routine tasks.

IPA in its full extent encompasses five core technologies:

- **Robotic process automation (RPA)***:* a software automation tool that automates routine tasks such as data extraction and cleaning through existing user interfaces. The robot has a user ID just like a person and can perform rules-based tasks such as accessing email and systems, performing calculations, creating documents and reports, and checking files. RPA helped one large insurance cooperative to reduce excess queue procedures affecting 2,500 high-risk accounts a day, freeing up 81 percent of FTEs to take on proactive account-management positions instead.
- **Smart workflow:** a process-management software tool that integrates tasks performed by groups of humans and machines (for instance, by sitting on top of RPA to help manage the process). This allows users to initiate and track the status of an end-to-end process in real time; the software will manage handoffs between different groups, including between robots and human users, and provide statistical data on bottlenecks.
- **Machine learning/advanced analytics***:* algorithms that identify patterns in structured data, such as daily performance data, through "supervised" and "unsupervised" learning. Supervised algorithms learn from structured data sets of inputs and outputs before beginning to make predictions based on new inputs on their own. Unsupervised algorithms observe structured data and begin to provide insights on recognized patterns. Machine learning and advanced analytics could be a game changer for insurers, for example, in the race to improve compliance, reduce cost structures, and gain a competitive advantage from new insights. Advanced analytics has already been implemented extensively in leading HR groups to determine and assess key attributes in leaders and managers to better predict behaviors, develop career paths, and plan leadership succession.
- **Natural-language generation (NLG):** software engines that create seamless interactions between humans and technology by following rules to translate observations from data into prose. Broadcasters have been using natural-language generation to draft stories about games in real time. Structured performance data can be piped into a natural-language engine to write internal and external management reports automatically. NLG has been used by a major financial institution to replicate its weekly management reports.
- **Cognitive agents:** technologies that combine machine learning and natural-language generation to build a completely virtual workforce (or "agent") that is capable of executing tasks, communicating, learning from data sets, and even making decisions based on "emotion detection." Cognitive agents can be used to support employees and customers over the phone or via chat, such as in employee service centers. A UK auto insurer that uses cognitive technology saw a 22 percent increase in conversion rates, a 40 percent reduction in validation errors, and a 330 percent overall return on investment.

Intelligent automation promises to improve efficiency, quality, customer experience, and more. It will have applications in all parts of the business, from IT to human resources, operations to finance.

CONCLUSION

RPA is:

- Virtual ‘robot’s integrated with existing software
- Configurations that automate manual and repetitive tasks
- Driven by simple rules and logic

It is normally applied to processes with the following characteristics:

- High volume and handling time
- Fixed procedures must be followed
- Standardized and mature
- Manual and rule-based
- Stable across IT systems

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