ISSN: 0976-3376

Available Online at http://www.journalajst.com

ASIAN JOURNAL OF SCIENCE AND TECHNOLOGY

Asian Journal of Science and Technology
Vol. 09, Issue, 05, pp.8242-8245, May, 2018

RESEARCH ARTICLE

DEVELOPING MEDICAL PROTOTYPES WITH GAMIFICATION

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ARTICLE INFO

Article History:
Received 17th February, 2018
Received in revised form
06th March, 2018
Accepted 16th April, 2018
Published online 30th May, 2018

Key words:
Gamification, Medical prototype, Performance management, Motivation.

ABSTRACT

The development of medical prototypes is an industrial process with a strong research and development component in the laboratory where all activities, although of a confidential nature, are monitored. In addition to being followed worldwide standards without a pharmaceutical sector, many of them defined by the US Food and Drug Administration (FDA), are not all the activities of the medical and pharmaceutical industry that involve the emission of different types of radiation; it is necessary to define a pattern in order to ensure that it is executed from running activities. This paper focuses on a literature review of different practices of industrial development of medical prototypes and application of the concept of Gamification to different projects, without context of performance management.

INTRODUCTION

More and more organizations create dynamic environments, where internal and external changes are constant, and the creation and use of innovative management and operation models is urgent. These models must be composed of business and industrial processes capable of dealing with this type of change and with the necessary constant innovation, so that the organizations become more competitive (Bradley *et al.,* 2011). According to (Kang and Han, 2008), the current industrial models of management, practiced on a large scale in many large companies, are based on military methodologies and practices, though sometimes discarded by many economists. However, in the conclusion of his study, while following a military analogy, he finds that a team consisting of very weak employees with salaries below the national average of the country concerned is not a threat on the market, as opposed to a team consisting of efficient collaborators and with above average salaries. In the perspective of (Bradley *et al.,* 2011), this is a strategic approach that allows defining a value-added business architecture, although its study focuses on the alignment between processes, technology and risk management. This document is structured as follows: i) Introduction, ii) Development of medical prototypes, iii) Use of the Gamification concept in performance management activities, and iv) Conclusions.

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Development of medical prototypes

Medical device prototyping is fundamental to your medical product design and development process. Creating early samples of your health technology products gives you the opportunity to test and evaluate the concept and work on further improvement. Get to market faster, with clinically significant and marketable products, and the main challenge of developing medical equipment. Medical devices in the United States are categorized according to their perceived risk. FDA uses a 3-tier system to classify devices of progressively higher risk (identified from low to high risk as Class I, II, or III devices). The process for creating novel medical prototypes benefits greatly from an understanding of the larger regulatory structure surrounding the healthcare industry.

Medical Device Classifications:

- Class I Medical Devices: The lowest risk classification a medical device can be labeled by the FDA is Class I. Class I devices are subject to "Special Controls." An example of a class I device might include medical wrap or handheld medical instruments;
- Class II Medical Devices: Class II medical devices are those devices that exhibit moderate risk to the user and for which "General Controls" have been found insufficient to ensure safety and effectiveness. Class II

devices are subject to both "General Controls" and "Special Controls". An example of a class II device might include acupuncture needles or a powered wheelchair

- Class III Medical Devices: Class III medical devices are those deemed to have the highest associated risk. They include things like pacemakers, coronary stents, and heart valves - all devices that are life-sustaining/supporting, of substantial importance to preventing the degradation of human health, or which present a significant risk to the user. Typically, Class III devices require Pre-Market Approval (PMA) from the FDA before they can be legally marketed. They are also subject to "General Controls." Getting PMA approval is a lengthy process requiring clinical data that demonstrates the safe and effective use of the device in its target population (Prutchi and Norris, 2005).

For development prototype in Biomedical Engineering, SOLIDWORKS is the preeminent software for computer-aided design and computer-aided engineering. Multiple parts can be combined together into assemblies by assigning relationships (called "mates") among various features. Both assemblies and individual parts can be turned into engineering drawings where things like dimensions, notes, and revision numbers are typically catalogued. The software is basically a one-stop shop for design so that you can turn ideas into reality. (Monteiro, 2017) After the design, the 3D printing solutions provide the flexibility for fast and cost-effective design optimization, so you can validate and verify your products sooner and reach the market faster (Marcão *et al.,* 2017). It would be counterproductive to go through the FDA process for a novel medical device without an exact replica of what the device will look like in the event that it is ever produced at scale. For this is important the design of the product and the 3D printing to create a prototype medical device.

Use of the gamification concept in performance management activities

In the context of performance management of a collaborator, its performance always appears as a variable dependent on motivation, where we can study the benefits of using the concept of gamification, according to (Marcão, *et al.,* 2017). According to (Marcão *et al.,* 2017), the main objective of this concept is to improve human motivation and performance in a given activity, and motivation can be leveraged by the systematic addition of benefits. Depending on the results obtained in the projection and development of products or services, it is possible to transform the professional activity of a collaborator in a game, which is possible through the definition of indicators. According to (Marcão *et al.,* 2016), indicators are metrics used to plan, execute and monitor business strategies, from which the key performance indicators (KPI), key risk indicators (KRI) and key control indicators (KCI) are highlighted. These determine the monitoring of the objectives to be fulfilled and allow the monitoring of the relative levels of control with certain tolerance, used in the organizations. Since the concept of gamification refers to a process that allows the improvement of a service, according to the research project conducted by (Marcão *et al.,* 2017), through the creation of value triggered by the collaborator himself, his potential is based on motivational support. This is distinguished into two types: i) intrinsic and ii) extrinsic. In case i), the motivation is rooted directly in a given task, while in case ii) the motivation is related to an economic compensation. In the perspective of (Herzig and Schill, 2012), gamification is considered as the new trend of capturing high performance in organizations, being a concept also used to improve employee engagement. This approach is especially promising in the business domain as business information systems focus on efficiency issues, rather than focusing on points such as motivation and satisfaction. In order to use this concept in the organizational context, business information systems responsible for business management and business effectiveness can act as mediators for introducing gaming techniques such as scorecards or rapid feedback on real business processes. From a psychological perspective, (Herzig and Schill, 2012) concludes that it produces significant improvements in collaborators.

According to the guidelines defined by (Bradley *et al.,* 2011), to acquire added value through the use of business architectures: i) avoiding the traditional approach in strategic planning, ii) outlining a future strategy that maximizes current performance, and iii) evaluating the intermediate effects of use of IT to generate added value; an enterprise architecture must be designed to capture maximum flexibility and agility, (Herzig and Schill, 2012). Further emphasizes that this point should be valued in order to improve the alignment between business and IT, from where it projects an architecture based on a gamification model, based on events (see Fig. 1). In the architecture presented, the game rules are created and managed through a Business Rule Management System (BRMS) and the engine evaluates each event according to its predefined game rules. This offset event is, in turn, processed by the game repository and stored in its database. Finally, an analytical component is used to analyze player behavior in order to improve game rules and optimize long-term employee engagement.

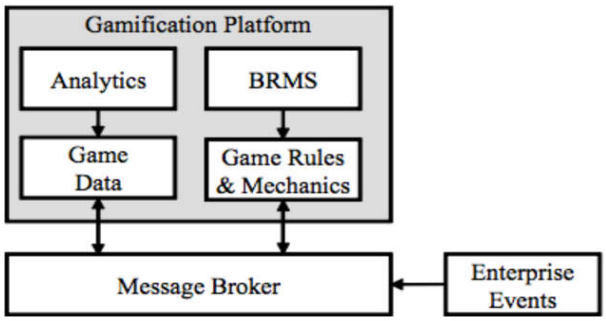

Fig. 1. Gamification platform, according to (Marcão *et al.*, 2016)

Although the studies surrounding performance management involve mainly the public health and professional services sectors, according to (Bradley *et al.,* 2012), it is a subject that easily covers the other sectors. In order to design, implement and manage new health information systems, by developing an enterprise architecture capable of capturing the effectiveness of IT and business resources (Bradley *et al.,* 2012), defines two types of input: i) financial motivations and various types of inter-organizational relationships, and (ii) pressure from patients who want health professionals to meet patients' needs, which supports technology in the perspective of providing a greater amount of resources electronically. Based on these inputs, it concludes that the relationship between the maturity stage of the business architecture and the organizational

impact of the use of IT is directly proportional, in a positive perspective, since its implementation allows organizations to obtain a greater competitive advantage. In this sense, as we evolve in the maturity stage of the enterprise architecture, we are able to address the different types of motivation defined previously. According to (Ryan and Deci, 2000), despite the observable evidence that humans are liberally endowed with intrinsic motivational tendencies, this wall propensity is expressed only under specifiable conditions, which contrasts with extrinsic motivation, as we can see in Fig. 2.

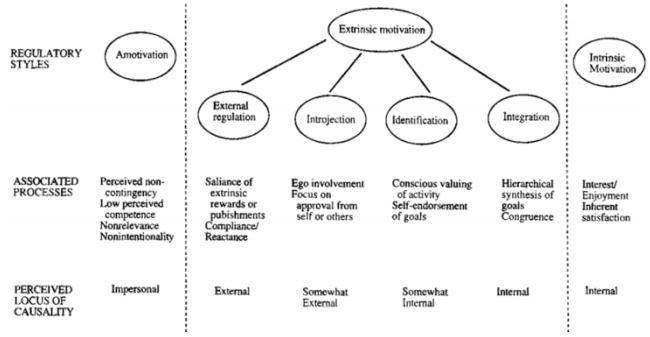

Fig. 2. Taxonomy of human motivation, according to [11]

In the perspective of studying the evolution of performance management, (Harrison and Qin, 2009) develops a method to discriminate failures, through a predictive control model. This method monitors the sequence of innovations of the Kalman filter, which can be obtained in closed industrial circuit, from where we can make an analogy to the use of the concept of gamification. According to the benchmarking study carried out by the author, the final result of the application of the method is an indication of the estimation of the sub-optimal state, which revealed the method contributes to the capture of the high yield. With the objective of producing a process of continuous improvement of a given economic activity, (Kang and Han, 2008) analyzes the performance of its management activities and states that the use of a Business Activity Monitoring (BAM) system can be used to monitor performance management in real time. Since a system of this kind monitors several enterprise systems simultaneously and shows exceptional situations in a dashboard, in case the symptoms of the problem are identified by predefined rules, (Kang and Han, 2008) considers it as a solution that feeds the globalization of the economic activity of the organization . However, since the good financial performance of an organization should accompany the motivation of its employees, according to (Besley and Robinson, 2010), an enterprise architect must contain a management control system capable of dealing with change, not only at the macroeconomic level, but also at the level of human resources and strategic and organizational planning, considers (Chenhall and Euske, 2007). For this reason, in conclusion of a study conducted by (Harrison and Qin, 2009), control at the level of a business process can be defined as any process by which managers direct attention, motivate and encourage the members of the organization to act in a desired way to achieve the company's goal.

Conclusion

Throughout the previous sections, the topic of performance management was addressed in different perspectives, focusing on the importance of defining and using different business architectures and mechanisms to capture the high performance of organizations, which is only possible through maximizing motivation of its employees. When the focus is industrial and involves the development of medical prototypes, since this follows a particular methodology with recurrent artifact validations, feedback is even more important. According to (Petkov *et al.,* 2011), it is one of the most important tools in all organizations, because it allows employees to evaluate their performance, contrasting their results in a temporal perspective. Since the definition of business architectures presupposes the alignment between business and technology, (Chenhall and Euske, 2007) it also considers that employee performance should be shared in different dashboards, as a perspective of real-time results sharing, which, together to an accompanying model based on a gamification system, according to (Vail, 2002), is very useful for the profitability of the employees' performance and the economic activity of the organization.

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