Internet of Things and the Risk Management Approach in the Pharmaceutical Supply Chain

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Abstract. Technology is advancing rapidly, accelerating and creating strategic innovations and new challenges in traditional business models. The Internet of Things (IoT) brings an opportunity to increase productivity and efficiency on the supply chain processes of the pharmaceutical industry. In this context, a new business vision, based on innovation and supported by new technologies, requires a risk and resources management approaches, encompassing the strategic-tactical-operational planning processes within the companies. This work aims to highlight the potential use of IoT features, considering a risk management approach to the pharmaceutical supply chain (PSC), based on an exploratory research methodology.

Keywords: Internet of Things · Pharmaceutical supply chain
Risk management

1 Introduction

The supply chain (SC) generally requires systematic and strategic coordination of all activities associated with the flow and transformation of inputs, finished goods, information and financial resources (Chopra and Meindl 2007). IoT, refers to end-to-end world connectivity, where objects and beings interact with virtual environment data in the same time and space, looking to a range of possibilities and within different environments (Evans 2011). Tang (2006) defines Supply Chain Risk Management (SCRM) as the coordination and collaboration between various partners in the supply chain to ensure continuity of operations and profitability. Christopher and Peck (2004) classify the risks in SC into three categories: internal risks to the company, external risks to the firm but internal to SC and external risks to the chain (environment). Identification and control of risks (internal/external) can positively affect the functioning of the chain, which can be approached in a coordinated way with mitigation and contingency plans to avoid supply chain disruptions and processes vulnerability (Olson and Wu 2010).

In the manufacturing of pharmaceutical products, it is essential to know the stability, control of the desired quality of the products and other problems subject to transport operations, predominantly composed of random variables, with limits of delivery time

M. Freitag et al. (Eds.): LDIC 2018, Lecture Notes in Logistics, pp. 284–288, 2018.
https://doi.org/10.1007/978-3-319-74225-0_38

(Novaes et al. 2017). The production environment cleanliness is a critical requisite to ensure the quality of the product. It involves complex processes management and the use of various equipment types (Pawar et al. 2011). Events like increase of operational and R&D costs, demand volatility, royalties management, etc., are leading them to unprecedented challenges to assure an competitive advantage (Khanna 2012). The main focus of this paper, the pharmaceutical SC, is to guarantee the pharma goods delivered on the right place, at the right time with the required quality (Enyinda et al. 2010) and to analyze the use of IoT associated with a risk management approach in the PSC.

2 PSC Planning: IoT and the Risk Management Context

This research is exploratory and the literature review is an essential step to cover the new theories and cases for a better understanding of this field of study (Easterby et al. 2012; Tranfield et al. 2003). The management of pharmaceutical products (medicines and vaccines) requires the control of parameters like temperature, humidity, impacts and vibration, that adds up a greater complexity to logistics operations along the PSC. The idea of adding intelligence to the SC is described in the literature as the development of a large-scale intelligent infrastructure that combines data, information, physical objects, products and business processes (Chui et al. 2010). This concept presents a vision of anything, anytime and anywhere connectivity, leading huge changes in the day-to-day life (Pang 2015). It is also extended to planning and execution of the supply chain processes.

Adding advanced technology to everyday devices, such as audio or video receivers, detectors, etc., and make them online connected, the data can be extracted through lots of sensors allocated on different parts of the supply chain flow (Gubbi et al. 2013; Whitmore et al. 2015). The challenge is how to process the data collected and use this information as a competitive advantage to improve the performance and react properly when unplanned tactical-operational issues occur over the supply chain.

2.1 Operational Risks in the PSC Distribution Sector

On a pharmaceutical environment, a risk can be explained as any event that affects the supply flow of the goods. This industry faces huge risks like regulatory changes, suddenly sales increase, demand anticipation, scarcity of raw material and quality issues (Jaberidoost et al. 2013; Narayana et al. 2014). The risk management approach is a systematic process for evaluating, monitoring, communicating and examining all the risks related to the quality of medicines through their life cycle. Based on the data collection and analysis, it is possible to take effective decisions based on risk evaluation, including mandatory regulation rules required on pharmaceutical industry, to support the development of procedures and methods for prevention and/or problem solving approaches into the PSC management.

The potential use of IoT solutions integrated with supply chain planning processes could be applied in different areas within the PSC as: tele-medicine and emergency

services, health social network, home care, intelligent pharmaceutical packaging, and so on (Fig. 1).

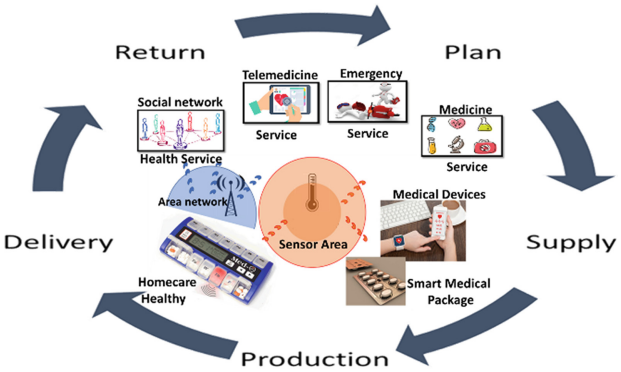

Fig. 1. IoT usage examples on supply chain planning processes (source: the authors)

One of the main challenges in the pharmaceutical industry is to assure an efficient quality control process across the supply chain. For instance, the control of the quality parameters (temperature, humidity, etc.) during the storage and transportation operations of vaccines, bio-pharmaceuticals, blood and transplantation products, requires a properly pro-active monitoring process control. Any deviation on the quality parameters during these SC processes needs an immediate management action to avoid losses and damages of the goods. A continuous risk assessment procedure is necessary to trigger alerts and drive the mitigation and contingency action plans to avoid goods flow disruptions in the PSC. Different risk situations and the real potential of IoT, are shown in Table 1.

Table 1. Risk assessment and IoT processes requirement (source: the authors)

IoT Process Requirement (CISCO 2017; Gubbi et al. 2013; Coetzee and Eksteen 2013)	Risk Assessment (SCOR 11.0)				
	Plan	Supply	Production	Delivery	Return
Networking and Communication	▲	■	▲	▲	■
IoT Infrastructure Management	■	▲	▲	▲	▲
Real Time Transportation Routing	■	■	▼	▲	▲
Emergency Response Planning	▲	■	■	■	▲
Security: Data and Physical	■	▼	▼	▲	▼

High Impact ▲ Medium Impact ■ Low Impact ▼

Networking and communication allow for the identification of data within a dynamic PSC, where devices and sensors are connected to diverse items, which are also interconnected. They are able to communicate data and this data can be analyzed for minimizing risk. The series and volume of data that is transmitted require additional power to transmit them under different conditions along the networked environment. In a former research of our group (Novaes et al. 2015), temperature of perishable food

transported in refrigerated vehicles was analysed with univariate capability indices. In the present research, with the support of a specialized logistic operator in Brazil, an initial analytic effort contemplates two basic parameters - temperature and humidity - using a multivariate statistical process (Wang et al. 2000) to control the quality assurance of pharmaceutical products in its distribution. A MKT (Mean Kinetic Temperature) analysis, based on the Arrhenius equation, will also be performed on temperature data (Taylor 2001).

IoT infrastructure management is needed to support storage capacity for temperature control, as well as enough space for the storage of all products, as to guarantee a successful management effort to reach homogeneous refrigeration conditions, therefore avoiding risks along the chain.

Dynamic and integrated transportation routing systems, with real-time information technology developed within an IoT environment, have a high impact on decision-making procedures to determine optimal driver assistance conditions, optimal delivery times, and optimum routing. With regard to emergency response planning, the devices connected to the system can significantly increase their efficiency and effectiveness. Data collected by IoT devices, which are processed and analyzed in data centers, are used to influence changes in real time actions to respond to emergency conditions. On the other hand, security (data and physical) offers a way to improve access control systems and solutions. While much progress has been made in standard solutions, more success is needed, especially in security, privacy, architecture, and communications.

3 Conclusion

The logistics operators and manufacturing industries must integrate data from multiple sources, automate data collection, analyze data to effectively detect practical information for minimizing risks. We adopted a risk management from a qualitative impact table, approach to the PSC based on critical investigation, where the potential elements to IoT were analyzed into the context processes, improving information to make better decisions, reducing costs, reducing risks and shortening project deadlines. IoT highlights an opportunity into the PSC context, and relates it to existing risks. This evaluation can guide future and scientific work as to where more substantial efforts, considering other parameters in the analysis in the table, should be invested with regard to this important logistics chain.

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