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RFID and track-and-trace in the pharmaceutical industry

An analysis of the application of RFID among pharmaceutical manufacturers

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The pharmaceutical industry has the important task to deliver drugs safely to the end customers. As it turns out, this task is complicated by a complex supply chain and the presence of counterfeiters. Track-and-trace technologies can help to monitor the supply chain. While current regulations mandate the use of 2D barcodes, the Radio-Frequency Identification technology could offer the same functionality, while giving additional advantages. This paper assesses the status of the application of RFID among pharmaceutical manufacturers. Moreover, it analyzes the general opinion on RFID and the reasons for not adopting the technology. Finally, this paper describes the expectations of the pharmaceutical manufacturers and the business experts about the pharmaceutical applications of RFID. The research was performed in three stages. First, a survey was sent out to retrieve information from the pharmaceutical manufacturers. Second, interviews with an RFID and an Auto-ID expert were taken. Third, the application of the technology was analyzed in a real-life application at GSK. The survey results show that only one pharmaceutical manufacturer actively uses the RFID technology, but that RFID is still being studied. Furthermore, RFID is most often linked to increased visibility and enhanced supply chain efficiency. The profitability of the implementation remains questioned. Most RFID projects were ceased because of economic reasons, like the cost of the RFID tag. The opinion on the future application of RFID is divided. According to most of the respondents, the technology will be used in combination with barcodes for track-and-trace. This paper shows that it is unlikely that RFID will be used on large scale for track-and-trace purposes in the pharmaceutical supply chain in the near future. The implementation of the technology requires huge investments, while there is little incentive within the industry to use RFID. The business case shows that RFID can be of great value in specific settings.

Keywords: RFID; track-and-trace; authentication; pharmaceutical supply chain; investment analysis

1. Introduction

The pharmaceutical industry is an important industry. It is a research-intensive industry that drives medical progress (EFPIA, 2014). Sales in the world pharmaceutical market amounted to 655 billion euros at ex-factory prices in 2013 (EFPIA, 2014). 41% of these sales occurred on the North-American market. Europe and Japan respectively account for 27.4% and 9.7% of the sales.

Thousands of people buy drugs every day without realizing the challenges and difficulties pharmaceutical companies are confronted with to get the drugs safely to their point of dispense. The European Federation of Pharmaceutical Industries and Associations (EFPIA) estimates the full cost to

bring a new medicine to the market at roughly one billion US dollars (EFPIA, 2014). As a result, reputational risks due to counterfeit or contaminated drugs need to be avoided at all cost. Nevertheless, the pharmaceutical supply chain characteristics and the high price of drugs make the industry vulnerable. Counterfeit products make up approximately 1% of the supply in developed countries, like the United States (US). In developing countries, this increases to 30% or 40% (Ramakrishnan & Yasmin, 2013).

Avoiding the manufacturing of counterfeit drugs is a hopeless task. The best way to assure the safety of supplies is by closely monitoring the supply chain. Mandates around the world require pharmaceutical companies to apply serialization by a country-specific target date. Serialization means that each individual physical item becomes uniquely identifiable. This enables verification at any point in the supply chain (Bansal, Malla, Gudala & Tiwari, 2013). European regulation, as well as regulation in most other countries, obliges the use of a 2D barcode as the carrier of the serialization number (Optel Vision, n.d.). However, 10 years ago, the industry expected that another technology would fulfill this requirement. This technology is called Radio-Frequency Identification (RFID). In 2006, the US Food and Drug Administration (FDA) even started recommending RFID to the pharmaceutical companies (U.S. FDA, 2006). Why, if the technology can offer additional advantages over barcodes, is it not widely adopted yet?

Recent research models focus on the drivers behind the adoption of RFID, like cost-split agreements or the perceived usefulness of the technology. Moreover, researchers have invested a lot of time and effort to determine the advantages that RFID can create and the challenges that are related to the implementation. They have also analyzed repeatedly how suitable the technology is to the pharmaceutical industry. However, not many papers have looked at the actual status of application of RFID among pharmaceutical companies.

Together with 4XScience, a management consultancy company, this study has been carried out in order to understand the role of RFID in the pharmaceutical industry. This paper focuses on the pharmaceutical manufacturing industry and explains why the adoption of RFID hampers. Moreover, it investigates the status of application of RFID among pharmaceutical manufacturers, the attitude towards RFID, the reasons for not using the technology and the expectations with regard to the pharmaceutical applications of the technology. The information is obtained by means of an online survey that is sent out to the pharmaceutical manufacturers. The results are complemented with the opinion of business experts. These opinions are retrieved through interviews. Finally, the obtained information is checked by investigating the implementation of RFID in a practical setting.

The remainder of the paper is organized as follows. The literature is reviewed in section 2. First, a short definition of the RFID technology, a classification of the anti-counterfeit technologies, the benefits and challenges of RFID and a short description of some related technologies is given. Second, the pharmaceutical supply chain is described in more detail. Special attention is given to the characteristics of and the challenges in the pharmaceutical supply chain. Third, the adoption of RFID

in the healthcare sector is discussed. The third section outlines the structure of the research and describes the methodology. The fourth section presents the results of the survey and the business case. Section 5 describes the limitations of the research and relevant areas for future research. Finally, section 6 contains the conclusions of and insights from this paper.

2. Literature review

2.1. Problem statement

The pharmaceutical supply chain has to contend with two big challenges. On the one hand, drugs are frequently being counterfeited. Counterfeit drugs belong to the broader category of substandard drugs. The term substandard refers to the fact that the drug composition does not comply with generally agreed specifications. One possible cause is a suboptimal manufacturing environment, which results in bacteria and fungi contaminating the drugs (Gunar, 2011). Counterfeiting is another cause. Counterfeiters gain money by selling replicates of well-known brands such as Avastin (cancer) and Tamiflu (influenza). The counterfeit drugs lack an (active) ingredient or contain other ingredients, such as rat poison or heavy metals. The occurrence of these counterfeit drugs necessitates the deployment of identification technologies. On the other hand, the complexity of the pharmaceutical supply chain makes it difficult to be controlled and visualized.

RFID is seen as a technological solution to mitigate the current challenges in the pharmaceutical supply chain. Since it is a track-and-trace technology, its adoption would open up new prospects to monitor products continuously throughout their lifecycle. The characteristics of the technology also allow it to be used in combination with temperature sensors to monitor the products in a cold chain. A drug that follows a cold chain, has to be stored and transported within the determined temperature limits.

A large number of studies describe the increase in efficiency and visibility that can be obtained by implementing an RFID system. Supply chain projects with RFID have already successfully been implemented by companies like Walmart. However, the technology is still not widely adopted by pharmaceutical companies.

2.2. The RFID technology

2.2.1. Definition of RFID

RFID technology is an example of a wireless automatic identification and data capture technology (AIDC). The three basis components of any basic RFID system are a tag, a reader and a middleware program (see Figure 1). The specific communication process between the tag and the reader depends on the type of tag that is used. The tag, also called transponder, can be active, passive or semi-active (Finkenzeller, 2010). Nevertheless, the working principle basically remains the same: The RFID reader and the tag communicate by means of radio waves. The reader then reads the signals

and sends the related data to the middleware. The middleware makes the data available for business applications. The reading range of the antennas of the reader and the tag depend on the polarization and orientation of the reader, the environment, the used frequencies, et cetera (Sarac, Absi & Dauzère-Pérès, 2010). For more technical details, please see the book of Finkenzeller (2010).

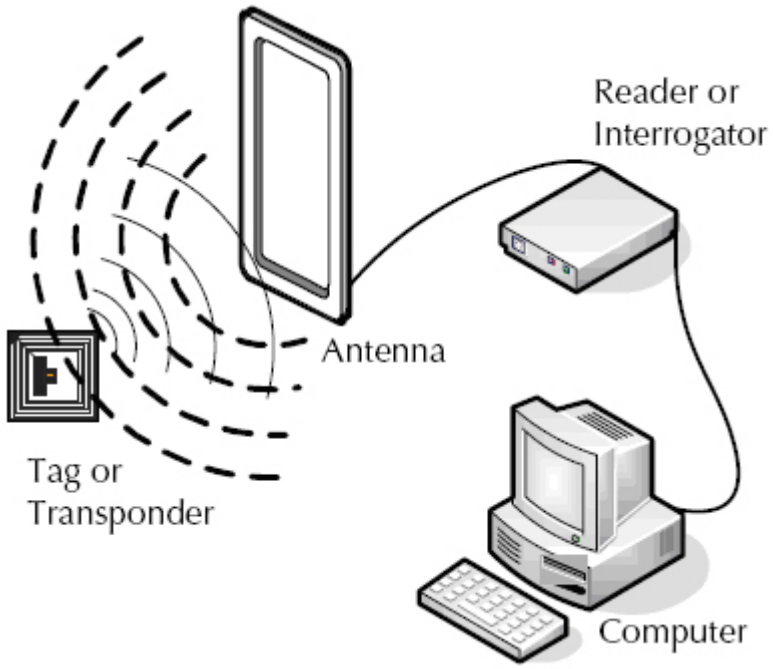


Figure 1: RFID tag, reader and middleware (EPC-RFID, 2013)

An important concept for the RFID technology is the electronic product code (EPC). Usually, data are stored on RFID tags in the form of these codes, which are universal identifiers for physical objects (GS1, 2014b). Standards for EPC have been documented by GS1. EPC data that is collected throughout the supply chain can be shared through a network: the EPCglobal network. However, EPC and RFID are not inextricably linked. EPC can be used in other contexts and the RFID tag can contain data that is not an EPC identifier (GS1, 2014b).

RFID has evolved into a well-studied subject over the last two decades. Fortunately, the enormous amount of research is summarized from time to time in literature reviews (Lim, Bahr & Leung, 2013; Ngai, Moon, Riggins & Yi, 2008). Between 1995 and 2005 research was mainly directed at the RFID technology itself. Afterwards, the focus shifted to the business and organizational applications (Lim et al., 2013). Supply chain management is one of the major trends in the RFID literature, which can be derived from the number of papers written on this subject (Lim et al., 2013).

RFID has many application areas. Wamba (2012) analyzes the articles on RFID that have been published in the Journal of Medical Systems between 1997 and 2011. He classifies the RFID applications in the healthcare sector in three categories: asset management, patient management and

staff management. Asset management is about managing the inventory and the flow of healthcare assets. Patient management is about the identification and the protection of patients. Staff management is about improving labor productivity and efficiency. Furthermore, the RFID technology can be used in other healthcare applications. For example, Johnson & Johnson applied RFID to see if their customers complied with its promotional schedule. The company found that the incremental sales of customers that complied with the schedule were higher (O'Connor, 2008). RFID applications in the apparel industry are a popular research topic as well. Kwok and Wu (2009) describe the design of an RFID-based system in the supply chain of the textile industry. Furthermore, RFID is used in diverse applications all over the world (Bluemner, 2014). For example, Orlando Attractions Park uses the technology for its no-swipe tickets and the company RadarGolf developed a tracking system that can accurately locate golf balls within a distance of one hundred meters if they get lost.

The full advantage of RFID can only be grasped once the applied research is taken to the next level (Ngai et al., 2008). Future research areas can be classified into the adoption dimension, the usage dimension and the impact dimension (Curtin, Kauffman & Riggins, 2007). The adoption dimension contains research questions on the development, the adoption and the implementation of the RFID technology. It is about technical capabilities and limitations, the role of RFID standards, the development of a business case for RFID adoption and about the adoption pattern and dynamics. The usage dimension is about how collaboration between industry partners can ease the RFID implementation. Moreover, it contains research questions on how RFID should be applied within organizations and processes in order to leverage the technology optimally. The literature on the risks and costs of RFID also belongs to this category. The last dimension bundles the research questions on how the RFID technology creates business value and how it impacts the way of doing business. This paper belongs to the first category.

2.2.2. Anti-counterfeit technologies

An efficient anti-counterfeit technology is characterized by its difficulty to be duplicated or reused. Besides, it should be easily visually identifiable, easy to notice when tampered with and easy to apply (Li, 2013). Bansal et al. (2013) also mention proven standards and legal compliance as characteristics of an ideal anti-counterfeit technology.

The RFID technology is especially promising because it can better ensure the authenticity of products, by preventing duplication or reuse. Authentication protocols have been developed to prevent the cloning of tags (e.g., Dimitriou, 2005).

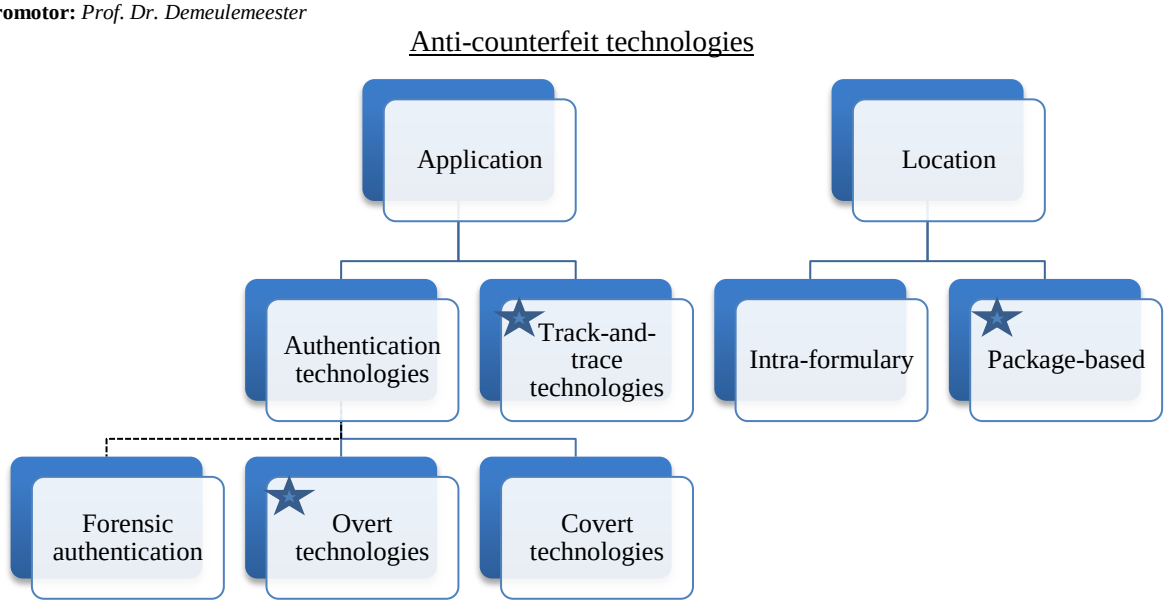


Figure 2: Categories of anti-counterfeit technologies
The stars mark how RFID is generally applied.

As shown in Figure 2, anti-counterfeit technologies can be categorized in two ways: according to their application and according to their location on the product. The stars in Figure 2 show how RFID is generally applied.

With regards to their application, anti-counterfeit technologies are used for authentication and track-and-trace purposes (Li, 2013). Among the authentication technologies, a further distinction is made between overt and covert technologies. Overt technologies, such as holograms and color-shifting ink, are visible to the users, in contrast to covert technologies, such as security packaging papers and hidden printed messages. Li (2013) drafts a table listing the different overt and covert technologies, each with their advantages and disadvantages. She includes biological and chemical taggants, basically markers, in the category of covert features. Bansal et al. (2013) separately classify this as a category named forensic authentication. Certain authentication technologies, such as barcodes and RFID, enable unique identification of units on item, case and pallet level. This characteristic allows to track and trace individual products. Tracking devices enable to keep track of the location of products at all times. This typically happens by scanning the unique code into a computer system that is connected to a central database. Tracing devices offer the functionality to retrieve historical data on the products, such as environmental storage conditions and time spent at each location (Koh, Schuster, Chackrabarti & Bellman, 2003). RFID, barcodes, laser marking and optically stored marks are examples of track-and-trace technologies (Li, 2013).

A second categorization method distinguishes between package-based and intra-formulary anti-counterfeit technologies (Koh et al., 2003). Although digestible RFID tags exist (Anonymous, 2011),

the RFID tags are mainly associated with packaging. As a result, it is plausible to consider RFID as a package-based technology.

Some identification technologies do not specifically function to prevent counterfeiting, but merely operate to increase efficiency. Kärkkäinen and Ala-Risku (2003) classify the identification technologies in four categories according to their application. Figure 3 depicts the applications: authentication, item tracking, process effectiveness and information management. These are not mutually exclusive and RFID is said to belong to all four categories.

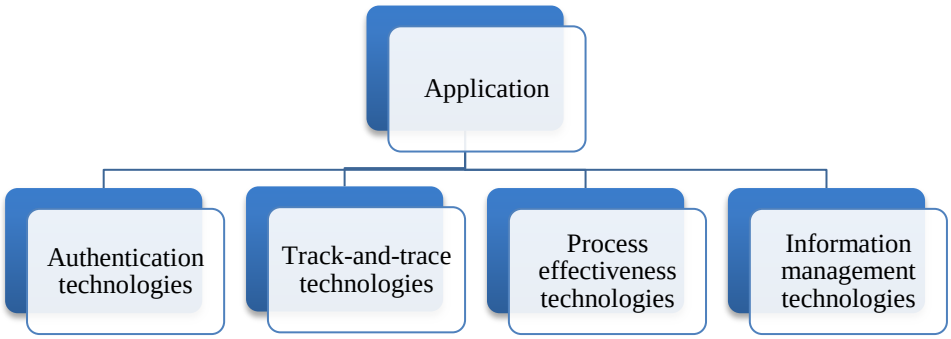


Figure 3: Identification technologies according to Kärkkäinen and Ala-Risku (2003)

2.2.3. Benefits and challenges of RFID

2.2.3.1. Benefits

Increased supply chain efficiency and enhanced supply chain visibility are two of the benefits that are most often associated with the deployment of RFID in the supply chain (Carr, Zhang, Klopping & Min, 2010). An RFID system communicates with radio signals and requires neither line-of-sight nor human intervention. This decreases material handling time, improving the supply chain efficiency (Hozak & Hill, 2010). The extent to which visibility is improved, depends on the extent to which data are shared. Bottani and Rizzi (2008) make an economic assessment of the implementation of RFID and the EPC system in the fast moving consumer goods industry, both in an integrated and in a non-integrated scenario. In the non-integrated scenario, there is no data sharing between the different supply chain partners, being manufacturers, distributors and retailers. Here, the benefits from RFID arise because of automation, the improvement of inventory accuracy and labor efficiency of internal processes. In the integrated scenario, additional benefits are possible because of data sharing between and real-time information from supply chain partners, resulting in reduced safety stocks and reduced stock-outs. It is the combined implementation of RFID and the EPCglobal network that results in improved visibility and the avoidance of inaccurate or outdated data. RFID can also increase visibility by providing real-time information on temperature and humidity. This functionality can be offered with active and passive RFID tags. It can be realized by an antenna structure that operates as a sensor. When the tags are read, they give data on the temperature and humidity (USP, 2015).

Sarac et al. (2010) discuss how RFID can improve inventory accuracy, decrease the bullwhip effect and facilitate replenishment policies. Inventory accuracy has different causes, such as transaction errors, shrinkage, misplaced items and supply errors. While RFID can not always avoid these errors from happening, the technology can help to detect the errors faster through the availability of real-time information. The bullwhip effect is the phenomenon that variations at the customer side, like demand shocks, become larger when travelling upwards the supply chain. Because Auto-ID technologies, such as RFID, enable companies to share data, a better view on the global supply chain can be established, resulting in a better control of the bullwhip effect. Replenishment policies, based on information on current stock levels, gain from the increased access to real-time information, which results in better policies.

RFID technology can also play an important role in the fight against substandard goods. On the one hand, the RFID technology can reduce the risk of counterfeiting by providing real-time information (Li, 2013). For example, drugs that leave the normal supply chain and invade it again at a later time, can be detected and filtered out. This decreases the probability that counterfeit products reach the end customers. On the other hand, the track-and-trace functionality significantly facilitates product recalls because products can be continuously monitored. Piramuthu, Farahani and Grunow (2013) show the influence of the traceability functionality of RFID on the recall process in a perishable food supply network.

2.2.3.2. Challenges

Challenges to the adoption of RFID have been studied widely (Wu, Nystrom, Lin & Yu, 2006). A distinction can be made between economic, technical, organizational and other challenges.

The implementation of RFID requires much higher investments than the implementation of barcodes (Finkenzeller, 2010). Despite declining over time, the costs to attach an RFID tag are still higher than the costs to print a barcode on a product (Smart, Bunduchi & Gerst, 2010). The necessary change in the organization's infrastructure to allow for an effective RFID implementation results in another huge cost. Furthermore, the uneven distribution of the implementation costs and benefits among supply chain partners complicates the adoption of RFID. Miragliotta, Perego and Tumino (2009) study the application of RFID in the fast moving consumer goods industry. They find that the RFID project on case level would significantly benefit the retailers. However, the lack of comparable benefits for the manufacturers hampers the adoption. Therefore, they conclude that a cost-sharing agreement could create an improved situation for both parties. However, they also acknowledge that the fact that information would have to be shared, poses a challenge to this solution. Gaukler, Seifert and Hausman (2007) analyze the effect from a cost-split agreement in a two-company supply chain in the retail industry. First, a centralized setting is analyzed: a setting with collaboration between a manufacturer and a retailer. Second, a decentralized setting is analyzed: a setting without collaboration. One of their main conclusions is that sharing RFID tag costs does not matter in a

decentralized setting where the dominant player is the manufacturer. However, in case the retailer is the Stackelberg leader, which means he decides on the quantity he is going to sell first, sharing costs is beneficial for total profits. How the costs are shared depends on the division of power between the two market players. On top of the previous challenges, companies still wonder whether RFID will pay off in the future (Lim et al., 2013). In order to create widespread adoption, RFID needs to shake off the doubts and companies must expect at least a positive Return On Investment (ROI). Sarac et al. (2010) depict a scheme to analyze the ROI of the RFID implementation in supply chains. They combine insights from other studies to provide this scheme. The benefits are divided into three categories; revenue, operating margin and capital efficiency, depending on how they are created. The costs are divided into six categories: hardware, software, system integration, installation service, personnel and business process reengineering. The outcome of an economic assessment of RFID depends on the level of RFID tagging. The lower the level of tagging, the higher the costs. This is the reason why, in some case-studies, RFID tagging is not beneficial on case or item level, while it is on pallet level (Bottani & Rizzi, 2008). However, higher levels of tagging also decrease the benefits that can be realized from the RFID technology. This explains why other studies conclude that the actual value of the application of RFID is on case level, while the application on pallet level has limited benefits (Miragliotta et al., 2009).

Some technical challenges hamper global RFID adoption as well. First, 100% detection is not guaranteed (Wu et al., 2006). For example, radio waves can be deflected by metals. Roberti (2009) stresses this problem and states that this imperfect read reliability evokes adoption hesitancy among many companies. The difficulty to identify which tags failed to be read, aggravates this problem (Wu et al., 2006). Second, concerns have risen that the electromagnetic field, created between the reader and the tag, has a dangerous effect in certain application areas. For example, the FDA does not allow RFID to be used for biological drugs, like vaccines, because the impact of the radio frequency (RF) radiation is not studied enough (U.S. FDA, 2004). In response, different studies have been carried out to study the non-thermal and thermal effects of RFID exposure on biologic pharmaceuticals. Uysal et al. (2010) study the non-thermal effects for five frequently used radiofrequencies. They conclude that the protein structure of biologic drugs remains unattached. Calcagnini et al. (2012) investigate the thermal and non-thermal effects on the drugs in case of the exposure to an ultra-high frequency (UHF) electromagnetic field during one hour. They noticed a temperature increase of 0.5° Celsius (C) in the exposed drugs, but this temperature change remained within the allowable limits for the drug. There were no non-thermal effects of the exposure to the electromagnetic field on the drug. Despite the positive outcome of these studies, the FDA has not changed its opinion. Third, RFID will link data that can be wirelessly accessed to people. This raises privacy concerns (Irani, Gunasekaran & Dwivedi, 2010). Governments have to regulate who can have access and how the inactivation of tags is ensured once a product is bought. The wireless access does also result in security issues. The reader, the transponder or the data transfers between reader and transponder can be the object of an

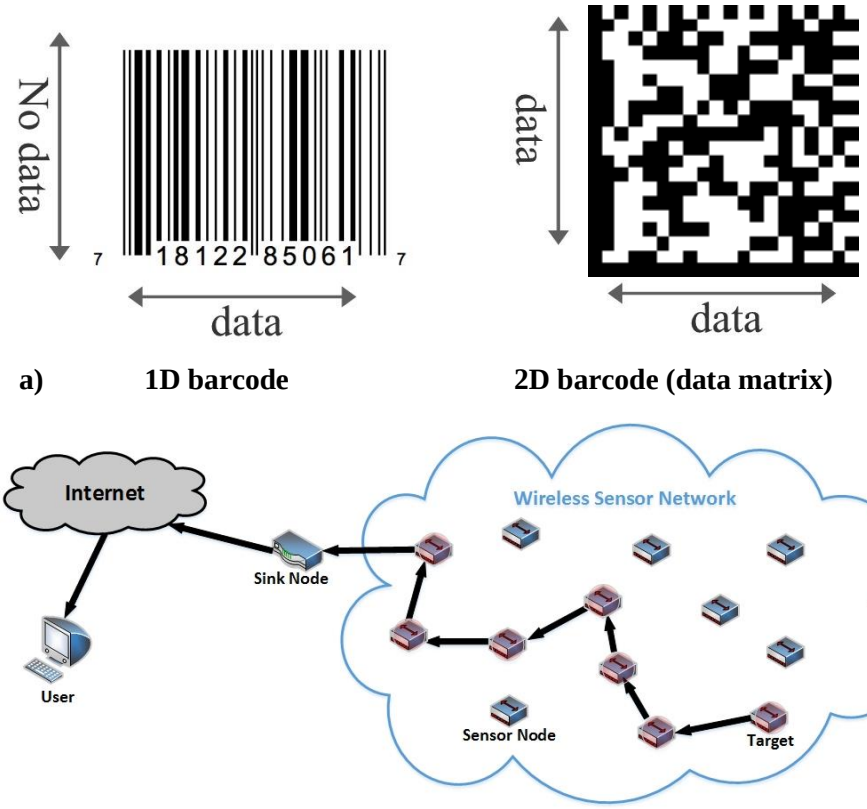
attack. Finkenzeller (2010) gives several options to protect the system from these attacks with cryptographic measures. Liu, Qin, Wang and Li (2013) discuss an authentication protocol that can enhance the security of the technology by offering protection against malicious data attacks. Finally, Smart et al. (2010) describe several technical challenges to adoption, referring to them as technology uncertainty costs. For example, the difficulty to attach the RFID tags to packaging materials (e.g., wood) or to integrate the RFID software with other applications and other complementary products. Also, the technological complexity of the RFID systems requires the personnel to possess the appropriate skills. The lack of these specialized skills results in inferior results from the RFID projects.

The establishment of a complete RFID infrastructure that is able to track every tagged item throughout the supply chain is a significant organizational challenge (Wu et al., 2006). Establishing the infrastructure means picking the right hardware and software. To pick the right RFID system, companies have to be aware of their own needs and the needs in their industry. Finkenzeller (2010) gives four selection criteria to choose the right system. The criteria are operating frequency, the required range of the RFID system, the security requirements of an application and the required memory capacity of the transponder. Fisher and Monahan (2008) show that, besides the difficulty to adapt the RFID system to the hospital setting, hospitals are confronted with obstacles like employee reluctance to use the RFID technology. As a result, change management becomes important. Furthermore, healthcare processes need to be designed in order to minimize readability issues. Wamba and Ngai (2013) apply the Delphi method to identify and rate key issues of RFID-enabled healthcare transformation projects. They conclude that the design and implementation of healthcare processes that efficiently deploy RFID is a top organizational issue. Furthermore, the optimal use of the RFID technology requires the presence of RFID throughout the global supply chain. Therefore, collaboration and trust between supply chain partners is crucial (Smart et al., 2010). This collaboration proved difficult between certain supply chain partners.

Other challenges include regulations, repackaging and alternative technologies. A regulation that has come up in January 2015 requires many companies to attach 2D barcodes to their secondary packaging (Optel Vision, n.d.). This obligation makes a choice between RFID and barcodes unnecessary. Support by the regulatory instances is one of the factors that can stimulate RFID adoption. Furthermore, an important note has to be made regarding package-based authentication and track-and-trace technologies. As repackaging is common in many industries, a burden is set on the usefulness of those technologies (Bansal et al., 2013). Furthermore, the existence of a good alternative such as the 2D barcodes and the feeling that the RFID technology is still immature can hamper the adoption of RFID (Smart et al., 2010).

2.2.4. Competitive and supplementary technologies

Different technologies compete with or supplement RFID. The next section briefly summarizes some related technologies (see Figure 4).



a) 1D barcode **2D barcode (data matrix)**

b) **Wireless Sensor Network (WSN)**

Figure 4: a) 1D and 2D barcodes (Fox, n.d.), (TEC-IT, n.d.) b) WSN (POSTECH, n.d.)

Currently, barcoding is one of the most ubiquitous identification technologies. A distinction can be made between one-dimensional (1D) and two-dimensional (2D) barcoding, depending on the dimensionality of the data representation. 1D barcodes can only represent about a dozen characters. In recent years, 2D barcode labels have evolved into the norm for secondary packaging because they have more storage capacity (Brown, 2012). There are different types of 2D barcodes. The data matrix is the one that is most often used in the pharmaceutical industry.

Barcode systems are cheaper than RFID technology, but they face some technical disadvantages. First, an RFID tag's data density is much higher, which allows to store significantly more data on smaller chips (Finkenzeller, 2010). Second, the tags are not hindered by dirt, damp or any other type of (optical) covering. Third, they are not influenced by degradation. Fourth, the reading speed and the maximum distance between data carrier and reader are higher with RFID applications. Fifth, barcoding requires each item to be scanned individually, while the data on RFID tags are read

simultaneously by radio wave communication. Time gains are a huge advantage in a fast moving consumer good industry like the pharmaceutical industry. Finally, barcodes are a unidirectional tool, which means that data can be stored from an external source on the barcode, but not the other way around. RFID tags have read-write functionality, which allows a broader array of applications (Carr et al., 2010).

In contrary to what people may expect, a rise in popularity of RFID does not entail the downfall of barcodes. On the one hand, the two technologies can be integrated (Bridgelall, 2001). On the other hand, the optimal choice for a technology depends on the intended use and the environment. 1D and 2D barcodes are ideal for applications with direct line-of-sight, while RFID is better when no direct line-of-sight is possible or when packages are susceptible to wear and tear (Cronin, 2008). Furthermore, the probability that RFID will completely displace barcodes in the near future is unlikely since barcodes can be installed at a much lower cost (Bansal et al., 2013).

A Wireless Sensor Network (WSN) is a multi-hop network (see Figure 4). This means that information collected at a particular node, may need to travel through other nodes before it reaches the data sink. A WSN operates by means of sensor nodes that collect, process, store and transfer environmental or product-related data (Vishwakarma & Shukla, 2013). In this way, a disturbance in a cold chain can be noticed immediately. Furthermore, the sensor thresholds can be programmed remotely (Haan, van Hillegersberg, de Jong & Sikkel, 2013). A WSN differs from an RFID network, which does not sense the conditions of an object, but rather determines its identity and location. Their combined characteristics create a more complete and secure system. Thus, RFID is not a pure substitute. Vishwakarma and Shukla (2013) and Liu, Bolic, Nayak and Stojmenovic (2008) study the integration of the two technologies. However, WSN adoption is slow in supply chains. It seems to face similar issues as the RFID adoption. Haan et al., (2013) study and explain the adoption process by using environmental and industry-related adoption factors. A returning issue is standardization. A standard that supports all the functions of a WSN has still not been established.

Technological development creates possibilities for counterfeiters to deceive regulators, end customers, et cetera, but it also provides pharmaceutical companies with new ways to prevent counterfeiting. Bowles and Lu (2014) study nanotechnology in the pharma-industry. Nanosensors are capable of detecting physical stimuli with dimensions in the order of nanometers and they can be used to actively track transport. The sensors can detect temperature shocks, hazardous gas and vapors and humidity. However, these nanosensors could be made so small that detection and destruction would become extremely difficult. This will certainly raize privacy and security concerns. Research needs to be extended to estimate the side effects of this technology such as labor loss and production risks. As with every technological innovation, adoption costs are still high as well (Bowles & Lu, 2014). The value that can be obtained by using nanoscale technology in supply chains is promising. Nevertheless, the technology is still in an embryonic phase and a lot of research is needed before it can be applied in the pharmaceutical supply chain (Bowles & Lu, 2014).

A technology that can avoid every loophole in the pharmaceutical supply chain is not developed yet. Variation in and the combination of anti-counterfeit technologies remains crucial.

2.3. Characteristics of the pharmaceutical industry

2.3.1. Structure of the pharmaceutical supply chain

The pharmaceutical supply chain is the network of companies and their linkages that guide prescription medicines from the very first supply chain actor to the end customers. Environmental, economic, political and social events and interactions between organizations, which are respectively causing external and internal risks, can distort the activities in any supply chain (Lysons & Farrington, 2006).

Figure 5 depicts the basic representation of the pathway of a prescription drug (The Health Strategies Consultancy LLC, 2005). The drug travels from the pharmaceutical manufacturer to the drug wholesaler. The drug wholesaler then sells the drug to retail pharmacies, hospital pharmacies, drug stores or dispensing doctors after which the medicine is dispensed to the patient. One pharmaceutical manufacturer possibly sells to many wholesalers and one wholesaler might sell drugs from different manufacturers.

However, throughout the years other distribution models have emerged. Walter, Dragosits and Said (2012a) compare the performance of five different distribution systems in the pharmaceutical wholesale sector in six European countries. These five systems are described as short-line wholesaling, full-line wholesaling, direct sales from manufacturers, Reduced Wholesale Arrangements (RWA) and Direct-to-Pharmacy (DTP) arrangements. Their study reports that full-line wholesalers are unparalleled in performance. Full-line wholesaling means that the wholesaler carries the whole gamut of drugs required by the patients in its country (Walter, Dragosits & Said, 2012b). Full-line wholesaling still accounts for the large majority of distribution systems. However, according to a study of 2011 by the London School of Economics, the DTP and RWA systems are becoming more popular, especially in the UK (Kanavos, Schurer & Vogler, 2011). A DTP scheme means that products are directly shipped from the pharmaceutical manufacturer to the pharmacist. To successfully implement this system only a few logistics services providers are needed. Although some pharmaceutical manufacturers adopted the system, it is unlikely that its implementation will get widespread in the near future ((Walter et al., 2012a). An RWA scheme means that the medicines follow the traditional pathway, but that pharmaceutical manufacturers work with a limited number of wholesalers, typically two or three, to move the medicines through that pathway.

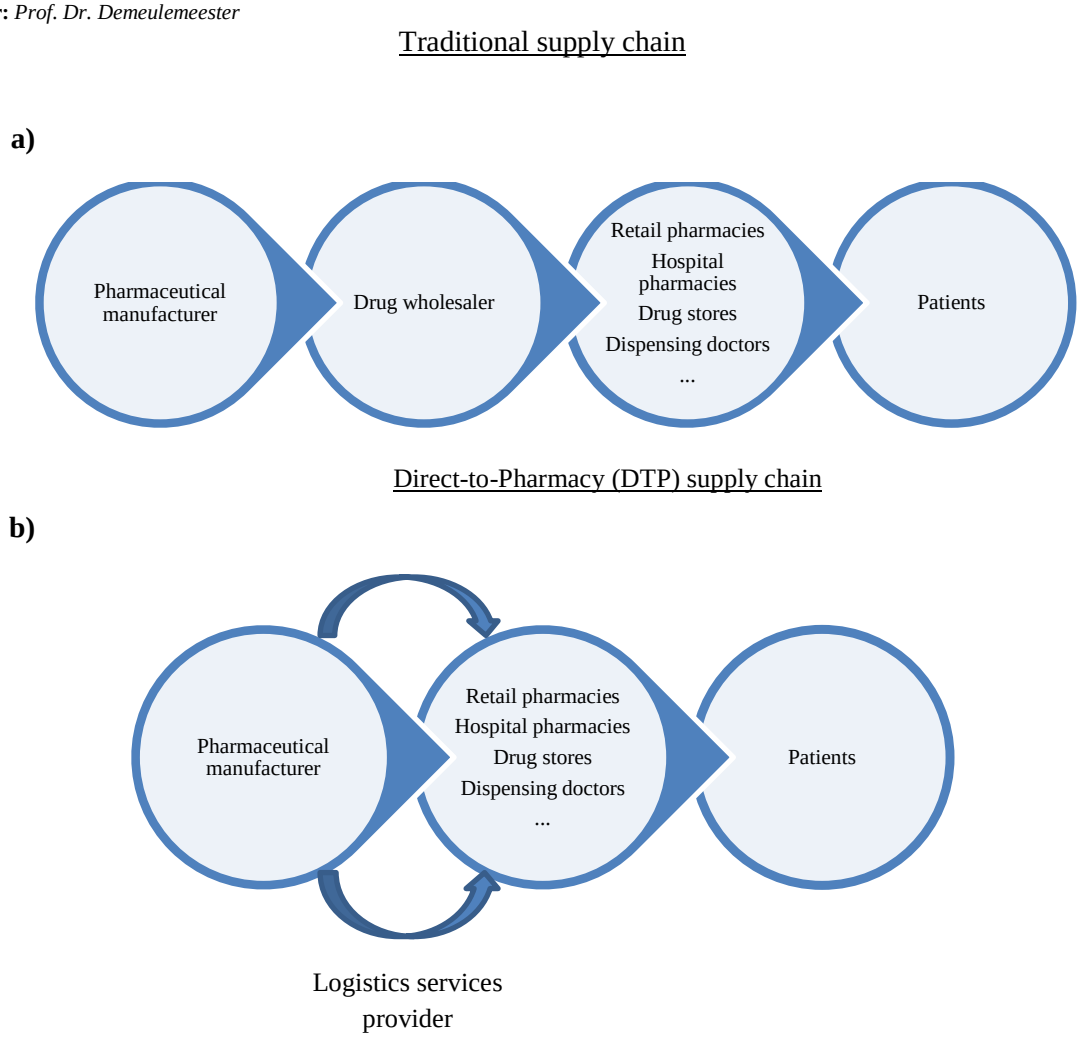


Figure 5: a) Traditional pathway b) DTP system

2.3.2. Key industries and companies

A pharmaceutical manufacturer sells brand-name drugs (e.g., Pfizer, Merck, …) or generic drugs (e.g., Mylan, Roxane, …) (The Health Strategies Consultancy LLC, 2005). Some pharmaceutical manufacturers sell both. While brand-name drug manufacturers spend a lot of their resources on scientific research and the development of new drug therapies, the generic drug manufacturers' business model is focused on developing a substitute for brand-name drugs as soon as the latter's patent expires. Compared to the other key players in the pharmaceutical industry, the pharmaceutical manufacturers typically have the biggest influence on prices. They try to stimulate demand by cooperating in studies that test their medicines and they have an important role in conserving and creating safety in the pharmaceutical supply chain (The Health Strategies Consultancy LLC, 2005).

A few large, multinational firms make up the bulk of the pharmaceutical manufacturing industry. Databank Statista estimated sales in the pharmaceutical market to be roughly 903 billion US dollars in 2014 (Statista, 2015). The US has the biggest share in this with 40% market value. As a result it is not

surprising that the number one pharmaceutical company by global sales in 2013, Pfizer, is a US company (see Table 1). The magnitude of this industry is illustrated by the fact that six of the 10 companies that appear in the top 10 list of sales also appear in the top 100 of Forbes' global 2000 list: 'The world's biggest public companies' (Forbes, 2014).

Table 1: Top 10 pharmaceutical companies by global sales (in million dollars)

Ranking	Company (country)	2013	2012
1	Pfizer (US)	47,878	51,214
2	Novartis (CH)	47,468	46,732
3	Roche (CH)	39,163	38,006
4	Merck & Co. (US)	37,437	40,601
5	Sanofi (FR)	37,124	39,511
6	GlaxoSmithKline (UK)	33,330	33,335
7	Johnson & Johnson (US)	28,125	25,351
8	AstraZeneca (UK)	25,711	27,925
9	Lilly (US)	20,962	20,567
10	Abbvie (US)	18,790	18,380

Note: UK = United Kingdom. FR = France. CH = Switzerland. (PMLiVE, 2014).

The wholesale distributor industry basically links the drug manufacturers to the drug dispensers. This extra link facilitates doing business in the drug market by lowering the number of business partners that drug manufacturers and drug dispensers have to deal with (Eastern Research Group Inc., 2001). Besides its core function, which is the delivery of drugs to dispensers, the wholesaler industry can offer a number of other services (e.g., special handling services for cold chain products). The industry is structured differently across different countries and regions. Overall, it is a highly concentrated market, which means that a few large wholesalers have control. In most European countries, wholesalers operating on a national scale have more than 50% market share (Kanavos et al., 2011). In the US the three biggest wholesalers generate 85 to 90% of the revenues in the drug distribution market (Fein, 2014). The three companies are AmerisourceBergen Corp., Cardinal Health, Inc. and McKesson Corporation. They are full-line wholesalers. The Eastern Research Group Inc. (2001) also distinguishes between regional wholesalers, smaller wholesalers and secondary wholesalers. However, the structure of the market is constantly changing. Developments such as the consolidation in the pharmacy industry and the expansions of the three biggest US drug wholesalers to other continents, like Asia and South-America, could have a substantial impact on the drug wholesaling industry in the future (Fein, 2014).

The next and traditionally the last link before pharmaceutical supplies reach the patient is embodied by the drug dispensers. Healthcare institutions and retail chains are the most common ways through which drugs are being dispensed (Eastern Research Group Inc., 2001). Besides these traditional retail pharmacies, there are also specialty pharmacies, mail-order pharmacies and long-term care pharmacies. Specialty pharmacies usually dispense high-cost drugs to treat chronic diseases. Mail-order pharmacies take the prescription drug business to the internet and long-term care pharmacies provide more extensive and specialized services than those in the retail pharmacies. When pharmacies purchase drugs they take responsibility for safe storage and dispensing (The Health Strategies Consultancy LLC, 2005).

As an example, Asamoah, Abor and Opare (2011) examine the pharmaceutical supply chain for artemisinin-based therapies in Ghana. Their study gives a realistic view on the variety of actors that are involved in a pharmaceutical supply chain. In short, the actors are drug-specific farmers, pharmaceutical manufacturers, government purchasers, medical stores, importers, drug wholesalers and pharmacies (e.g., hospitals, clinics, drug stores). Production starts with farmers, controlled by manufacturers such as GlaxoSmithKline, and eventually products enter Ghana either through a public or private channel. International organizations such as the World Health Organization (WHO) and the United Nations Children's Fund play a role in the distribution towards developing countries.

2.3.3. Challenges

Being able to control the supply chain is important since an effective supply chain management results in better logistics processes, creating an improved organizational performance (Green, Whitten & Inman, 2008). However, the specific characteristics of the pharmaceutical supply chain cause supply chain management to be especially challenging.

2.3.3.1. Specific pharmaceutical supply chain characteristics

The pharmaceutical supply chain is very geographically dispersed. As an example, 40% of the drug intake in the US originates from imports and roughly 80% of the active pharmaceutical ingredients in American drugs are processed in foreign countries (Autor, 2011). A drug safety report from the Government Accountability Office dating from 2010 states that only 11% of the 3.765 foreign establishments in their database could be controlled by the FDA (Jaskot et al., 2011). If no extra facilities would be added, they predict that it would still take the FDA nine years to inspect all foreign facilities. Geographical dispersion also complicates the recall process because it can impede the identification of the ultimate destination of a contaminated product.

The pharmaceutical supply chain is special because the products that move through it require special care and attention. On the one hand, pharmaceutical medicines are perishable. Therefore, the process of delivery of drugs needs to account for timing requirements. Certain drugs also need to be

stored and transported in areas that are temperature-monitored. The terminology that is used to describe this process, is the cold chain. Herbon, Levner and Cheng (2014) study the advantage that can be obtained by using time-temperature indicators (TTI) for perishable inventory management. The TTI-based automatic device they describe can detect products that are damaged before the expiration date. However, the complexity of the supply chain network and the need for controls decelerates the delivery process.

Visibility is required to omit the harmful effects of manufacturing errors, contamination and counterfeiting. Visibility is a valuable characteristic in every supply chain. It is the degree to which a product can be followed throughout its lifecycle and it can be achieved by track-and-trace processes (Musa, Gunasekaran & Yusuf, 2014). It results in better control and therefore a higher level of safety. Different academic architectural frameworks for visibility have been developed. Musa et al. (2014) describe four RFID deployment architectures to achieve end-to-end visibility. One of the architectures is the EPC network, developed by a joint venture between GS1 and GS1US. The SaviTrak system, the Microsoft BizTalk RFID and the Sun Java System RFID are extensions of the EPC network. These three systems are proprietary standards, which are used to integrate RFID in existing business systems. In contrast, the EPC network is a concept architecture, which uses open, worldwide standards supported by GS1. GS1 is a not-for-profit organization that offers standards for sharing information of detailed physical and digital objects. For example, its RFID standard describes what data should be on a tag and in what format (GS1, 2014a). The EPCIS specification, developed by GS1, specifies a data sharing interface, but it does not describe how the system should be implemented.

2.3.3.2. The threat of counterfeit drugs

Product counterfeiting is both a serious problem and a popular practice. The main problems of counterfeiting are the health risks it poses, the damages to the environment and the decrease in revenues of companies and governments (Chaudhry & Zimmerman, 2013). A proper valuation of the counterfeit market is extremely difficult due to the illegal nature of the market and the disagreement about the estimation methodology (Chaudhry & Zimmerman, 2013).

The pharmaceutical industry is an especially attractive prey to counterfeiters. Pharmaceutical medicines are high-tech products, requiring intensive R&D. Due to these characteristics they belong to one of the four categories that are identified as being most vulnerable to counterfeiting (Jacobs, Samli & Jedlik, 2001). Highly visible, high volume, low-tech products like tooth paste, high-priced, high-tech products like computer games and exclusive, prestige products like perfumes complete the list. The sales of counterfeit drugs accounts for the highest proportion of drug sales in developing countries, especially where regulatory and enforcement systems are weak (WHO, 2012).

Real-life examples of counterfeiting

Between November 2007 and March 2008 a drug drama occurred in the US. Baxter sold end customers contaminated heparin, a popular blood thinner. Complaints on the product started rising in November 2007 and Baxter decided to recall the drugs. Nevertheless, the complexity of the pharmaceutical supply chain complicated the recall and people still received contaminated heparin. Over the next five months hundreds of people suffered from allergic reactions and dozens died (Harris & Bogdanich, 2008). The contamination is assumed to be caused by contaminated raw ingredients sourced from Changzou Scientific Protein Laboratories (SPL), a Chinese factory that was not granted a drug certificate by China's drug agency (Bogdanich & Hooker, 2008). The US Food and Drug Administration (FDA) allowed this company to supply, without performing the necessary controls, the ingredients to the parent company SPL. This case painfully uncovered the vulnerabilities in the supply chain, being complexity, visibility and insufficient control. To this day, it is not clear how many victims the contaminated heparin made (Dooren, 2012)

The occurrence of counterfeit malaria medicines provides another example of the severe threat of counterfeits. Since 2000 malaria mortality rates have decreased more than 25% (WHO, 2013). The World Health Organization argues that the existence of an efficient artemisinin-based therapy is an important driver behind these falling rates. However, artemisinin-resistance is occurring in the Greater Mekong subregion (WHO, 2013). Drug resistance can be caused by substandard drugs that are not compliant with the general drug specifications. According to the FDA, more than one third of anti-malaria drugs available in Sub-Saharan Africa and South-East Asia are counterfeit or substandard (U.S. FDA, 2013). At present, there is no alternative anti-malarial medicine, which is equally effective. As a result, further development and spread of immunity would mean a huge setback in the percentage of healed patients (WHO, 2013).

2.4. The adoption of RFID in the healthcare industry

Studies on RFID adoption in the healthcare industry show that perceived risk and resistance to change are negatively correlated to the perceived usefulness of the RFID technology (Carr et al., 2010). In contrast, the presence of supplier support to provide technical help to speed up the learning process is positively correlated to the perceived usefulness of RFID. Furthermore, perceived usefulness is significantly linked to the intention to use RFID. Carr et al. (2010) find that the complexity of the RFID technology does not necessarily have a negative influence on the intention to use it in the healthcare industry. Tsai, Lee and Wu (2010) show opposite relations in the retail industry, which proves that this factor depends on the type of industry.

The likelihood of RFID adoption in the healthcare industry is also shown to depend upon technology-push and demand-pull factors (Lee & Shim, 2007). The technology-push theory states that technological developments drive the innovation in an industry. The demand-pull theory states that it is the needs of the customers that drives innovation, more than the discovery of a new technology. Lee

and Shim (2007) show that technology-push factors, like the pressure of vendors, and demand-pull factors, like market uncertainty, are positively related to the adoption of RFID. Furthermore, they argue that the presence of a champion, a member of the management who acknowledges the value and supports the implementation of the new technology, is an important driver behind RFID adoption. Finally, Lee and Shim (2007) also find that organizational readiness is a positive stimuli for RFID adoption in healthcare.

The presence of a gap between the actual and the potential value of RFID in the pharmaceutical industry is generally acknowledged and widely being studied. Different sources report on and discuss the application and adoption of RFID in the healthcare sector.

First, providers of the technology have an incentive to inform the industry since general acceptance of RFID in the pharmaceutical supply chain could increase their sales considerably. No manager will take the risk of adopting a new technology if he does not understand the value it adds to his business. As a result, it is not surprising that some of the more important RFID providers have teamed up to report on the suitability of the technology for pharmaceutical applications. For example, Impinj, Alien and four other RFID providers have written a white paper on item level applications in the pharmaceutical industry (ADT/Tyco Fire & Security et al., 2006). Besides promoting RFID in general, they also promote UHF RFID tags by discussing the myths that exist about them. In fact, they report that UHF tags are the best type of tag for most applications, even if liquids and metals appear in the reader field. Furthermore, the companies give instructions on strategic and business issues. According to their study, UHF tags outperform high frequency (HF) tags for item level applications. However, the question remains whether pharmaceutical supply chain applications can effectively use the UHF RFID tags at the moment.

Second, several research groups focus on the adoption pattern of RFID in their own country. For example, students of the Copenhagen University College of Engineering analyzed the Danish market (Khaji, Martin, Polak, Sossna & Hernandez, 2008). Their study reveals that only Nomeco, a large Danish pharmaceutical wholesaler, considered using the technology in 2008. The other companies hesitate because of the typical challenges: costs, a lack of information and no regulatory enforcement. In addition, the Danish market is very dependable on international trade. The slow adoption in the US and the European markets certainly enforces the reserved attitude in Denmark. The situation in Korea is different. The Korean government allows both barcodes and RFID technology for its serialization requirements. Moreover, it funds RFID projects of pharmaceutical manufacturers (Swedberg, 2012). As a result, the adoption pattern in Korea is bound to be faster. Hanmi Pharmaceutical, the largest Korean pharmaceutical manufacturer, was the first company to implement an RFID tagging system on item level (Namgung, Choi & Kwon, 2011). It introduced the technology in its production line in 2009 and currently uses it on all of its products. A study, executed in 2006, describes what was needed at that time to facilitate the adoption of RFID in Korea (Lee & Chung, 2006). The proposals in

the research study include a study to decide between HF and UHF RFID tags, an intense collaboration between the responsible agencies and financial and educational support for the implementers. The content of the necessary studies might have changed over time, but the principle remains the same. Studies, collaboration and financial and educational support can help to successfully install RFID on the production lines.

Third, research to describe what an organization needs to do in order to adopt the technology appears regularly. For example, Grackin (2012) suggests that everyone should install a knowledge center, that companies need to do ROI studies on a regular basis and that collaboration with trading partners is necessary.

3. Research methodology

3.1. Overview

The research started with a meeting with 4XScience to discuss the focus and methodology of the study. 4XScience is a management consultancy company, located in Kortenberg, that has developed the expertise to successfully implement processes and technologies in order to achieve product integrity throughout the supply chain. The company has guided top-performing pharmaceutical companies in their integrity projects. The know-how and expertise of the company was shared through regular phone calls, mails and meetings with Sara Doucé, a business consultant at the company.

A literature study provided the necessary background to understand the strengths and weaknesses of RFID as well as the opportunities and threats specific to the pharmaceutical industry. Furthermore, insight into the difficulties with the implementation of RFID in the pharmaceutical supply chain was gained.

With this information, a survey could be created that is up-to-date. The survey follows a branch structure, which makes sure only relevant questions are asked. The answers on the questions give insight into the status of application of RFID in the pharmaceutical industry, into the reasons for this status and into the expectations about RFID in the pharmaceutical industry. The use of a survey made it possible to reach a big group of pharmaceutical manufacturers. The survey is built in cooperation with 4XScience. It is tested on consistency and clarity by peers in the field of production and logistics, by academics and by professionals in the pharmaceutical industry and serialization.

In order to put the survey results in perspective, an analysis of the data was presented to an RFID expert and an Auto-ID expert. The interviews were taken by means of video conferences and face-to-face conversations. The structure of the interviews largely agreed with the survey structure.

Finally, a business case was executed with GSK to analyze the implementation of RFID in-depth in a specific context. The business case allows to compare the general results, obtained from the literature and the survey analysis, with the results within the specific setting of GSK.

3.2. Survey sample, content and structure (See Attachment 1)

Because of the specificity of the subject and the complexity of the terminology used in the survey, the respondents had to be chosen wisely in order to minimize error sources (Cooper & Schindler, 2008). Therefore, the internet was browsed to find people that were involved in case-studies or projects at a pharmaceutical manufacturer. These people were asked to fill in the survey or to refer to another person at the company if they were not the appropriate contact person themselves. As a result, the respondents of the survey have been actively involved in or have supervised the RFID projects at their company. They are familiar with the RFID technology and they understand the specific terminology that is used in the survey questions. Their function in the organization varies from director of IT to supply chain director or managing director. The anonymity of the pharmaceutical manufacturers has been assured to prevent the respondents from hiding info. The survey has been sent out to 50 pharmaceutical manufacturers. A number of consultants also responded to the survey, but their answers were kept out of the analyses.

As shown in Figure 6, the survey pulls for information in four areas.

The first part is titled benefits and potential of RFID. It asks for experiences with and expectations of RFID in general. The answers on these questions allow to discover the opinion of the respondents about RFID. This knowledge can reveal the underlying reasons for the slow adoption of the technology. As a result, this part helps to answer the reasons for the status of the application of RFID in the pharmaceutical supply chain.

The second part allows to check the status of the application of RFID in reality. More specifically, it asks when and for which application the pharmaceutical manufacturers researched the technology. The status of application in the companies is divided in nine well-defined categories and a category that accounts for special situations (e.g., outsourcing of an RFID study). In short, these nine categories can be summarized by three situations: a situation in which there has been no action towards RFID, a situation in which a study is in progress and a situation in which a study is completed.

The third part is about the results of recent RFID projects within the companies. It is represented by two sections in the survey. The first section asks for the results of the RFID projects (e.g., faster and more focused recalls). The second section asks for the reasons why the study has not been continued (e.g., the unit cost of the RFID tag). This part revealed the characteristics of the project, the realized benefits and the difficulties involved in the implementation. It helps to explain the status of the application of RFID.

Finally, the company representatives are invited to give their outlook on the future. More specifically, they answer questions about their expectations of pharmaceutical RFID applications and about the required changes from an economic, organizational, technical and other point of view before they would increase their RFID activities. This part allows to answer questions about the current status of application of RFID and future application areas.

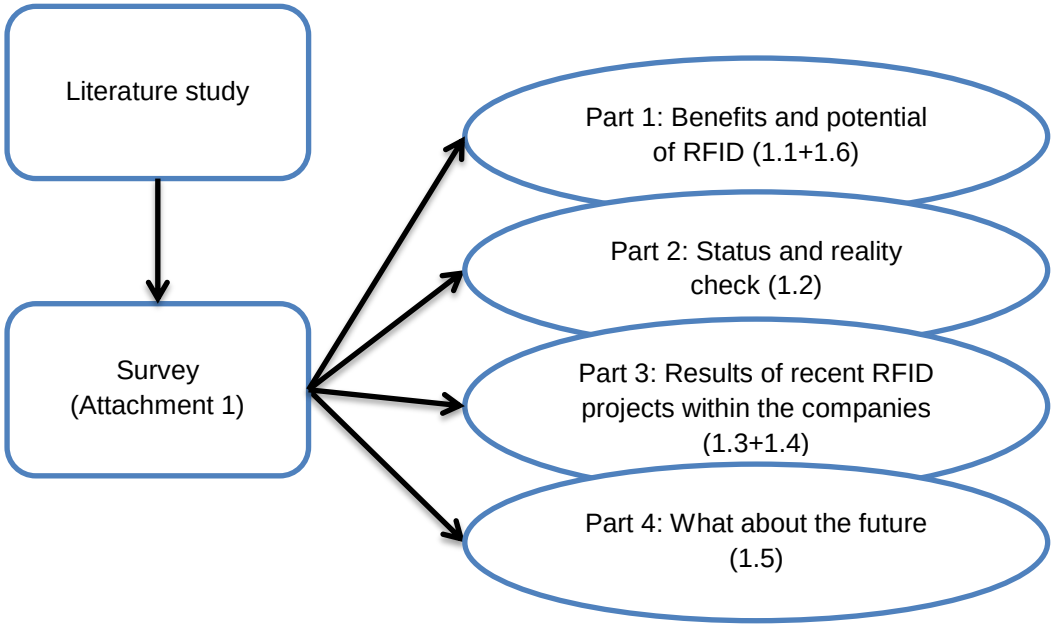


Figure 6: Content and structure of the survey

The survey mainly draws upon three types of questions.

The first type is the checklist. The checklist forms a perfect match with the exploratory character of the research. It appears regularly in the survey, because it allows to group a variable (e.g., benefits, reasons) into multiple categories that are mutually exclusive and collectively exhaustive (Cooper & Schindler, 2008). For example, RFID has numerous benefits and the question has to measure which of these benefits a certain company has experienced.

The second type is an ordinal rating question. It is particularly useful when an opinion or attitude needs to be checked. It appears in part 1, where the respondents are asked to report on their expectations and experiences with RFID. The ordinal rating question allows to get feedback on issues that are brought up in the literature. Some of these issues (e.g., presence of an external consultant) did not make up the core of the research, but could uncover useful information.

The last type is the open text question, which allows respondents to state any information they deem important. The survey tries to summarize a complex and extensive research area into 21 questions. Certain issues, brought up in research projects, are not mentioned in the survey. The open text question assures that important information, that is not explicitly asked for, is retrieved.

3.3. Expert interviews

After the results from the survey had been retrieved, the results were analyzed and checked with the opinions of two business experts. The interviews were based on the questions in the survey and the answers from the pharmaceutical manufacturers. By doing an interview, the key issues as well as the points of disagreement could be discussed in more detail.

The first interviewee, Jan Merckx, is a pharmacist and an RFID specialist. He worked as RFID expert for PwC/IBM from 2001 to 2007, after which he started his own company, Time2Trace. Currently, he works on a project for the Flemish institute for logistics. Throughout his professional career, he has executed several RFID case studies including leading pharmaceutical manufacturers. Two video conference calls, of approximately 1.5 hours each, were set up. In the first call the survey results were discussed. The second call was set up to ask for advice on the business case with GSK.

The second interviewee, Eddy Van Herbruggen, is an Auto-ID specialist. From 1983 to 2013 he was a group specialist for RFID and wireless local area network security at Zetes, a company specialized in Auto-ID in supply chains. Currently, he still works at Zetes as a technology consultant. Since 2009, he is also a technical consultant at FROS amateursportfederatie. The information was gathered by means of a face-to-face interview in the buildings of Zetes. The conversation lasted for about 1 hour.

Furthermore, Tom Aelbrecht, from Johnson & Johnson, and Jayjay Han, from Hanmi Pharmaceutical, were contacted in person and by mail to discuss other parts of the research.

3.4. Business Case

In addition to the survey a business case is executed. On the one hand, it allows to check if the findings from the practical case are the same as the conclusions from the literature and the survey analysis. On the other hand, it allows to check for the occurrence of new issues. The business case intends to provide an exploratory analysis by pointing to the difficulties with the RFID implementation and by giving a rough estimate of the economic outcome of the project. It is executed in close collaboration with GSK, a world leader in the pharmaceutical industry.

The research was executed in three stages. The first stage concentrated on finding a good application area for the RFID technology within the setting of GSK. The second was devoted to visualizing the vaccine manufacturing process. The final stage consisted of determining the benefits and costs that would occur by implementing RFID in the chosen application area. For each stage, a specific research methodology was used.

A kick-off presentation, that was organized by GSK, showed the company's internal structure and business processes. A company visit provided the necessary background. Together with a company representative, a relevant research subject was chosen.

In the second stage, details on the vaccine manufacturing process were retrieved through daily contact with a manufacturing expert at GSK. This contact consisted of phone calls, mails and a second company visit.

In the third stage, the literature, the expertise of an RFID expert, Jan Merckx, and the expertise of the manufacturing expert at GSK, Jean-François Lecocq, provided the information on the costs. The information that was necessary to calculate the benefits was obtained through phone calls and mails with GSK. During the second company visit, it was checked if the benefits were realistic.

4. Results: RFID in the pharmaceutical industry

4.1. Survey results and interviews

The online survey investigates the benefits and potential of RFID, includes a status and reality check, asks for the results of recent RFID projects within the pharmaceutical companies and asks the respondents to reveal their wishes regarding the progress of the RFID technology and their expectations regarding RFID's pharmaceutical applications.

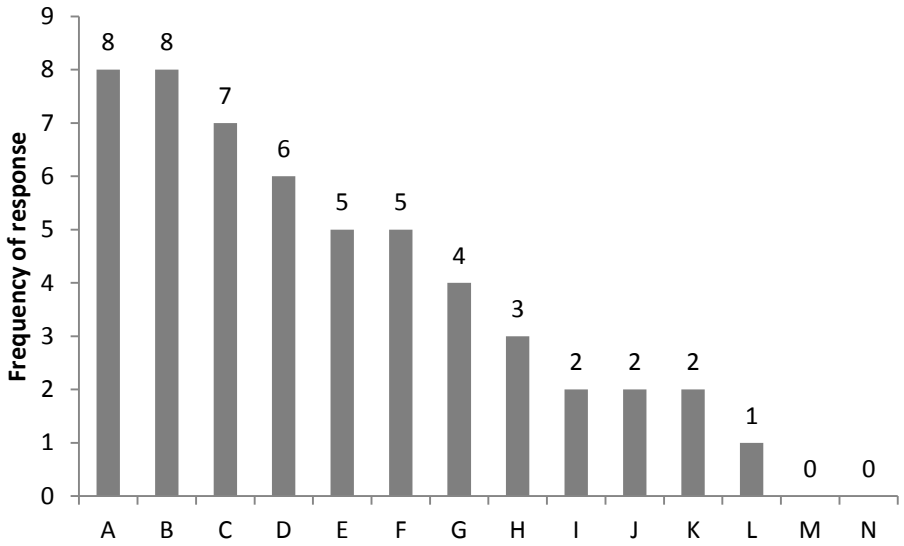
4.1.1. Response rate

Nine pharmaceutical manufacturers engaged in the study, which agrees with a response rate of approximately 20%. The engaging companies originate from the US, Europe and Asia (Japan). Five companies of the top 10 biggest companies in global sales cooperated.

The process of retrieving answers was difficult for three reasons. First, the right contact people had to be found in order to get relevant responses. Many research projects date from 2005, 2006 or 2007 and a lot of potential respondents had moved to other pharmaceutical companies. They could not reveal details on the RFID projects. Second, many of the research projects were mentored by IT consultants. Some of the responses make clear that the involvement of 4XScience made these consultants less willing to share information. Finally, pharmaceutical companies are very afraid to share confidential information. The pharmaceutical industry is highly competitive. Several companies were not interested in sharing information.

4.1.2. Benefits and potential of RFID

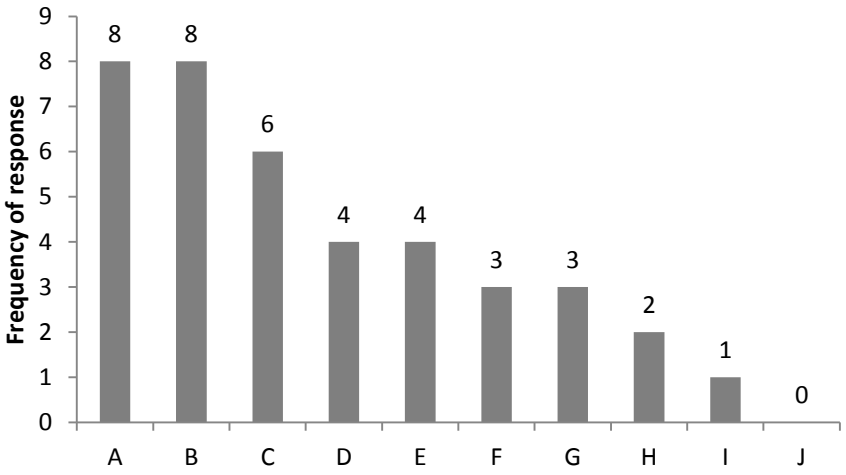
Figure 7 shows that eight pharmaceutical manufacturers identify RFID with enhanced product visibility and increased supply chain efficiency. More than half of the respondents think that RFID enables data intelligence, that it improves inventory accuracy, that it causes recalls to be faster and more focused and that it enhances product and supply chain security. Less than half of the respondents think that RFID results in reduced shipment errors, shorter lead times, reduced need for safety stocks, shorter cycle times or more effective and efficient marketing. Only one respondent is convinced that RFID results in increased profits, whether the initial investments are excluded or included. RFID is not linked to increased sales or decreased obsolescence.



A	Enhanced product visibility (e.g., to control diversion, cold chain monitoring)
B	Increased supply chain efficiency (e.g., to help product tracking)
C	Enable data intelligence
D	Improved inventory accuracy (e.g., less frequent out-of-stocks)
E	Faster and more focused recalls
F	Enhanced product and supply chain security (e.g., to prevent / solve cargo theft)
G	Reduced shipment errors
H	Shorter lead times (= cycle time + waiting time)
I	Reduced need for safety stocks
J	Shorter cycle times (e.g., minutes per customer, hours per part)
K	More effective and efficient marketing (e.g., to facilitate targeted marketing)
L	Increased profits (exclusive and inclusive investment costs)
M	Increased sales
N	Decreased obsolescence

Figure 7: Perceived benefits of RFID

As shown in Figure 8, eight pharmaceutical manufacturers dedicate the advantages of RFID to the fact that it enables readability without line-of-sight and automation of authentication. Six respondents say the technology is advantageous because it eases data gathering. Other frequently mentioned advantageous characteristics are: no hinder of (optical) covering, high density of data on RFID, easy integration with other supply chain nodes and a high reading speed. A small minority of the respondents think that RFID is beneficial because it is easy to integrate with the EPCglobal Network or because it is a more complex technology. No degradation is not checked as an answer.



A	Readability without line-of-sight
B	Automation of authentication (no human scanning)
C	Ease of data gathering
D	No hinder of (optical) covering such as dirt or dust particles
E	High density of data on RFID
F	Integration with other supply chain nodes (exchange of information / communication)
G	High reading speed
H	Ease of integration with EPC global network
I	Increased complexity of technology compared to barcodes
J	No degradation

Figure 8: Advantageous characteristics of RFID

Three main insights can be gained from Figures 7 and 8.

First, RFID is often perceived to be the remedy for limited supply chain visibility. On the one hand, the RFID tag can be the data carrier in a serialized environment. This serialization can largely improve the product and supply chain visibility. However, as mentioned in the literature review, serialization is perfectly possible with 1D or 2D barcodes as well. In this respect, the RFID technology offers little extra value compared to the barcode technology that is currently being used in the pharmaceutical industry. In the same way, the faster and more focused recalls are a result of serialization and the RFID technology itself does not improve these processes (E. Van Herbruggen, personal communication, April 2, 2015). However, RFID can increase the benefits that are created by serialization, because it supports an automated process. With barcodes, items have to be scanned before they are visualized. Since the scanning takes a lot of time and effort, it will not always happen. In this scenario, RFID can increase visibility, because the data sharing requires less time and effort (J. Merckx, personal communication, May 7, 2015).

Relative to the barcode technology, RFID can also offer added-value in cold chains. Temperature sensors can be integrated with the electronic circuits in the RFID chip. This makes it possible to monitor the temperature electronically in real-time. In this respect, visibility can be improved significantly. As a result, the cold chain is an ideal environment for the RFID tag to prove its value.

Visibility is often related to inventory accuracy. For example, every store of Decathlon, that is located in Belgium, uses passive RFID tags. These tags enable the personnel to check quickly how many items of a specific sports good are in inventory. Improved inventory accuracy also appeared in the literature as one of the benefits from RFID. As a result, it is not surprising that six respondents link RFID with improved inventory accuracy. However, readability issues with RFID hinder the technology to become widely used for this purpose in the pharmaceutical industry. In this industry, the inventory checks have to be 100% correct (E. Van Herbruggen, personal communication, April 2, 2015). Up to this moment, technical and organizational issues impede perfect read rate accuracy.

Second, the pharmaceutical manufacturers agree that RFID increases supply chain efficiency. The benefits from RFID can be obtained because the radio waves enable readability without line-of-sight. This enables an automated process with reduced material handling times (e.g., cases do not need to be opened to read RFID tags on item level, dirt or dust particles do not hinder readability). As a consequence, the data gathering process becomes easier. If the data is managed appropriately, data intelligence can be enabled.

Third, a positive ROI is crucial to carry on with any investment in any commercial industry, but only one respondent associates RFID with increased profits. This result does not come as a surprise since the literature already referred to the doubts regarding the profitability of an investment in RFID.

Figure 9 indicates that most respondents expect the strongest benefits from RFID to occur on tertiary packaging level (shipping case). Roughly half of the respondents think that the highest benefits occur on secondary packaging (carton box/item), primary packaging (vial/syringe/blister/bottle) or pallet level. Only one respondent says that the highest benefits will occur on bundle level.

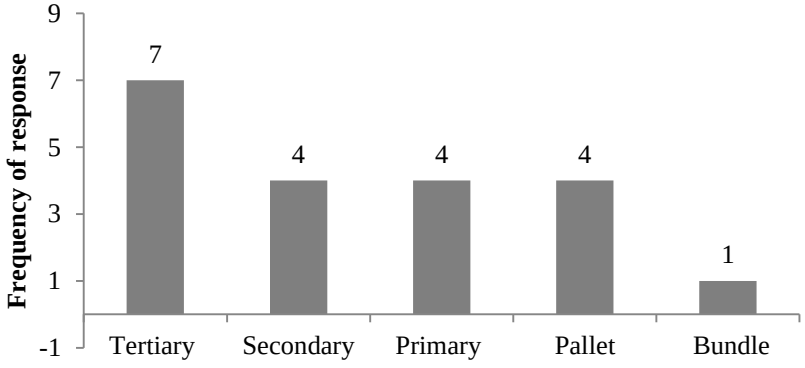


Figure 9: Level where the respondents expect the strongest benefits from RFID

In the literature review, it became clear that higher levels of tagging could be more beneficial to pharmaceutical manufacturers because of the lower operational costs. As a result, it is not surprising that the pharmaceutical manufacturers expect higher benefits on tertiary packaging level than on primary and secondary packaging level. A possible reason why the effect does not extend to the pallet level is that pharmaceutical manufacturers assess that the decline in benefits from visibility is bigger than the decline in operational costs when the level of application changes from shipping cases to pallets.

As shown in Figure 10, a pattern can be observed in the pharmaceutical manufacturers' expectations of where the strong benefits from RFID will be realized. According to this pattern, the benefits get stronger further down the supply chain. Most pharmaceutical manufacturers think that the strong benefits occur at the plant warehouses, the distribution centers and the wholesalers. Once the products move away from the wholesalers the number of pharmaceutical manufacturers that expect strong benefits decreases again.

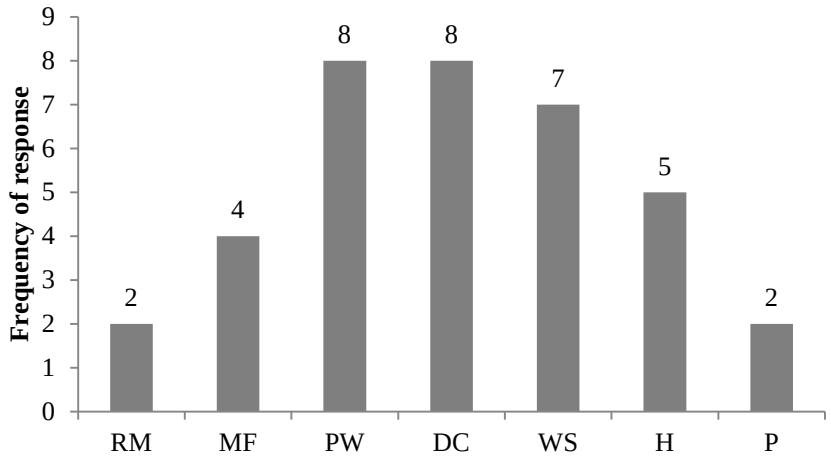


Figure 10: Where the respondents expect strong benefits to occur
RM = supplier of raw materials, MF = manufacturing facility, PW = plant warehouse, DC = distribution center, WS = wholesaler, H = hospital and P = patient.

Figure 10 shows that the pharmaceutical manufacturers generally agree that the strongest benefits from RFID do not occur at the manufacturing facilities, but further down the supply chain. However, the costs that the pharmaceutical manufacturers have to bear to implement the technology are not lower. T. Aelbrecht (personal communication, March 3, 2015) confirms this result by stating that the pharmaceutical manufacturers would create a situation in which visibility can be improved, but that it is not sure how they could benefit from this situation. This indicates why a cost-split agreement could be beneficial to stimulate the adoption of RFID.

Every respondent expects that the benefits from RFID can be realized in supply chain management and inventory management. Respectively six and five respondents think that RFID

would enhance product security and operations management. A small minority of the respondents think that demand, quality, brand, and master data management would be enhanced. RFID is not linked to benefits in finance.

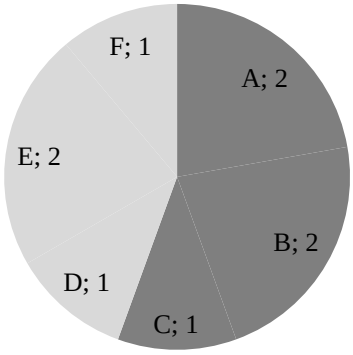
Three respondents agree with the statement that a professional consultant is crucial to the success of the RFID project. Six respondents agree that a good internal project leader is crucial to the success of the RFID project. Only one respondent does not agree with the statement that the endorsement of a good sponsor is crucial. Four respondents think that RFID is a safe investment if it is properly implemented and tailored to the needs of a specific company.

In the study of Lee and Shim (2007) it became clear that the support of a member of the management was crucial to the adoption of RFID. The survey results show that, in general, pharmaceutical manufacturers place more value on a good internal project leader than on an external consultant. The survey results do also show, by pointing on the importance of a good sponsor, that the implementation costs are an important factor in the adoption decision. Finally, the results confirm that there are still doubts on the safety of an investment in RFID, which was mentioned in the study of Lim et al. (2013).

4.1.3. Status and reality check

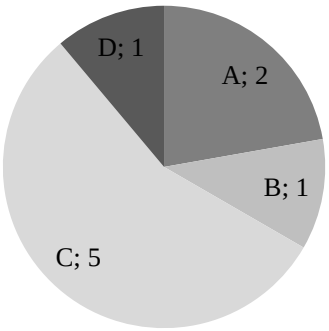
Figure 11 indicates that four respondents executed a strategic analysis or a pilot study in the past and declare that they do not use RFID (A and B). Three respondents declare to be in progress with a pilot study or a strategic analysis (D and E). Finally, two respondents declare either that they have not taken any actions (C) or that they actively use RFID for all of their pharmaceutical products (F). There was no respondent that was actively using RFID only for a share of its pharmaceutical products.

Figure 12 shows that most of the participants have been working on or with RFID for 5 to 10 years. Only one company has been working on or with RFID for more than 10 years. two companies have started their research less than 3 years ago. One of these companies has already stopped its involvement in the projects. The other companies that have quit, had been studying RFID for more than 5 years. There is no company that has been studying RFID for less than 1 year.



A	Completed: strategic analysis/study on RFID and decided not to proceed with RFID
B	Completed: pilot study and decided not to proceed with RFID
C	No actions with regard to RFID
D	In progress: strategic analysis/study on the use of RFID
E	In progress: pilot study
F	In progress: actively using RFID for all pharmaceutical products

Figure 11: RFID status of the respondents



A	1-3 year
B	3-5 year
C	5-10 year
D	> 10 year

Figure 12: Time that the respondents work on or with RFID

4.1.4. Results of recent RFID projects within the companies

Figure 13 shows the level on which the pharmaceutical companies explored the RFID technology. The application of RFID was explored on the tertiary packaging level by eight out of the nine respondents. The application on the secondary packaging, primary packaging and pallet level was each explored by six respondents. Only two respondents explored the application of RFID on the bundle level.

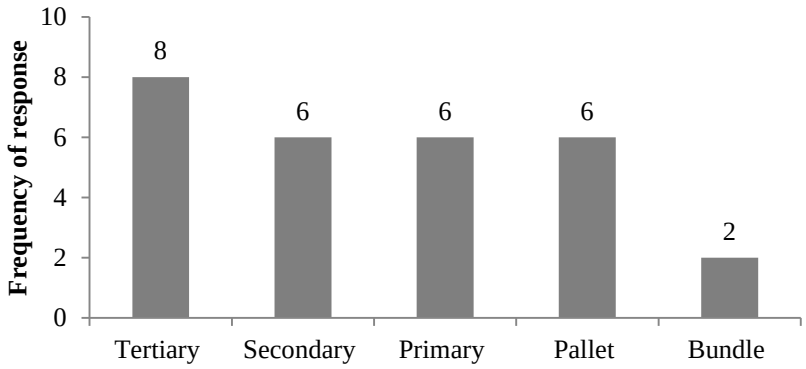


Figure 13: Level on which the respondents explore RFID

The results are in line with what could be expected from Figure 9. Most of the respondents carried out a study on the tertiary packaging level, where they expected the highest benefits from RFID. Likewise, the least explored level is the one where the respondents did not expect high benefits: the bundle level.

A substantial amount of companies could not say what business benefits they gained or expected to gain from the application of RFID and where these benefits occurred because their study was not finished yet. Therefore, these results will not be given in this paper.

The following results were obtained by questioning the five pharmaceutical companies that started a strategic analysis or a pilot study and that did not carry on with RFID.

As can be seen in Figure 14, each of these respondents mentioned that the decision to stop the project was mainly based on economic grounds. Respectively four, three and one of these respondents mentioned that technical, organizational or regulatory problems were also main reasons to end the study.

Apart from the main reason to stop the project, additional reasons within four categories were asked for. The three most mentioned reasons per category are listed in Figure 15.

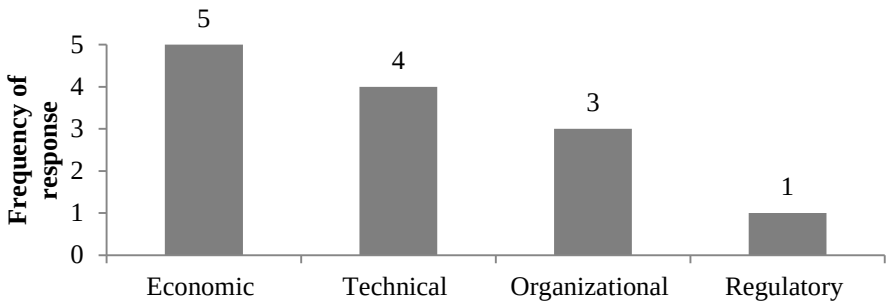


Figure 14: Main reasons to stop the RFID projects

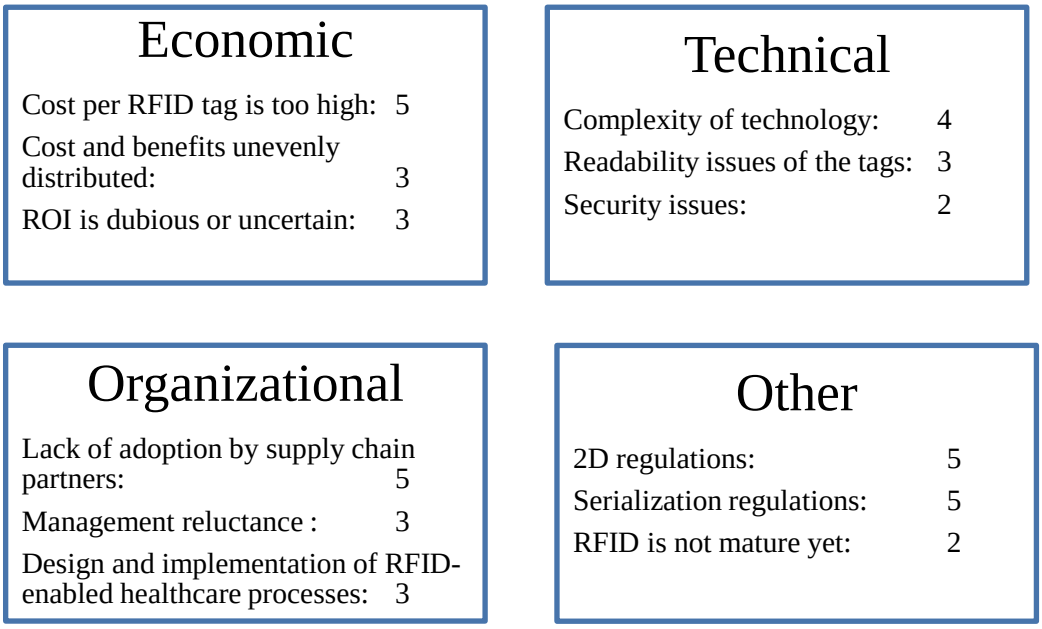


Figure 15: Most important reasons to stop the RFID projects per category

The most important economic reason to stop the RFID projects was the cost per RFID tag. Every respondent says that the RFID tag was too expensive. The issue that the costs and benefits of the technology were not evenly distributed was an important shortcoming for three of the responding companies. The same number of companies says the fact that the ROI was dubious or uncertain made them stop their project. Two respondents devote the discontinuation to the high cost of the required infrastructural changeover. Only one respondent declares that a negative ROI caused them to stop their work with RFID.

The fact that only two respondents stopped the project because of the cost of the infrastructural changeover is slightly surprising. From the literature, it became clear that significant infrastructural changes were necessary to install RFID-enabled processes. These changes would require large investments in hardware, software and knowledge. Apparently, the infrastructural changeover cost was not a main issue for the implementation.

The most important technical reasons for not carrying on with the project were the complexity of the technology, the readability issues and the security of the technology. Four respondents say that the technology was too complex, three respondents doubted the readability and two respondents thought the technology was not secure enough. The negative impact of RF waves, attaching difficulties and complementarity issues with the current technology architecture have been mentioned only once as a significant reason to stop the deployment of RFID. Connectivity issues of the technology to the company network were not mentioned as a reason to stop the project.

Overall, these results agree with the information in the literature. The technology does indeed require specialized knowledge and many readability issues remain unresolved. However, because of the strict regulations on the use of RFID and the prohibition to apply it for certain products, it could be expected that the negative impact of RF waves on the drugs would play a more important role. A possible explanation is that the companies executed their projects in areas where RFID is allowed by the FDA.

The most important organizational reason is the lack of adoption by the supply chain partners in the pharmaceutical industry. Every respondent says that this has contributed to their decision to stop the ongoing projects. Three respondents answer that the company's decision was taken due to management reluctance to use the technology. In comparison, not a single company says that the discontinuation was driven by the reluctance of employees to change their way of working. Three respondents say that the design and implementation of RFID-enabled healthcare processes lied at the basis of their decision. No respondent says that the required infrastructural changes were the reason for the discontinuation of the project.

These results seem to indicate that the existence of collaboration across company borders is a more important determinant to the continuation of the RFID project than the will to change the organization internally. This complicates matters because the adoption of the technology does not only depend on the company itself but also and to a large extent on the actions of external players. The results also show that the design of RFID-enabled processes is a bigger issue than the infrastructural changeover within the company. This signifies that some companies are willing to change their infrastructure, but that they do not succeed in creating the appropriate processes. Here, the expertise of an external RFID consultant can help. However, remember that only three out of the nine respondents agreed with the statement that an external consultant was crucial to the success of the RFID project. Although the internal project leader is also crucial, his knowledge about the company's supply chain should be complemented with the expertise of a professional RFID consultant. Furthermore, the results show that the managers, and not the employees, were reluctant to use the technology. This can be explained by the fact that a lot of the challenges with the RFID implementation only become clear at management level. For example, when the integration within the rest of the organization is discussed, the knowledge of higher level managers is required. Also, the implementation of RFID could lower the working pressure for the employees due to more automation.

Finally, the most important other reason is related to the regulations. Every respondent that did not continue its RFID efforts, answered that the serialization and the 2D regulations gave them a disincentive to deploy the technology. One respondent remarks that the adoption of RFID was considered for counterfeit sensitive products 5 or 6 years ago. However, further considerations were made unnecessary when the authorities made 2D barcode marking mandatory. The maturity of the technology and the emergence of another technology were a problem for two respondents and one respondent mentions that the technology was not adopted because it was too expensive due to repackaging. Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) have not been mentioned by the pharmaceutical manufacturers as a reason to discontinue the RFID projects

The fact that 2D regulations gave the respondents a disincentive to continue their RFID projects is not surprising. However, every respondent also answers that serialization regulations caused them to stop their project. This is surprising because RFID can also be used for serialization. Furthermore, the immaturity of the technology could be expected to play a larger role in the cases. The RFID technology has evolved a lot in the past 10 years. The projects that started 10 years ago will have experienced issues related to the immaturity of the RFID technology. According to E. Van Herbruggen (personal communication, April 2, 2015) the technology has become mature now, which means that more recent projects will not face the same issues anymore.

4.1.5. The future of RFID

4.1.5.1. Incentives to increase the RFID involvement and expert opinions

This section discusses the required changes from an economic, technical, organizational and other point of view before the pharmaceutical companies would consider to increase their RFID involvements. Figure 16 depicts the three most mentioned required changes per category. The opinion of the nine pharmaceutical manufacturers is compared to the opinion of an RFID expert (Jan Merckx) and an Auto-ID specialist (Eddy Van Herbruggen).

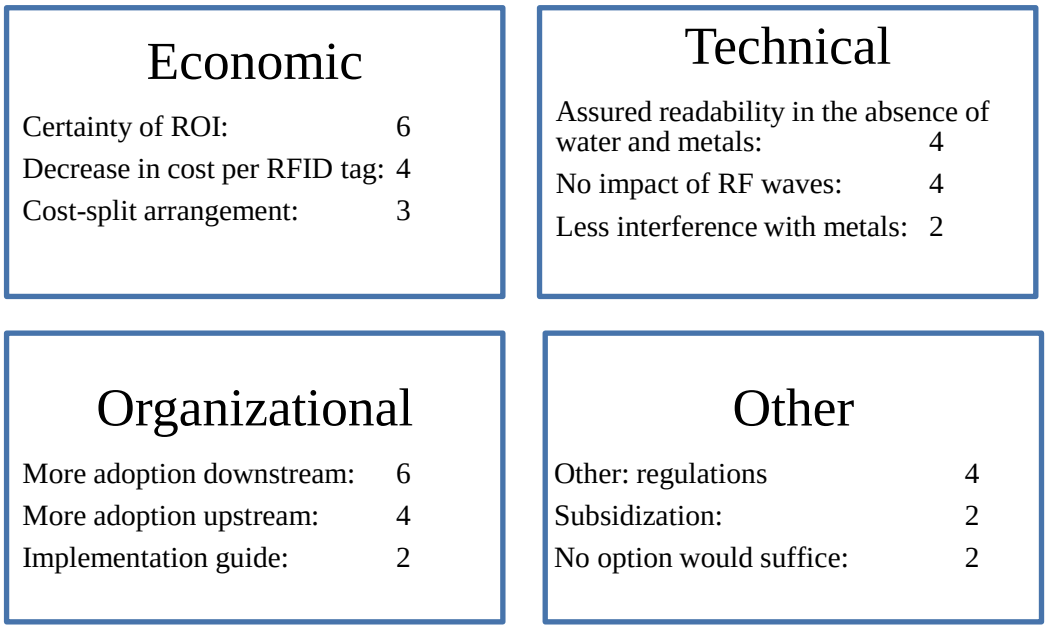


Figure 16: Biggest incentives per category to increase RFID activities

From an economic point of view, the companies want to be sure that their investment pays off. Six respondents want a certain return on their investment. Four respondents say to increase their RFID activities once the cost per RFID tag has decreased. Three respondents stress that they want to split costs between the supply chain partners before they increase their engagement. Only one respondent answers that a decrease in the cost of the RFID readers and the other initial investments would make a difference. A decrease in the maintenance cost would not be a sufficient incentive for any of the pharmaceutical manufacturers in order to increase their activities towards RFID.

The fact that four respondents want to see the unit cost per RFID tag decrease before increasing their RFID activities is a remarkable result. In large quantities, a simple RFID tag costs approximately five dollar cents more than a simple barcode. These costs will probably stay the same for another 5 to 10 years, after which new printing technologies could make the tags less expensive (J. Merckx, personal communication, March 19, 2015). However, the RFID expert and the Auto-ID specialist argue that the unit cost per RFID tag is not the biggest issue in most business cases (J. Merckx, personal communication, March 19, 2015; E. Van Herbruggen, personal communication, April 2, 2015). Usually, other issues are the ones that kill the business case. First, the reader technology is overpriced because big R&D investments are necessary to keep up with the evolution of the tags. Currently, the cost of a reader accounts only for a small share of the price (E. Van Herbruggen, personal communication, April 2, 2015). For example, RFID readers cost around 1,000 or 2,000 euros at the moment. Potentially, this amount can decrease to a few 100 euros once the reader technology is thoroughly researched and sales of the readers have started to pick up. Second, there is a very big software problem (E. Van Herbruggen, personal communication, April 2, 2015). A system based on barcodes is supported and guided by operators. A system based on RFID needs to be able to frame the

events automatically. This requires to install and extensively test new software applications. Third, the pharmaceutical supply chain has to comply with GMP and GDP regulations. The GMPs ensure that the pharmaceutical products are manufactured and controlled according to certain quality standards, while the GDPs ensure that these drugs are properly distributed (ISPE, n.d., 2014). Setting up an RFID system while staying GMP and GDP compliant can be hard because of the protection measures that have to be taken.

So why do the pharmaceutical manufacturers think that the RFID tag is the problem? One explanation is that their research is not up-to-date anymore. 10 years ago, the technology was not mature and the tags did cost a lot more. The value of RFID is often wrongly assessed because the benefits are underestimated and the costs are overestimated (J. Merckx, personal communication, April 9, 2015).

From a technical point of view, the responses to the survey questions are widely dispersed. The reassurance of the readability in the absence of water and metals, the certainty of no impact of the RF waves on the medicines and a solution for the interference with metals are most frequently mentioned as required areas for improvement. Apart from those, the invention of an easier way to attach the products (e.g., smaller tags) and the possibility to use the same tag on item, case and pallet level would incentivize two respondents to increase their RFID activities. A better understanding of the technology and less problems with water contact have each been mentioned only once. Finally, one respondent added that he wants the tag to become more durable and reliable before increasing his RFID activities.

The business experts agree with the pharmaceutical manufacturers on the criticality of the readability. Readability needs to be optimized by means of well-organized processes. Figure 17 depicts three configurations of items in a case. With RFID-based processes only the first configuration should be allowed. In the second and third configuration the system will not be errorproof because the antennas of the overlapping tags hinder each other. This limitation is typical of the RF technology and will not be remedied in the near future (E. Van Herbruggen, personal communication, April 2, 2015). The RFID technology can confirm the content of a case or a pallet, but it can not be used to identify which item is not scanned in case a tag is not operational. As long as manual processes are involved somewhere along the chain, errors are likely to occur. If processes are fully automated, the principle of the first configuration in Figure 17 can be assured. For example, Hanmi Pharmaceutical proves that the deployment of RFID in an automated setting can result in a beneficial situation. The Korean pharmaceutical manufacturer delivers its shipments directly to the pharmacies in 75% of the cases (J. Han, personal communication, March 5, 2015). This direct distribution system obliges them to apply heterogeneous packaging. Therefore, they adopted RFID and they created an optimal working environment to enable the technology. Their processes assure a good orientation of the items, cases, et cetera.

Besides the organization of the processes, the working environment and the application area are crucial for good read rates. For example, readability of UHF RFID tags in the presence of water and metals is still problematic (E. Van Herbruggen, personal communication, April 2, 2015). This makes the technology difficult to use in the vaccine supply chain because a vaccine contains water.

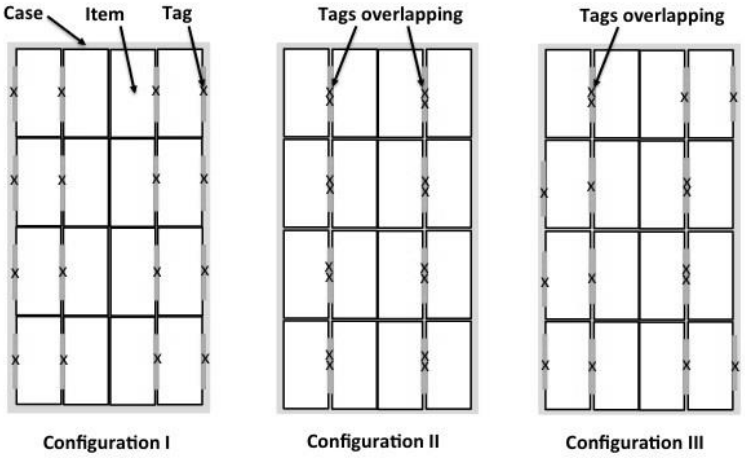


Figure 17: Examples of case compositions (Catarinucci, Colella, Blasi, Patrono & Tarricone, 2011)

From an organizational point of view, increased adoption further down the supply chain would give six pharmaceutical manufacturers an incentive to increase their own RFID activities. Four respondents answer that increased adoption among supply chain partners upstream would give them the same incentive. Two respondents say to increase their RFID activities in the presence of a good implementation guide or action plan. The same number of respondents clarify that a mandate from the wholesalers, hospitals or another external partner would be needed to convince them.

The importance of the influence of industry partners is confirmed by Tom Aelbrecht, who was involved with the RFID projects at Johnson & Johnson. T. Aelbrecht (personal communication, March 3, 2015) says the reason why RFID was quickly adopted by some of Walmart's suppliers is that they would lose Walmart as an important customer if they did not. A strong pharmaceutical supply chain partner downstream that requires its suppliers to attach RFID tags can make a difference. The problem is that the pharmaceutical manufacturers lack customers like Walmart that can influence their decisions (T. Aelbrecht, personal communication, March 3, 2015). However, Walmart did not obtain the results they had hoped for either: by 2010, only 1% of their suppliers engaged in the RFID project, that started in 2003. This forced them to reshape their RFID strategy (Lee & Lee, 2010). Furthermore, if RFID was adopted upstream, the manufacturers could reuse this technology for their own benefits. One respondent reasoned that the initiative has to come from external partners, like the FDA, because 1D and 2D barcodes currently fulfill the needs. However, RFID must not be considered

to be a replacement of barcodes. It must be seen as an evolution (J. Merckx, personal communication, March 19, 2015).

E. Van Herbruggen (personal communication, April 2, 2015) reasons that the confidentiality in the industry is a big organizational challenge. More specifically, pharmaceutical manufacturers are extremely cautious to reveal data about their products or processes. Three manufacturers who share a common point in their chain will apply three different systems in order to protect their data. Each manufacturer will bear the complete infrastructural cost and the opportunity to divide the cost between them will not be taken.

Finally, from another point of view, most reasons are related to the regulations. One respondent asks for more regulatory clarity and customer commitment to use RFID. A second respondent would only be incentivized when regulations mandate RFID over 1D and 2D barcodes. A third respondent wants a clearer business case. A subsidization by the government would encourage two respondents to increase their RFID activities. Only one respondent would consider increasing its RFID activities if an innovative method was invented to recuperate RFID tags.

The fact that subsidization would convince only two respondents is surprising because government funding could be one of the main reasons that the technology is being adopted in the Japanese pharmaceutical industry (J. Han, personal communication, March 5, 2015). One explanation is that the European government has chosen to mandate 2D barcodes and companies already struggle to comply with these regulations. Therefore, the implementation or even the preliminary study of a technology that is not required and that does not guarantee a positive ROI is a stumbling block.

4.1.5.2. Future outlook on the RFID technology

Table 2 shows that the opinion of the pharmaceutical manufacturers on the future application of RFID in the pharmaceutical industry is divided. Four respondents think that there is no future for the RFID technology in the pharmaceutical industry. The other five expect the RFID technology to be used for pharmaceutical applications. They expect that the technology will be used in combination with barcodes to track and trace the drugs, as a standalone solution for track-and-trace or in combination with barcodes for authentication. One respondent sees a potential use in internal logistics and supplier integration.

Table 2: Outlook on the RFID technology in the pharmaceutical industry

Yes (5)		**No (4)**	
In combination with barcodes for track-and-trace	5	1D and 2D barcodes are better suited overall	2
In combination with barcodes for authentication	1	Economic reasons	2
As a standalone solution for track-and-trace	1	Technical reasons	2
As a standalone solution for authentication	0	Regulatory reasons	1
For brand management and marketing purposes	0	Operational reasons	1
For product security	0		
Other: In internal logistics and supplier integration	1		

The business experts share the point of view of the majority of the respondents. They say that there is a future for the RFID technology in the pharmaceutical industry.

Currently, some pharmaceutical manufacturers already use RFID in their supply chain (E. Van Herbruggen, personal communication, April 2, 2015). First, the technology is often attached to high-value products that are transported in bulk packaging to hospitals in countries that are susceptible to fraud. For example, in the case of medicines for cancer treatment, pharmaceutical companies have to be able to prove that they have delivered the right medicine in the right condition and in the right dose. In that case they can not be accused when something goes wrong in the subsequent delivery process. Also, the value of the quantity of high-value medicines in bulk packaging justifies the investment in an RFID tag. Second, some large pharmaceutical companies use the technology for their clinical trials. In these trials it is crucial to administer the drugs in the right dose and in the right circumstances. With RFID the companies can monitor the clinical trials closely.

The technology also has potential in other areas. RFID could enable the WHO to monitor the temperature of their drugs (E. Van Herbruggen, personal communication, April 2, 2015). The WHO often buys drugs to deliver them to third world nations. Some drugs, for example vaccines, require that the temperature stays between specified limits. However, up to half of the drugs that leave to third world nations lose their healing power before they reach the patients. The combination of RFID and serialization could also enable the pharmaceutical companies to detect when products that are intended for the low-priced market appear in high-priced markets.

However, E. Van Herbruggen (personal communication, April 2, 2015) is convinced that the deployment of RFID on a large scale for track-and-trace in the pharmaceutical supply chain is not for

the near future. First, most companies experienced that RFID is hard to implement and quit their trials. The underlying applications are complex and the software in the pharmaceutical companies is not always adapted to those applications. In fact, it could take another 10 years before the software is optimally adapted to RFID. Second, currently, the 2D data matrix is a good alternative. It requires discipline to scan the tag at every control point, but that discipline is present. Third, he says that the added value of RFID for track-and-trace in the pharmaceutical industry is not big at the moment, certainly not in Europe. The European supply chain is already controlled meticulously and fraud is a smaller problem in Europe than in the rest of the world (E. Van Herbruggen, personal communication, April 2, 2015). Nevertheless, counterfeit drugs are a serious threat in Europe as well. Between 2005 and 2006 the number of counterfeit medicines that were intercepted at the European customs increased by 384%. Operation MEDI-FAKE, a EU coordinated action of 2 months, prevented 34 million illegal drugs from entering the European Union in 2008 (European Commission, 2008).

According to E. Van Herbruggen, an ideal application for RFID in the pharmaceutical supply chain can be found in the postal industry. There, a letter is labeled with an RFID tag and sent through the entire supply chain. Each post office is equipped with a reader. Test letters with an RFID tag travel continuously between the post offices to provide useful information, like the travel times. The question remains: who will take the initiative in the pharmaceutical industry?

4.2. Business Case

The literature review, the survey analysis and the abutting conversations with the business experts reveal the challenges that an RFID project poses to pharmaceutical manufacturers. This section discusses a business case with GlaxoSmithKline, one of the biggest pharmaceutical manufacturers in the world. It tests the RFID deployment in the manufacturing process of a vaccine that prevents cervical cancer. The fact that the internal logistic processes are considered, is kept in mind during the analysis. Moreover, issues that come up in the survey and the literature could be less crucial in the business case and vice versa. The execution of a business case gives insight into the difficulties with the application of RFID. As a consequence, it exposes factors that possibly slow the adoption down.

The remainder of this section is structured as follows. The first subsection describes the vaccine manufacturing process in detail. The second subsection describes the application of RFID in this process. First, the application areas are discussed. Second, the most important components of the RFID technology are described. The requirements of and the challenges that are imposed to the technology receive special attention. The third subsection gives a rough estimate of the costs and the benefits of the investment.

4.2.1. The vaccine manufacturing process at GSK

Attachment 2 depicts the vaccine manufacturing process at GSK. The manufacturing process is simplified at some points in order to reduce complexity or to overcome informational limitations. It consists of two processes. In between the two processes the batch is stored in a fridge at -70° C.

Process 1 starts when a vial, filled with approximately 3 milliliters of cell structure, is brought into the manufacturing building. This vial originates from a reservoir with the original seeds. Once received in the manufacturing building, the vial is stored in one of the fridges in logistic area 1. Subsequently, it is transferred to the thaw cabinet into a bath of 27° C. Once thawed, it moves to production room 1, where the cell structure is transferred into a petri dish. In this room, sugars and proteins are added to the cell culture in order to stimulate cell growth. Throughout the growth process the cell culture is moved from small to bigger boxes until it is finally harvested in a container of 1 or 2 liters. Next, this container moves, via logistic corridor 2, to the freezing machine, where the cell structure is cooled with liquid nitrogen. The minimum temperature of -196° C only occurs where the nitrogen enters the freezing machine and lasts only for a few seconds. The temperature increases to -100° C and the container remains in the machine for around 20 minutes. When the operator retrieves the containers from the freezing machine, he will ship them to the freezers in the fridge. The containers are stored in these freezers at temperatures of -70° C for one or two years.

The second process starts in thaw cabinet 1 or 2. When the containers are thawed, they are shipped to production room 2 or 3. Here, the operator transfers the developed cell culture into a vessel. This vessel is linked with tubes to a vessel in production room 4. This vessel is again linked with tubes to another vessel, which is located in the filtration room. This last vessel can contain 200 liters of cell culture. After the cell culture completes the filtration, purification and final filtration it is moved in the final filtration room into 25 different eight-liter-boxes. From here, the eight-liter-boxes are shipped to logistic area 3. As soon as the final filtration is finished, the cold chain starts, which means that the eight-liter-boxes have to be stored between specific temperature limits. Each time the temperature limits are not respected, the operator adds time to an indicator. The maximum allowable time on the indicator is determined by pretesting.

4.2.2. Application of RFID in the vaccine manufacturing process

4.2.2.1. Selection of the application area

The case study has to picture RFID in a realistic application area. The application has to be permitted by the FDA, beneficial for GSK and obtainable from a technical and organizational point of view. Regulatory, economic, technical and organizational limitations come into play immediately.

From a regulatory point of view, FDA approval is necessary for any application of RFID on biological medicines. Although several studies prove that RFID could be used, supplementary tests will most probably be required before the FDA approves the application of RFID on biological drugs

(J.-F. Lecocq, personal communication, April 16, 2015). The cost of these tests could make the project economically infeasible.

From an organizational point of view, several vaccines have to move between different facilities during their manufacturing process. As a result, equipping one facility costs a lot, but is not effective.

From a technical point of view, the fact that RFID uses different radio ranges across the world makes the international application hard. The frequencies have to be harmonized or there would need to be a double infrastructure. In addition, the direct attachment of RFID tags to the vaccines is not possible because these vaccines consist of water. Also, the transport of the eight-liter-boxes happens by means of pallet cages. These are surrounded by metal, which makes the readability of the tags on the eight-liter-boxes problematic.

From an economic point of view, GSK Wavre wants to be sure it can grasp the benefits from the investment in RFID. For example, it is possible that the facility-wide application of RFID results in huge costs and limited benefits for one of the facilities, while resulting in huge benefits and limited costs for another facility. In this scenario, the annual account of GSK Wavre could possibly be negatively influenced.

The case study analyses two areas of application. Both application areas are related to the vaccine manufacturing process. The two areas of application have been selected because some of the previously mentioned issues disappear. Organizationally, the vaccines do not move between different facilities. In this way the implementation of RFID can be studied on a reduced scale, while staying representative. Technically, the project stays in Belgium, so there is no problem with varying frequency standards. Economically, if there is added value from the project, it is noticeable at GSK Wavre. The areas of application cover the flow of two processes: the drugs in the vaccine manufacturing process and the environmental sample follow-up. FDA approval is not necessary for applications in the environmental sample follow-up.

In the vaccine manufacturing process, a set of RFID tags will follow the cell culture from the moment it is transferred into a container of 500 milliliters in production room 1 until it moves, inside 25 different eight-liter-boxes, to logistic area 3. The first tag will not be attached to the first and smallest container because of physical limitations. Figure 18 shows the number of tags that are required to follow one batch. A batch agrees with the complete volume of the initial cell culture. At the start of the process this agrees with 3 milliliters. At the end of the process, the cell culture has grown into a substance of 200 liters. Every new manufacturing cycle will require a new set of tags. For one complete internal process 31 tags are required. As soon as the data on TAG 5 is transmitted onto TAG 6, TAG 1-5 are disposed and a new process with new materials and new tags starts. The only RFID tag that is recuperated in each process is TAG 6 on the final vessel of 200 liters. In contrast to the other preparation materials (e.g., vials, containers, vessels) on Figure 18, the final vessel is cleaned and reused.

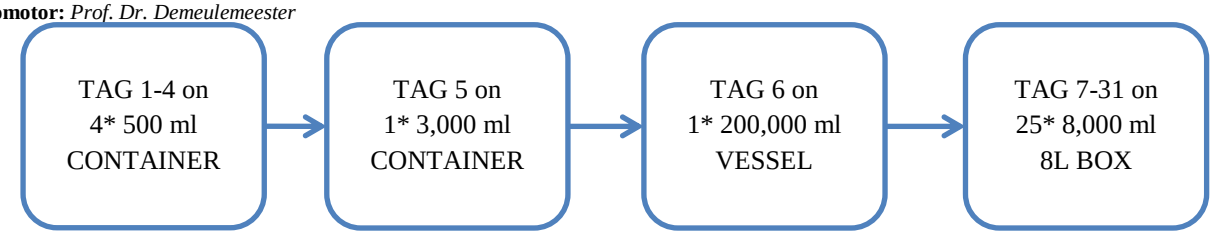


Figure 18: RFID tag placement and flow

In the environmental sample follow-up each RFID tag identifies one sample. Samples are taken throughout the complete vaccine manufacturing process. For example, every 20 minutes an environmental sample is taken in the sterile area of the first production room. When the batch moves to another room, a case, filled with samples, stays behind. As shown in Attachment 3, the samples are transferred to logistic area 4. The number of samples add up to 100 per day or 20,000 per year (one year = 40 productive weeks). Once received in logistic area 4, the operators will check whether samples are missing in the case. Subsequently, the complete cases are shipped by truck to the reception at the Quality Control (QC) Center. Here, the samples are checked again. From there, they move to the dispatch room, storage rooms and through the logistic corridor to the labs. After a stay of one week in the lab, the samples arrive in the identification room, where they are analyzed and identified.

The introduction of RFID is expected to have the highest chance on success in the environmental sample follow-up. On the one hand, the approval of FDA is not required to start the project (J.-F. Lecocq, personal communication, April 16, 2015). On the other hand, it is not a disaster when a tag is not read, because the tags do not follow the final product.

4.2.2.2. Selection of the RFID technology

4.2.2.2.1. Vaccine manufacturing process

Hardware

Table 3 indicates the requirements for the RFID tag and the environmental challenges it will have to endure during the vaccine manufacturing process. The table identifies the most significant issues that have come up during two weeks of brainstorming and is not claimed to be exhaustive.

Table 3: Requirements of and challenges to the RFID tag in the vaccine manufacturing process

Requirements
Identification
Information readable by humans
Sterilizable
Read range of approximately 3 meters
Environmental challenges
Temperature shock of -196° C in liquid nitrogen (few seconds)
Extremely cold temperature of -70° C in freezer (2 years)
Water bath of 27° C
Exposure to dry fog

In table 3, four important requirements are mentioned. First, the tag is the unique identifier that triggers the RFID readers and that enables the system to know where the product is. Therefore, the tag needs to contain a unique ID number that is detectable by the readers. Second, GMP regulations oblige the pharmaceutical manufacturers to add identification information like the name of the product in human readable format on the preparation materials (e.g., container). These data need to be printed on the tag by an industrial printer in a non-sterile area. Third, the tag will be attached to containers that enter the sterile areas. Therefore, the tag needs to be made sterile. However, the sterilization methods that are used to prepare the preparation materials can not necessarily be used for the tags. Gamma radiation and autoclaves can destroy the RFID tag. One solution is to sterilize the tag with ethyl alcohol or isopropanol, assuming that the tag can resist this. Fourth, the tag needs to make a connection with the readers. Depending on the location of these readers, the tag's read range needs to be bigger or smaller. As a conservative estimate, a read range of approximately 3 meters will be necessary.

The vaccine manufacturing environment poses numerous challenges to the tag. The first challenge is a temperature shock of -196° C in the freezing machine and the second challenge is a two-year period in temperatures of -70° C inside the freezers. Battery-powered active tags do not survive in this environment, but passive RFID tags can remain readable after exposure to such temperatures (Topflight, 2014). Nevertheless, a special material needs to protect the adhesive of the tag to the container. The third challenge appears in the thaw cabinets, where the container is put into water. This challenge could be remedied by putting the tag into a plastic bag that is sealed by heat. This bag would prevent water from affecting the tag. The fourth challenge emerges because dry fog is used to sterilize some of the rooms. The RFID tag should be made of a material that does not degrade after being brought in contact with dry fog.

Concluding, the requirements and the harsh environmental circumstances demand a properly protected tag.

Table 4 shows the requirements of and the environmental challenges that are posed to the fixed reader technology. The reader technology has to be selected wisely. It needs to be compatible with the RFID tags and, in the ideal case, it will discriminate between movements in and out of the room. For the moment, these movements are registered in an Excel sheet, where even numbers represent movements in the room and odd numbers represent movements out of the room. If one line is not filled in, the subsequent movements are wrongly assigned. An automatic detection method can prevent this inconvenience. Some RFID manufacturers, like Impinj, offer readers with the tag movement detection ability (RFID Update, 2007). Another option is to combine sensors with antennas. While the antenna reads the tags, the sensors read if a product goes from a to b or from b to a (Oikawa, 2011). Oikawa (2011) proposes a third method, the double-antenna method, for gate systems. Two antennas are placed behind each other. The read time differences allow the reader to determine the direction of movement.

Table 4: Requirements of and challenges to the fixed reader technology in the vaccine manufacturing process

Requirements
Compatible with RFID tag
Discriminate between tag movement direction
Environmental challenges
Located within 3 meters of RFID tag
Penetration through ceilings and floors

The reader technology must also be located wisely. The technical levels above and below the production level are the best positions to locate the fixed readers for two reasons. On the one hand, the readers in the technical rooms will not have to be cleaned. On the other hand, a lot of space will be saved in the production rooms. As a result of this decision, two environmental challenges need to be addressed. First, the distance between the readers and the tags must be less than 3 meters. Second, the radio waves must go through the ceilings and floors. The distance is not an issue since the containers and the vessels will be maximum 2 meters from the reader if the reader is installed beneath the floor (J.-F. Lecocq, personal communication, April 10, 2015). The penetration through the floor and ceilings can be an issue. However, most of the ceilings and floors are made of gyproc, which can easily be penetrated by the radio waves.

In some cases, it remains necessary to read with mobile readers. On the one hand, a handheld reader will have to be used (e.g., when the container enters the freezing machine). The freezing

machine is made out of metal, which can not be penetrated by radio waves. The fixed reader will not be put in front of the freezers because a container could be read, while it has not actually entered the freezer yet. In this case, a manual process, with handheld readers, is better suited. On the other hand, a mobile personal computer (pc) will have to be bought. This pc will be used in the sterilized area in production room 1. To sterilize this area, dry fog is used. This dry fog affects most metals. Each time the room is sterilized, the mobile reader could leave the room to be sterilized by a different process. Eventually, the mobile pc will be reentered in the room.

Throughout the vaccine manufacturing chain, mobile pc's, handheld readers and fixed readers will be needed. The rooms in which fixed readers will be installed are marked with the symbol of an RFID gate in Attachment 2. The rooms and areas where mobile readers will be used are marked with the symbol of a handheld reader or the symbol of a mobile pc. Only one handheld reader is required per area.

Attachment of the tag to the product

Attaching the tag to the containers, vessels and eight-liter-boxes is possible by means of a chord. As shown in table 5, three issues occur.

Table 5: Issues related to the attachment of the tags

Issues
Shape of the containers
Location on preparation materials
Extreme cold temperatures

The first issue is the shape of the containers. It does not allow a tag to be attached. A solution, such as the redesign of the containers, has to be worked out with the agreement of the FDA. The second issue is the location of the tag on the preparation materials. The tag needs to be read, but the reading signals must not affect the vaccine. When the tag is attached to a metal, it needs to be a few centimeters away from the metal to prevent interference. If the tag is attached to a plastic, it needs to be far enough from the cell culture to prevent a temperature increase or an undesirable non-thermal effect. The third issue is that the attachment method needs to survive the nitrogen machine, the thaw cabinet, et cetera. The cord is possibly not strong enough to resist these circumstances.

Software

Two methods are considered to integrate RFID into the software of GSK. A first possibility is to activate the RFID functionality in Systems, Applications and Products in Data Processing (SAP). A second possibility is to rely on the services of an RFID expert, who installs his own integration

applications. Although the second option is cheaper, GSK opts for the RFID functionality in SAP since it is a safer choice regarding future compatibility and maintenance.

4.2.2.2.2. Environmental sample follow-up

The RFID tags that need to be attached to the samples, are not subjected to the same requirements and environmental challenges as the ones in the vaccine manufacturing process. Therefore, these tags are simpler. The readers that are needed for the environmental sample follow-up are marked with the symbol of an RFID gate or a handheld reader in Attachment 3. The readers can be installed in the logistic areas. There is no need to place them in technical rooms since the logistic areas are not subjected to the requirements of sterility. Since there is no need to get approval from the FDA for the samples, an attachment solution for the RFID tags can be worked out more easily.

No extra software has to be installed for the application of RFID in this area. The RFID functionality in SAP can be reused in other buildings and facilities.

4.2.3. Investment analysis

In this section the ROI of the RFID investment is estimated over a five-year period. The analysis focuses on the situation where RFID is implemented in both application areas at the same time. The additional benefits and costs are calculated based on a comparison to the current situation at GSK.

4.2.3.1. Costs

Table 6 shows a classification of the costs in capital expenditures and operational expenditures.

The capital expenditures consist of the initial investments such as hardware (exclusive tags) and software. Bottani and Rizzi (2008) and Miragliotta, Perego and Tumino (2009) both estimate the cost of an RFID reader around 2,000 euros. The cost of an antenna is estimated at 260 euros. It is assumed that a fixed reader is always equipped with two antennas. In agreement with GSK a cost of 4,000 euros is taken for the fully equipped mobile pc. Throughout the vaccine manufacturing process five fixed readers, two handheld readers and one mobile pc are required. Throughout the sample's path, four handheld and six fixed readers are necessary. No mobile pc is required. The estimated cost for the RFID functionality in SAP amounts to 100,000 euros (J. Merckx, personal communication, April 9, 2015). The most significant cost is related to the implementation of the RFID project. Expensive RFID experts are consulted to guide the project, a pilot study is set up and followed up, the project is evaluated, the hardware and software is installed in the building, the equipment is tested again, the project is followed up, et cetera. Based on previous studies (Schapranow, Müller, Zeier & Plattner, 2011), a cost of 500 euros per day per Full-Time Equivalent (FTE) is accounted for (J.-F. Lecocq, personal communication, April 9, 2015). It is assumed that two FTEs would have to work 300 days to implement the RFID project, from the material selection up to the project closure. Among the capital expenditures, a distinction is made between initial investments and recurring costs in case a second

building, the QC Center, is equipped. Some costs, for example the IT installation, do not have to be duplicated. Other costs, like the material selection cost, the training cost for the employees and the hardware cost, occur every time a new building is equipped.

The operational expenditures consist of the RFID tags and the maintenance costs. Tag prices range from less than 5 eurocents for the most basic one to 20 euros for tags in the most extreme circumstances (J. Merckx, personal communication, April 9, 2015). As a conservative estimate, a price of 20 euros per tag is chosen for the vaccine manufacturing process. A price of 37 eurocents is accounted for in the environmental sample follow-up. This is a high price for a simple tag. Approximately 1,500 robust RFID tags and 20,000 simple tags are required. The maintenance costs are estimated to be 10% of the initial investment costs, exclusive project management and software.

Table 6: Classification of the costs in capital and operational expenditures

Capital expenditures		
Component	Unit cost	Source
Reader equipment		
Device (Fixed and handheld)	€ 2,000	Bottani and Rizzi (2008)
Mobile pc	€ 4,000	(J.-F. Lecocq, personal communication, April 15, 2015)
UHF RFID antenna	€ 260	Miragliotta et al. (2009)
Industrial printer	€ 3,500	Schapranow et al. (2011)
Implementation /consulting	€ 500 / FTE	Schapranow et al. (2011)
RFID software in SAP	€ 100,000	(J. Merckx, personal communication, April 9, 2015)
Operational expenditures		
Component	Unit cost	Source
Simple tag	€ 0.37	Schapranow et al. (2011)
Robust tag	€ 20	(J. Merckx, personal communication, April 9, 2015)

4.2.3.2. Benefits

The benefits are indicated in Table 7. These benefits were determined by investigating the activities that occur in the vaccine manufacturing process. The activities that benefit from the adoption of RFID were marked and the ones for which the value of the benefits was most significant, were analyzed in more detail. Four big categories of benefits could be distinguished. First, a shrinkage of the batch record. Every time a handling is done in the vaccine manufacturing process, this has to be noted in the batch record. The batch record is a paper document of approximately 1,000 pages,

consisting of checklists. The assumption is made that the adoption of RFID will result in a 10% decrease of the batch record. This information will now be stored electronically. The shrinkage of the batch record results in time gains when the printed batch record is checked for errors at the beginning, when the batch record is completed during and when the batch record is checked again at the end of the vaccine manufacturing process. Second, large gains are expected by moving the environmental samples in a more efficient manner to the laboratories. These gains relate to the fact that cases, filled with environmental samples, do not have to be opened anymore in order to be read. Third, the faster retrieval of information creates time gains to detect and find problems. Together with GSK, it is decided that this will result in one day of production saved every year and some additional cost savings due to the reduction of the search time. Fourth, at the end of the manufacturing process, everything that has happened to the vaccines has to be checked. RFID allows to do these checks faster. A faster check results in a faster delivery. The faster check can also save a batch in case of an emergency. For example, when a mistake is made, the decision has to be made whether the whole batch will be checked or whether it will be disposed. The check has to happen within a limited time frame, otherwise the batch has to be disposed either way. If the checks can be done faster, the managers will have more incentives to do them. It is assumed that every year one month is gained in delivery time and that one batch can be saved every 5 years.

Table 7: Classification of the benefits

Activities (savings per year)	Benefits
Shrinkage of Batch Record (BR) due to automatic registration of movements	
Value of time reduction in verification of print-out	€ 2,000
Value of time reduction in completing the BR	€ 16,667
Value of time reduction in checking the BR at finish	€ 3,200
Shrinkage of Environmental Samples (ES) follow-up time	
Value of time reduction in checks on sample level	€ 20,000
Value of time reduction in checks on case level	€ 12,000
Gains due to faster/better retrieval of information	
Once a year 1 day of production is not lost	
Saved employment costs	€ 19,200
1 day of biopharmaceutical production saved (building)	€ 100,000
1 day delay in delivery time prevented	€ 2,500
Search time reduced in case of problems	€ 50,000
Savings due to more efficient checking at the end	
Value of the saved batches	€ 100,000
Immediate detection of problems / faster delivery	€ 50,000

4.2.3.3. Results

Table 8 pictures the investment analysis over 5 years considering the introduction of RFID to track and trace the drugs and the environmental samples throughout the vaccine manufacturing process. The investment is evaluated over a period of 5 years because this is deemed a reasonable time period to pay the investment back. The discount rate is determined by using the average interest rate between 1998 and 2015 reported by the European Central Bank (Trading Economics, 2015). The investment is already recovered after 3 years. Moreover, the ROI over 5 years is 90%. The net present value (NPV) over 5 years is 724,585 euros. The initial investment roughly amounts to 810,000 euros. In the first year a gain of a 321,079 euros is registered. A large part of the yearly gains can be accounted to the batch saving every 5 years and the gain of 1 month in delivery time every year. Based on this exploratory analysis, the project would result in large savings.

Table 8: Investment analysis over 5 years

	Years					
	0	1	2	3	4	5
Discount rate	1	0.98	0.95	0.93	0.91	0.89
Cost - Cost savings						
Tagging and labelling		-€ 37,420	-€ 37,420	-€ 37,420	-€ 37,420	-€ 37,420
Maintenance		-€ 9,522	-€ 9,522	-€ 9,522	-€ 9,522	-€ 9,522
Shrinkage BR		€ 21,867	€ 21,867	€ 21,867	€ 21,867	€ 21,867
Shrinkage ES follow-up		€ 32,000	€ 32,000	€ 32,000	€ 32,000	€ 32,000
Faster retrieval of info		€ 171,700	€ 171,700	€ 171,700	€ 171,700	€ 171,700
Batch savings		€ 100,000	€ 100,000	€ 100,000	€ 100,000	€ 100,000
Faster delivery		€ 50,000	€ 50,000	€ 50,000	€ 50,000	€ 50,000
Investment	-€ 808,764					
Net cash flow	-€ 808,764					
Discounted cash flow	-€ 808,764	€ 321,079	€ 313,707	€ 306,504	€ 299,467	€ 292,591
Net present value	€ 724,585					
ROI	90%					

Note. BR = Batch record. ES = Environmental samples.

If the gains from the batch savings were omitted, the investment stays beneficial. Over a 5-year period the NPV is still 257,989 euros and the ROI is 32%. If the gains from the faster delivery times are omitted as well, the ROI drops further to 3%.

If only 5% of the batch record could be stored electronically, the ROI would decrease to 83%. However, if the project would be more beneficial than expected and results in 30% of the batch record being stored electronically, the ROI of the project increases to 115%.

If the better retrieval of information would result in one day of production saved once every 5 years, the ROI would drop to 59%. If it results in two days of production saved per year, the ROI increases to 185%.

The profitability of the project largely depends on three factors: the number of days of production that can be saved, the reduction in delivery time and the number of batches that can be saved every year. A saved day of production is very valuable because of the large number of employees in a building, the energy that is required to produce the drugs and the value of these drugs.

5. Limitations and future research

This research project faces several limitations.

The survey was sent out only to the pharmaceutical manufacturers. To get a realistic view on the complete pharmaceutical industry, the application of RFID should also be studied among the other industrial key players, being the wholesalers and the drug dispensers. As it turns out, the potential benefits from RFID could be larger for these companies. Furthermore, only nine pharmaceutical manufacturers answered on the survey. The pharmaceutical industry consists of hundreds of pharmaceutical manufacturers. As a consequence, the survey analysis can not reliably represent the complete pharmaceutical manufacturing industry. Because of the large implementation costs of RFID, the survey was mainly sent out to the big pharmaceutical manufacturers. As a result, the answers could not accurately represent the status of application and opinion of the small pharmaceutical manufacturers.

The business case also faces several limitations. First, the FDA needs to approve the RFID project on the vaccines in the manufacturing process. Therefore, GSK would need to carry out extra tests. The testing costs are not accounted for in the analysis. It is possible to execute the project on the samples without approval, but the gains would not be the same without a simultaneous project on the final vaccines. In the ideal scenario, the biggest pharmaceutical manufacturers would collaboratively carry out a test project. The government could also think about subsidizing the tests, because the project can lead to more safety and less spillage. Second, the RFID tags and readers need to be adapted to the process. No specific solution has been offered in this paper. The material selection and testing costs are accounted for, but this study does not say that the technology already exists. Third, this positive investment outcome is due in part to the extremely valuable vaccines. Saving a batch worth 500,000 euros once every 5 years would not be a realistic estimate in most other industries.

Future research should be carried out to determine the status of adoption among other supply chain partners. Further research could address how collaboration between the supply chain partners

could be established and what benefits would be achieved in this situation. Relevant research could also exist out of investigating how the government benefits from the adoption of RFID. Furthermore, useful research would compare the Korean pharmaceutical supply chain with the European or US pharmaceutical supply chain and investigate if RFID is better suited in Korea and why. Finally, future research should focus on the EPC network. This paper focused on the RFID technology, but without the EPC network the most important gains from RFID would not be established.

6. Conclusions and insights

This paper investigated the adoption of RFID in the pharmaceutical industry. The FDA started to stimulate the use of this technology in the early years of the new millennium. However, the adoption did not seem to take off. This paper analyzed the current status of application among the pharmaceutical manufacturers, as well as the reasons for not adopting the technology and the expectations about the application areas of the technology.

This paper finds that RFID is not frequently adopted among pharmaceutical manufacturers, but that the technology is still being studied. Three out of the nine respondents are in progress with a pilot study or a strategic analysis. Only one respondent is actively using RFID. Five respondents are not using or studying the technology.

RFID is mostly linked to enhanced product visibility and increased supply chain efficiency. For visibility, the added value of RFID relative to barcodes is promising for the monitoring of the drugs in cold chains. The increase in supply chain efficiency is the highest when the processes can be fully automated, as the case of Hanmi Pharmaceutical showed. However, the results also showed that RFID is not linked to increased profits.

The main reason for the discontinuation of the RFID projects was based on economic grounds. Moreover, every pharmaceutical company that stopped the project, partly did so because of the cost of the RFID tag. Four out of the five respondents mentioned that the main reason was based on technical grounds. More specifically, the technology was too complex to implement. Three out of the five respondents said that the reason to cease the project was mainly due to organizational issues, with the lack of adoption by supply chain partners being the most mentioned organizational challenge. Only one respondent stated that the main reason to stop the RFID project was related to the regulations. However, when specifically asked for regulatory challenges, every respondent mentioned the 2D regulations.

Overall, the certainty of the ROI from the RFID project and the increased adoption downstream the supply chain would give the most pharmaceutical manufacturers an incentive to increase their RFID activities. These incentives were mentioned by six out of the nine respondents. Decreased readability issues with the technology, the certainty of no impact of radio frequency on the product,

increased adoption downstream the supply chain and regulations in favor of RFID were each mentioned four times as being a sufficient incentive to increase the RFID activities.

The opinion of the pharmaceutical manufacturers on the future of RFID in the pharmaceutical industry is divided. Only five out of the nine pharmaceutical companies think that there is a future for RFID in the pharmaceutical industry. The opinion that is most often shared, is that RFID will be used in combination with barcodes for track-and-trace. The RFID and Auto-ID expert also think that RFID will eventually be used for track-and-trace purposes in the pharmaceutical supply chain. However, the Auto-ID expert argues that this can take another 10 years due to the fact that RFID is hard to implement and that 2D barcodes are a good alternative at the moment.

The business case of the vaccine manufacturing process showed that RFID can be of great value for applications at the pharmaceutical manufacturers. The biggest benefits arose because of the reduction in delivery time, the savings of a batch of drugs and the fact that a day of production could be saved. The sensitivity analysis showed that the ROI was robust against variations in the benefits. The NPV depended the most on whether a day of production could be saved and the frequency of this event occurring. Some implementation issues, like the attachment difficulties, the big organizational changeover, the regulations and the imperfect readability were similar to the ones mentioned in the literature review and the survey results. Some issues, like the requirements of the RFID tag to survive extreme circumstances, were typical to the manufacturing process under investigation. As expected, the tag costs were much lower than the implementation costs.

The investment analysis of the RFID implementation at GSK showed extremely positive results. Finding a good application area requires hours of brainstorming, but it also requires an open mind of the directors and the personnel of the company. Finally, the business case makes clear that it may be necessary for the regulatory instances to provide support. The expensive tests, that could be required by the FDA to use the technology in the vaccine manufacturing process, can prevent the pharmaceutical manufacturers to use a technology that results in benefits for the companies as well as for the patients.

Future research should address the adoption of RFID in the wholesaler industry and the drug dispensing industry. It should also address how supply chain partners could collaborate and whether the application of RFID in the complete supply chain would result in joint profits. Also, a study on the ways in which RFID would benefit the government can provide useful insights. Furthermore, the differences between the Korean pharmaceutical supply chain and the European or US pharmaceutical supply chain could be studied to determine how the benefits from the application of RFID depend on the supply chain structure. Finally, the importance of the EPC network should be studied in more detail.

Tibo Steen
RFID and track-and-trace in the pharmaceutical industry
Promotor: *Prof. Dr. Demeulemeester*

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Tibo Steen
RFID and track-and-trace in the pharmaceutical industry
Promotor: *Prof. Dr. Demeulemeester*
Attachment 1: Survey

RFID in the pharmaceutical industry

Master's thesis at KU Leuven

Radio-frequency identification (RFID) is a hot topic in the pharmaceutical industry. The past 10 to 15 years, a lot has been written and told about this technology. This benchmark is part of a renewing study executed in collaboration with the Catholic University of Leuven (KU Leuven), Belgium and the management consultancy company 4XScience. By means of this questionnaire, sent out to the leading pharmaceutical manufacturers, we hope to gain insight into the state of adoption, the use of RFID and the attitude towards RFID in the pharmaceutical industry. Filling in the survey will take about fifteen minutes and it will significantly improve the quality of our results. In return, you will receive at no cost an electronic report of our research. Note that your anonymity will be respected and that no references to your company will be made in the report. I kindly ask you to fill in this benchmark before March 20, 2015.
In case you have any further questions or concerns, please do not hesitate to contact me on tibo.steen@student.kuleuven.be.

Many thanks in advance for your time and effort,

Tibo Steen
Master Commercial Engineer
KU Leuven
Belgium

General information

Your contact information will not be connected to your survey responses in any way. It will exclusively be used in case of a problem or in case further contact is allowed.

What is your name? *

What is the name of your company? *

What is your function? *

What is your e-mail address? *

What is your phone number?
Please add the international calling code (e.g., +32 for Belgium).

Do you allow to be contacted for any further discussion regarding your responses? *
Contact will consist of an e-mail or a 15 minute telephone call and will serve to resolve ambiguities or to elaborate on a specific question.

- ○ Yes
- ○ No

1.1 Benefits and potential of RFID

Answer the questions on this page based on your general expectations of and overall experience with RFID.

What benefits do you identify with RFID? *
Multiple answers possible

- ○ ☐ Increased sales
- ○ ☐ Increased profits (exclusive investment costs)
- ○ ☐ Increased profits (inclusive investment costs)
- ○ ☐ Improved inventory accuracy (e.g., less frequent out-of-stocks)
- ○ ☐ Reduced need for safety stocks
- ○ ☐ Shorter lead times (= cycle time + waiting time)
- ○ ☐ Shorter cycle times (e.g., minutes per customer, hours per part)
- ○ ☐ Decreased obsolescence
- ○ ☐ Faster and more focused recalls
- ○ ☐ Reduced shipment errors
- ○ ☐ More effective and efficient marketing (e.g., to facilitate targeted marketing)
- ○ ☐ Enhanced product and supply chain security (e.g., to prevent/solve cargo theft)
- ○ ☐ Enable data intelligence
- ○ ☐ Enhanced product visibility (e.g., to control diversion, cold chain monitoring)
- ○ ☐ Increased supply chain efficiency (e.g., to help product tracking)
- ○ ☐ Other: ____

On what level do you expect the benefits from RFID use to be the greatest? *
Multiple answers possible

- ○ ☐ Primary packaging level (vial/syringe/blister/bottle)
- ○ ☐ Secondary packaging level (carton box/item)
- ○ ☐ Bundle level
- ○ ☐ Tertiary packaging level (shipping case)
- ○ ☐ Pallet level
- ○ ☐ Other: ____

In what functional area can the benefits be realized? *
Multiple answers possible

- ☐ Supply chain management
- ☐ Demand management
- ☐ Inventory management
- ☐ Operations management
- ☐ Quality management
- ☐ Brand management
- ☐ Product security
- ☐ Master data management
- ☐ Finance
- ☐ Other: ____

Where can the benefits be realized? *

	No benefits	Very weak benefits	Weak benefits	Strong benefits	Very strong benefits
Supplier of raw materials	○	○	○	○	○
Manufacturing facilities	○	○	○	○	○
Plant warehouses	○	○	○	○	○
Distribution Centers	○	○	○	○	○
Wholesaler	○	○	○	○	○
Pharmacies	○	○	○	○	○
Hospitals	○	○	○	○	○
Patients	○	○	○	○	○

Why is RFID able to deliver these benefits? *
Multiple answers possible

- ☐ Integration with other supply chain nodes (exchange of information/communication)
- ☐ Automation of authentication (no human scanning)
- ☐ No hinder of (optical) covering such as dirt or dust particles
- ☐ High density of data on RFID
- ☐ Ease of integration with EPC global network
- ☐ Readability without line-of-sight
- ☐ No degradation
- ☐ Increased complexity of technology compared to barcodes

- ☐ High reading speed
- ☐ Ease of data gathering
- ☐ Other:

1.2 Status and reality check

What is the status of RFID within the company? *

- ○ No actions with regard to RFID
- ○ In progress: Strategic analysis / study about the use of RFID
- ○ In progress: Pilot study
- ○ In progress: Actively using RFID for a limited amount of pharmaceutical products (<10)
- ○ In progress: Actively using RFID for a wide range of pharmaceutical products (>10)
- ○ In progress: Actively using RFID for all pharmaceutical products
- ○ Completed: Strategic analysis / study about RFID and decided not to proceed with RFID
- ○ Completed: Pilot study and decided not to proceed with RFID
- ○ Other:

How long have you been working on/with RFID? *
e.g., 1-3 means 1 inclusive 3 exclusive

- ○ < 1 year
- ○ 1-3 year
- ○ 3-5 year
- ○ 5-10 year
- ○ > 10 year

1.3 Completed strategic analysis / study

On what level did the study explore RFID? *
Multiple answers possible

- ☐ Primary packaging level (vial/syringe/blister/bottle)
- ☐ Secondary packaging level (carton box/item)
- ☐ Bundle level
- ☐ Tertiary packaging level (shipping case)
- ☐ Pallet level
- ☐ Other:

What business benefits were most significant to the company according to the study *
Multiple answers possible

- ☐ Increased sales
- ☐ Increased profits (exclusive investment costs)
- ☐ Increased profits (inclusive investment costs)
- ☐ Improved inventory accuracy (e.g., less frequent out-of-stocks)
- ☐ Reduced need for safety stocks
- ☐ Shorter lead times (= cycle time + waiting time)
- ☐ Shorter cycle times (e.g., minutes per customer, hours per part)
- ☐ Decreased obsolescence
- ☐ Faster and more focused recalls
- ☐ Reduced shipment errors
- ☐ More effective and efficient marketing (e.g., to facilitate targeted marketing)
- ☐ Enhanced product and supply chain security (e.g., to prevent/solve cargo theft)
- ☐ Enable data intelligence
- ☐ Enhanced product visibility (e.g., to control diversion, cold chain monitoring)
- ☐ Increased supply chain efficiency (e.g., to help product tracking)
- ☐ Other: _____

Where in the supply chain did the study point out to deliver those benefits? *
Multiple answers possible

- ☐ Supplier of raw materials
- ☐ Manufacturing facilities
- ☐ Plant warehouses
- ☐ Distribution center
- ☐ Wholesaler
- ☐ Pharmacies
- ☐ Hospitals
- ☐ Patients
- ☐ Other: _____

1.4 RFID: Why not?

Why did you not implement RFID? *
Multiple answers possible

- ☐ Economic reasons
- ☐ Technical reasons

- ☐ Organizational reasons
- ☐ Regulatory reasons
- ☐ Other: _____

Economic Reasons *
Multiple answers possible

- ☐ Cost per RFID tag is too high
- ☐ Cost to change infrastructure is too high
- ☐ Cost/benefits unevenly distributed across supply chain partners
- ☐ ROI is dubious or uncertain (ROI = Return On Investment)
- ☐ ROI is negative
- ☐ Not applicable
- ☐ Other: _____

Technical reasons *
Multiple answers possible

- ☐ Readability issues of the tags
- ☐ Security issues (e.g., privacy)
- ☐ Attaching difficulties on product
- ☐ Connectivity issues of authentication technology to the company network
- ☐ Negative impact of waves on product
- ☐ Complexity of technology
- ☐ Complementarity issues with current technology architecture
- ☐ Not applicable
- ☐ Other: _____

Organizational reasons *
Multiple answers possible

- ☐ Infrastructure changes
- ☐ Employee reluctance to change current way of working
- ☐ Management reluctance to RFID adoption
- ☐ Design and implementation of RFID-enabled healthcare processes
- ☐ Lack of adoption by companies downstream and upstream
- ☐ Not applicable
- ☐ Other: _____

Other reasons *
If (one of) your answer(s) is 'Emergence of another technology', please specify which technology in the box 'other'. Multiple answers possible

- ☐ 2D regulations

- ☐ Serialization regulations
- ☐ GMP/GDP regulations (Good Manufacturing Practice/Good Regulation Practice)
- ☐ Repackaging of products makes RFID too expensive
- ☐ RFID is not mature yet
- ☐ Emergence of another technology
- ☐ Not applicable
- ☐ Other: _____

1.5 What about the future?

Do you see a future for RFID technology in the pharmaceutical industry? *

- ☐ Yes, as a standalone solution for track and trace
- ☐ Yes, as a standalone solution for authentication
- ☐ Yes, in combination with bar codes for track and trace
- ☐ Yes, in combination with bar codes for authentication
- ☐ Yes, for brand management and marketing purposes
- ☐ Yes, for product security
- ☐ No, 1D and 2D bar codes are better suited overall
- ☐ No, other technology will be selected due to economic reasons
- ☐ No, other technology will be selected due to technical reasons
- ☐ No, other technology will be selected due to regulatory reasons
- ☐ No, other technology will be selected due to operational reasons
- ☐ No, other technology will be selected due to other reasons
- ☐ Other: _____

Economic: What would be a sufficient incentive to increase your activities towards RFID? *
Choose the strongest incentive. Checking multiple options means that the combination of those options is a sufficient incentive. Multiple answers possible

- ☐ Decrease in cost per RFID tag
- ☐ Decrease in cost of RFID readers and other initial investments
- ☐ Cost-split arrangement with supply chain partners
- ☐ Certainty of ROI
- ☐ Reduced maintenance costs
- ☐ No option would suffice
- ☐ Other: _____

Technical: What would be a sufficient incentive to increase your activities towards RFID? *
Choose the strongest incentive. Checking multiple options means that the combination of those options is a sufficient incentive. Multiple answers possible

- ☐ Possibility to use the same tag on item-, case and pallet level
- ☐ Tags less prone to water contact
- ☐ Tags less influenced by interference with metals
- ☐ Assured readability in the absence of water and metals
- ☐ Better understanding of RFID technology
- ☐ Easy attachment / smaller tags
- ☐ Certainty of no negative impact of waves on product
- ☐ No option would suffice
- ☐ Other: _____

Organizational: What would be a sufficient incentive to increase your activities towards RFID? *
Choose the strongest incentive. Checking multiple options means that the combination of those options is a sufficient incentive. Multiple answers possible

- ☐ Increased adoption of RFID by supply chain partners downstream
- ☐ Increased adoption of RFID by supply chain partners upstream
- ☐ The existence of a good implementation guide / action plan
- ☐ No option would suffice
- ☐ Other: _____

Other: What would be a sufficient incentive to increase your activities towards RFID? *
Choose the strongest incentive. Checking multiple options means that the combination of those options is a sufficient incentive. Multiple answers possible

- ☐ Postponement / abolishment of 2D regulations
- ☐ Postponement / abolishment of serialization regulations
- ☐ Creation of an innovative method to recuperate RFID tags
- ☐ Subsidization by the government
- ☐ No option would suffice
- ☐ Other: _____

1.6 General opinion

*

	Totally disagree	Disagree	Neutral	Agree	Totally agree
RFID technology	○	○	○	○	○

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Promotor: *Prof. Dr. Demeulemeester*

	Totally disagree	Disagree	Neutral	Agree	Totally agree
is a safe investment if it is properly implemented and tailored to the needs of a specific company (safe = certainly positive ROI)					
The presence of a good internal project leader is crucial to the success of the RFID project					
The presence of a professional external consultant is crucial to the success of the RFID project					
The endorsement of a good sponsor is crucial to the success of the RFID project					

Any other comments?

Please feel free to signal any problems you may have encountered filling in the survey or any comments you may want to make

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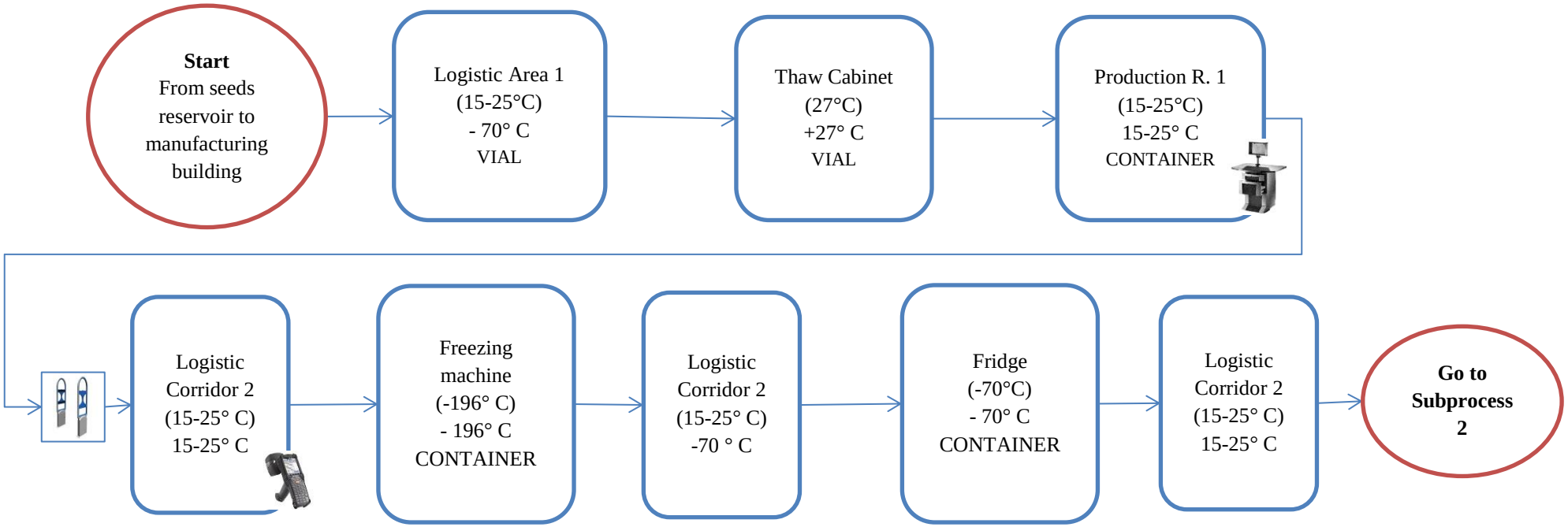
Attachment 2: Vaccine manufacturing process

SUBPROCESS 1

KEY: = fixed reader = mobile pc

= mobile reader R. = room

Building
(Temperature in the room)
Temperature of the product
PREPARATION MATERIAL



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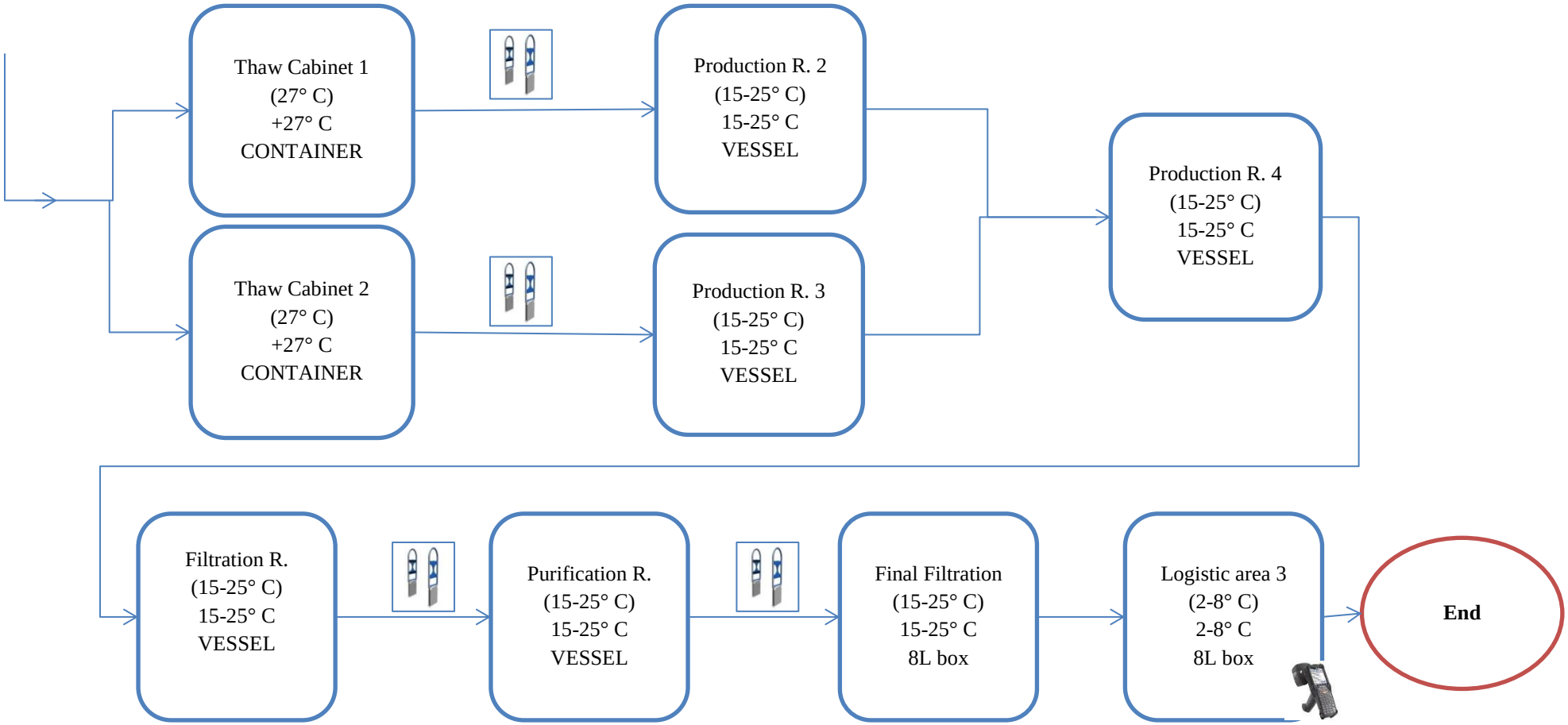
SUBPROCESS 2



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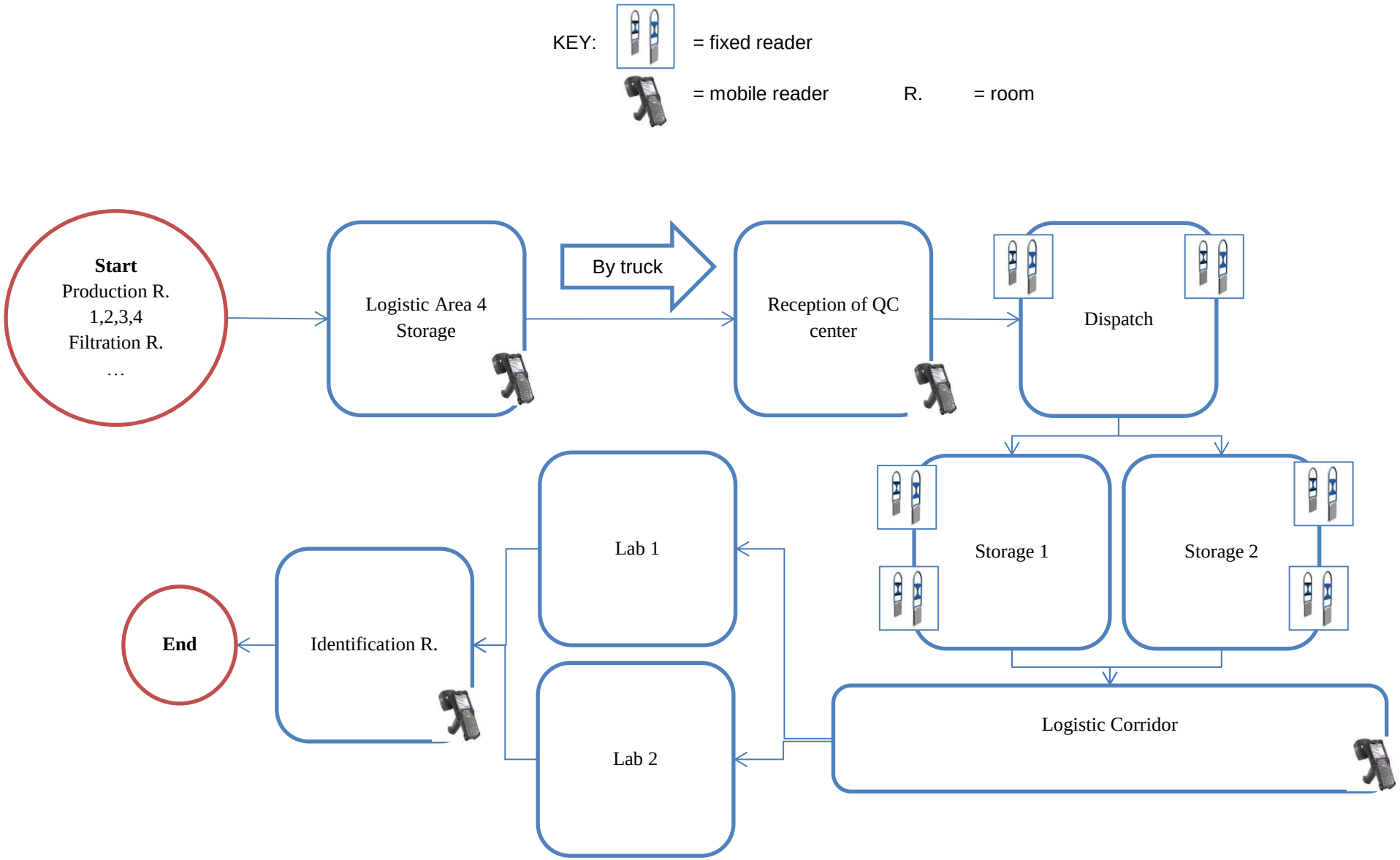
Attachment 3: Environmental sample follow-up



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