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Impact of RFID and EPCglobal on Critical Processes of the Pharmaceutical Supply Chain

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1. Introduction

The need to implement and guarantee effective item-level tracing systems is becoming more and more important for a wide range of business applications, such as manufacturing, logistics, healthcare, and anti-counterfeiting. Among these, the pharmaceutical supply chain, with millions of medicines moving around the world and needing to be traced at item level, represents a very interesting reference scenario. Furthermore, the growing counterfeiting problem raises a significant threat within the supply chain system. Recently, several international institutions (e.g. Food and Drug Administration, European Medicines Agency, European Federation of Pharmaceutical Industries and Associations, GS1) are encouraging the use of innovative solutions in healthcare and in the pharmaceutical supply chain, to improve patient safety and enhance the efficiency of the pharmaceutical supply chain, with better worldwide drug traceability (FDA, 2004).

Currently, the most popular auto-identification technology is optical one. Although the bar code (one- or bi-dimensional) is a very low cost solution, there are many valid reasons for not considering it as the primary auto-identification technique (Schroeter, 2008) in the near future. In fact, every kind of bar code technology requires line-of-sight (LoS), it cannot be written or read in bulk, it can be easily counterfeited, it can limit the speed of packaging line operations, etc.

On the contrary, RFID (Finkenzeller, 2003) technology promises to optimize the critical processes in the Supply Chain Management (SCM) systems and to improve the patient safety, resolving problems of traditional optical auto-identification solutions.

Passive RFID tags can be classified according to the frequency band used and the type of coupling between tag and reader antennas. The use of RFID solutions, in particular those working in Ultra High Frequency (UHF) band, could easily exceed the previous performance problems justifying the initial investment required by a process re-engineering of the pharmaceutical supply chain. Recent works (Uysal, 2008; De Blasi, 2010; Catarinucci, 2010) have highlighted that passive UHF RFID tags represent the more suitable solution for item-level tracing systems in a supply chain.

Another fundamental element that is increasing exponentially the diffusion of the RFID in the automate logistics processes is the asserting of some international standards related to goods traceability, such as EPCglobal (Barchetti, 2009; Thiesse, 2009), GS1 (Global Standard 1) (Barchetti, 2010) and ebXML (Electronic Business using extensible Markup Language) (Barchetti, 2010), which are just a few interesting examples. The EPCglobal consortium,

mainly represented by the GS1 organization, defines the standards for developing a universal identification system and an open architecture able to guarantee interoperability and data sharing in a complex multi-vendors scenario. In particular, it proposes the EPCglobal network architecture, whose main feature is represented by the use of the Electronic Product Code (EPC), a code able to uniquely identify each item. This architecture is composed of a set of standards for hardware devices (e.g. reader), software systems, network services, and data interfaces that allow EPCglobal network to play a very important role in traceability systems. EPCglobal is an open architecture, based on a distributed database, able to guarantee effectiveness, flexibility, and scalability.

Although, the use of these technologies promises many benefits, today's RFID and EPC adoption is still limited its deployment in the healthcare and pharmaceutical sectors due to barriers such as: (i) hardware technology current weaknesses (Catarinucci, 2010; Niktin & Rao, 2006) (e.g. data reliability, read rate in critical conditions, lack of unified standard for interoperability), (ii) software weakness (e.g. scalability, single-point of failure, integration with informative systems), (iii) relatively high costs related to tags, software customization and systems integration, (iv) security issues (Mirowski, 2009), (v) lack of scientific literature on the evaluation of potential effects of RFID exposure on molecular structure and potency of drugs (Acierno, 2010; Acierno, 2011; Cox, 2006; Uysal, 2010).

These open issues amplify some scepticism remains in the community of potential adopters of these technologies since there is no clear indication of the model to follow when assessing the impacts and benefits of RFID-based tracing systems in the supply chain. In particular, return on investment is uncertain if one attempts to assess both cost reductions and value added at each stakeholder of the supply chain.

Several studies have been performed on different supply chains (e.g. fashion, agro-food, cargo, etc.) by using different approaches. Most works attempt to evaluate, through particular methodologies such as Key Performance Indicators (KPIs) or Critical Successful Factors (CSFs), the potential benefits due to applying innovative technologies such as RFID in re-engineered processes of the supply chain. Unfortunately, this kind of analysis is strongly dependent on a particular application scenario. Currently, it is not easy to find exhaustive analysis of these performance indicators on the pharmaceutical supply chain.

The main goal of this chapter aims to analyze main processes of the pharmaceutical supply chain and to evaluate the impact of the combined use of RFID and EPCglobal in some critical processes. Particular attention is focused in the wholesaler because it represents a middle point of the supply chain very stressed in terms of constraints and products flow. Taking into account the main inefficiencies highlighted in the defined AS IS model, a re-engineered TO BE model has been proposed. Furthermore, some KPIs have been defined for the wholesaler in order to make easier a quantitative analysis of the benefits due to the re-engineering.

The rest of the chapter is organised as follows. Section 2 summarizes a brief state of the art of related works on the evaluation of potential benefits provided by the use of innovative technologies in supply chain management systems. A description of the reference scenario, the pharmaceutical supply chain, is reported in Section 3. Section 4 provides a brief overview on the three main standards (i.e. RFID, EPCglobal, and ebXML) and summarizes a recent pilot project focused on the traceability at item level in the pharmaceutical supply chain. A detailed analysis of the main processes of the wholesaler, representing the AS IS model, is reported in Section 5. Instead, in Section 6 is reported the TO BE model that shows the main re-engineered processes of the wholesaler by a combined use of RFID and EPCglobal. A discussion on the main methods to evaluate potential benefits related to the

combined use of RFID and EPC in the pharmaceutical wholesaler is reported in Section 7. Finally, Section 8 reports conclusions and future works.

2. Related works

Some attempts have been recently carried out by using different approaches to different scenarios in order to give qualitative and quantitative indications on the usefulness to perform process re-engineering procedures exploiting RFID and EPCglobal.
Previous works on the evaluation of impacts of RFID and EPCglobal on main business processes in a supply chain can be classified, taking into account the adopted approach, in two different groups: theoretical, and test bed.
The first includes conceptual papers that describe some critical trends and implications of applying RFID to supply chain management systems or suggest interesting strategies and technology solutions to optimize traceability and business messages interchange (Barchetti, 2010; Srivastava, 2004; Gunasekaran & Ngai, 2005; Pramataris, 2005). In this category, many mathematical and simulation approaches are also included. For instance, (Lee, 2004) demonstrates the potential benefits of RFID in inventory reduction and service level improvement in manufacturer-retailer supply chains. (Gaukler, 2005) reports a model of benefits of an item level RFID system to two members of a supply chain. (Hou & Huang, 2006) proposes six models of cost-benefit analysis for RFID applications in different logistics activities in the printing industry. (Ustundag & Cevikcan, 2007) presents a methodology for the adaptation of RFID technology to the service processes of a cargo firm. (Bottani, 2009) introduces a detailed mathematical model to assess the economic impact of RFID technology and EPC network adoption for traceability management within a supply chain. (Bottani, 2008) reports a discrete event simulation model reproducing the adoption of RFID technology for the optimal management of common logistics processes of a Fast Moving Consumer Goods (FMCG) warehouse. (Vue, 2008) analyzes the pharmaceutical supply chain, in particular, some processes of the manufacturer, and attempts to summarize the main CSFs (Critical Success Factor) when RFID is applied in pharmaceutical enterprises.
The second approach aims to focus the attention on studies that have allowed to estimate performance indicators and costs by using test bed carried out in laboratories or in field. Among papers with empirical results, (Loebbecke, 2005) analyses some Metro group pilots in Germany, highlighting that the use of RFID in combination with particular kind of marketing is able to increase significantly the sales. (Hardgrave, 2008, 2009) present some studies where the influence of RFID on potential improvements is analysed. (Bottani et al. , 2009) analyses the potential impact of these innovative technologies in the fashion supply chain exploiting an empirical approach based on questionnaires, interviews and measurements in field. In particular, Bottani et al., 2009) is one of the few works that attempts to evaluate the benefits due to a combined use of RFID and EPC. (Gandino, 2007) reports interesting experiences carried out in the agro-food chain. It describes and validates a new tracing system by using tests in a laboratory and in a working fruit warehouse.
All works analysed highlight the need to evaluate potential benefits due to re-engineering procedures performed on most critical processes of a supply chain and hypothesizing the use of innovative technologies such RFID. Furthermore, an empirical test case, carried out directly in the field, is able to obtain very interesting results taken from potential adopters of these new technologies. This increases the complexity of this kind of studies because it requires performing customized analyses for each scenario.

3. Description of the pharmaceutical scenario

The pharmaceutical supply chain, shown in Fig. 1, is a complex scenario with millions of pharmaceutical products moving around the world each year. The actors of the pharmaceutical supply chain that have a significative impact on the traceability of products are three: (i) the *manufacturer,* who produces the packaging of pharmaceuticals, (ii) the *wholesaler,* who buys and resells large quantities of medicinal products, and (iii) the *pharmacy retailer*, who in general is a pharmacy or hospital. Let us observe that the pharmaceutical scenario follows the traditional manufacturer-retailer model used for the most supply chains except that medicinal products are not returned but destroyed once they exceed their sell-by date. In fact, every product that can no longer be sold is sent to the *disposal company,* another minor actor in this supply chain. It is very useful to consider some data able to characterize the reference supply chain. Each year, about 30 billion packages of pharmaceutical products are produced by European industries (Fuhring, 2009). The European supply chain incorporates about 2,200 manufacturers, 50,400 wholesalers, and 142,000 retailers.

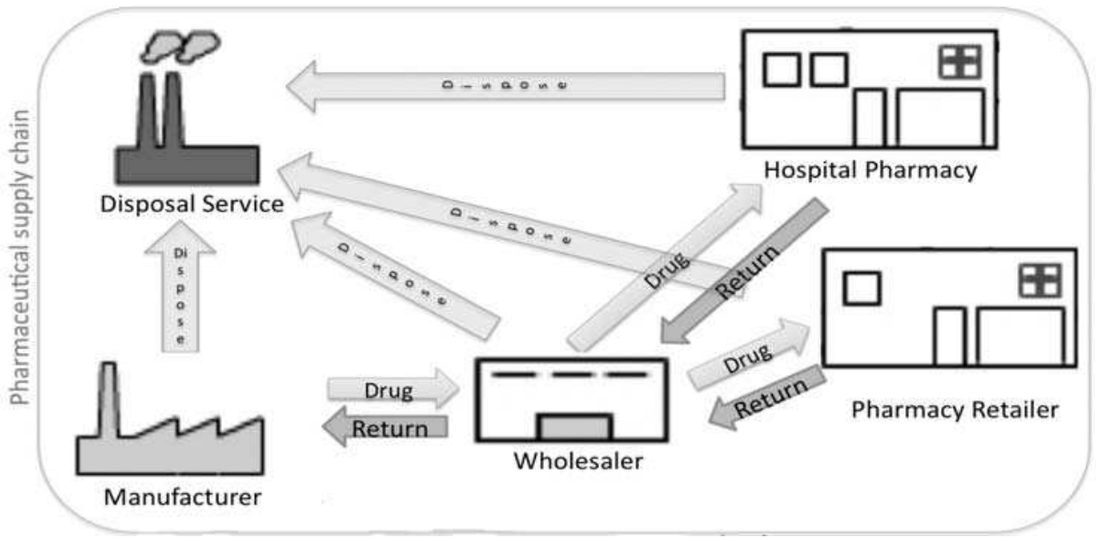

Fig. 1. Pharmaceutical supply chain

A small-scale, but very interesting, vision of the pharmaceutical scenario is offered by the Italian market that is composed of about 320 manufacturers, 140 wholesalers, and 18,000 pharmacy retailers. The average number of pharmaceutical items managed by one wholesaler per year is greater than 50,000. Furthermore, there are strict requirements, in terms of delivery time and dispatching order time, imposed by national laws. This vision introduces the need to understand how an efficient tracing and tracking procedure is strongly desired by all members of the pharmaceutical supply chain.

The item-level traceability of drugs starts just after the packages are filled during the manufacturing process. In this step, each tagged product is individually scanned on the conveyor belt and then cased to be sent to the wholesalers. The wholesalers separate the products according to their identifiers and place them onto the shelves. Wholesalers receive orders from retailers. These orders often consist of small quantities of different products; they may contain a large number of items. The products in the orders of the retailers are picked and put into some large envelope bags that are scanned and confirmed before their

distribution. Upon receipt, the pharmacy retailer scans the contents of each bag without opening it.

4. Overview on the main innovative solutions for the Supply Chain Management

4.1 International standards

The three main keywords able to improve significantly a SCM system are RFID, EPCglobal, and B2B. Recent works (Barchetti, 2009, 2010) have demonstrated that the combined and coordinated use of these technologies delivers enormous advantages for every actor in the pharmaceutical supply chain. Some basic concepts related to the roles of these technologies in traceability management in the whole supply chain are briefly reported below.

RFID is a very interesting auto-identification wireless technology that promises to replace the traditional barcode. It guarantees the ability to trace and track individual objects in the whole supply chain. Typically, an RFID system consists of three main components: RFID tags, RFID readers, and data processing systems. RFID transponders, often called "tags", can be passive, semi-passive, or active. In a passive RFID system, the reader transmits a modulated RF signal, which is received by the tag antenna. The RF voltage generated on the antenna is converted into DC (direct current). This voltage powers up the chip, which sends back the contained information. Passive RFID tags can be classified according to the frequency band used (LF, HF, UHF, etc.) and the type of coupling (magnetic or electromagnetic) between tag and reader antennas. An RFID tag is attached to the items or conveyance, e.g., pallet, packaging material, or the product itself. One key benefit is that RFID does not require LoS with a reader, whereas barcodes require a scanner to pass over each item. Recent works (De Blasi, 2010; Catarinucci, 2010) have highlighted that passive UHF is most promising technology for item-level tracing systems on the whole supply chain. The success of UHF can be mainly attributed to the asserting of EPCglobal international standard (Thiesse, 2009).

The EPCglobal standard is an open architecture for tracking and tracing objects over the Internet. EPCglobal aims to develop an efficient distribute database that can be queried to obtain quickly every data fragment associated to the history of a given object. In fact, it defines a full protocol stack to enable item-level data sharing about products that move in the whole supply chain. The EPCglobal architecture, shown in Fig. 2, is mainly based on the Electronic Product Code (EPC), Application Level Events (ALE), EPC Information Service (EPCIS), Object Naming Service (ONS), and Discovery Service. The EPCglobal architecture is able to guarantee effectiveness, flexibility, and scalability. Furthermore, it is important to observe that this architecture was designed to exploit all advantages of RFID technology, but continues to also be valid in the presence of other automatic identification solutions.

The third component, fundamental for successful SCM solutions, is related to the ability to support the interoperability among different firms to overcome problems about the e-business messages interchange on a whole supply chain. There are consolidated standards, such as ebXML, that have improved SCM from an e-business perspective. An interesting approach aims both to provide a high degree of freedom in the business process design and formalisation of the specific business message and to suggest to the companies the use of a single technology of interchange that is flexible and easy to integrate with the company's information system. The recent challenge is to have a supply chain characterised only of automatic data flows to increase the effectiveness and to reduce human errors. Some works

(Barchetti, 2009, 2010) have suggested the combined use of ebXML, as the data interchange standard, and UBL (universal business language), as the standard for defining e-business messages.

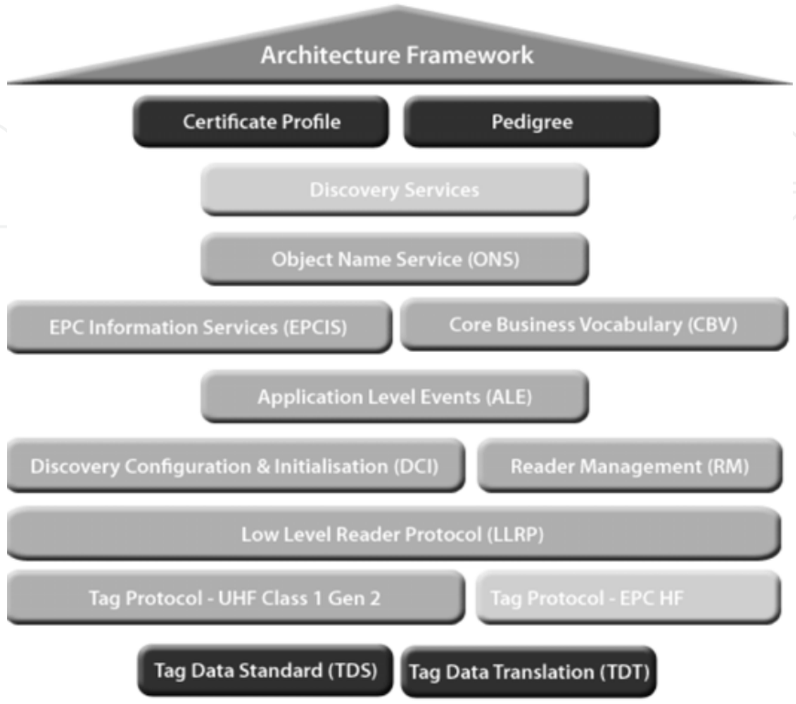

Fig. 2. EPCglobal network architecture (EPCglobal, 2005)

4.2 Description of a pilot project in the pharmaceutical scenario

In (Barchetti, 2009, 2011) is described an pilot research project that aims to apply, in combined mode, the previous technologies in a prototypal system able to guarantee item-level traceability in the pharmaceutical supply chain. The main research activities of this pilot faced the following two challenges: (i) development of an innovative software framework compliant with EPCglobal standard for traceability in the pharmaceutical supply chain, and (ii) performance evaluation of passive UHF RFID tags in critical operating conditions (e.g. presence of liquids and metals, misalignment between reader and tag antennas, etc.). Two important features of this innovative framework are: ebXML as the proper standard to guarantee the interoperability among different firms, and EPCglobal as the proper standard to guarantee the identification and traceability of products and goods. The data interchange system is based on ebXML and uses an application layer to guarantee an e-business messages exchanging service according to the UBL standard. The defined software architecture has been designed by merging the two main previous components: EPCglobal protocol stack and the ebXML for messaging services. In this way, the overall system is able to answer the requests from factory users by sending reports and information about a specific product, marked by an EPC code, or providing the possibility to perform messaging operations such as, for example, sending an order. In order to guarantee high flexibility and reliability, the overall framework is based on two open-source implementations provided by the scientific community: (i) the e-business message exchange

sub-system is modelled by the freebXML project, which provides an open-source implementation of the ebXML standard, and (ii) the traceability sub-system is modelled by the Fosstrak framework, which provides an open-source RFID software platform that respects exactly the current standards provided by EPCglobal.
The performance evaluation, carried out in a particular test environment (see Fig. 3) configured to simulate the main steps and characteristics of the pharmaceutical supply chain, allowed to obtain very interesting experimental results related to the use of passive UHF RFID tags in item-level tracing systems. Some results, reported in (De Blasi, 2010), demonstrated that RFID UHF tags could suffer of performance degradation when used in presence of electromagnetically hostile materials, such as metals and liquids, as well as under very stressful conditions such as high scanning speed, possible misalignment between tag and reader antennas, and multiple reading of tags. In order to face these performance problems, some enhancements, proposed in (Catarinucci, 2010), show very impressive findings and clearly demonstrate that well designed ad hoc Far Field UHF tags effectively improve the performance of any item-level tracing system.

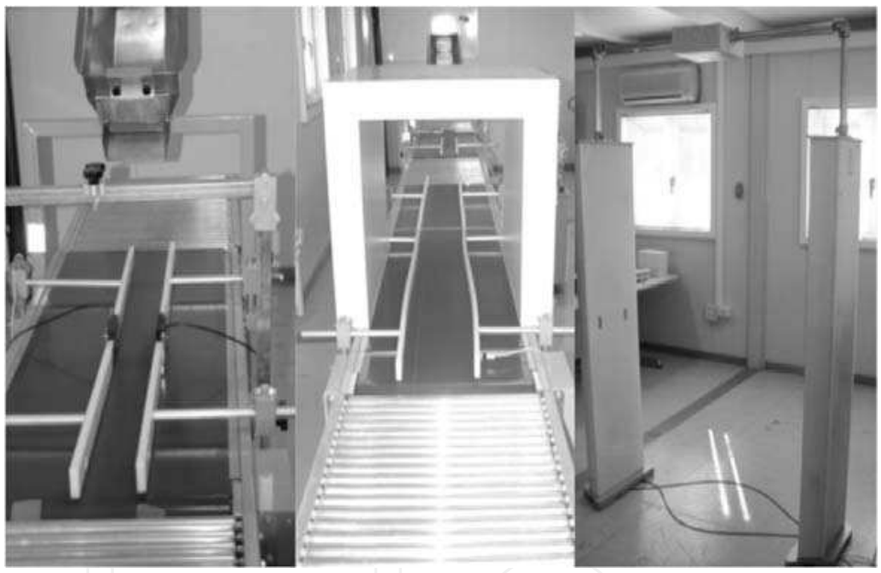

Fig. 3. Test environment to simulate the supply chain

Furthermore, this pilot project, characterized by encouraging results in software and communication engineering fields, has recently stimulated further scientific collaborations with some biologist groups in order to define a multidisciplinary approach able to investigate potential exposure risks of RFID devices in UHF band on the molecular structure and potency of a biological drug. Some recent works (Acierno, 2011), carried out on human insulin preparation and Gonal-F, have demonstrated that the drug molecular structure was unaffected by UHF exposure.

5. AS IS model analysis

The enormous complexity of the reference scenario has suggested starting this analysis focusing particular attention to one of stakeholders of the pharmaceutical supply chain: the wholesaler. The choice is motivated by the fact that it represents the most stressed condition

in terms of products flows. Furthermore, a wholesaler interacts with manufactures, other wholesalers, and pharmacy retailers. For these reasons, it is a very critical member of the supply chain

The defined AS IS model summarizes the main features of the most critical processes of the wholesaler such as: products receiving, storage, picking, products outgoing, return flows management (from pharmacy retailer or to manufacturer), and products deadline management. An overall vision of these critical processes are shown in Fig. 4 and is described in this section in order to highlight main points where the use of innovative technologies, such as RFID and EPCglobal, could improve the logistics aspects of the wholesaler.

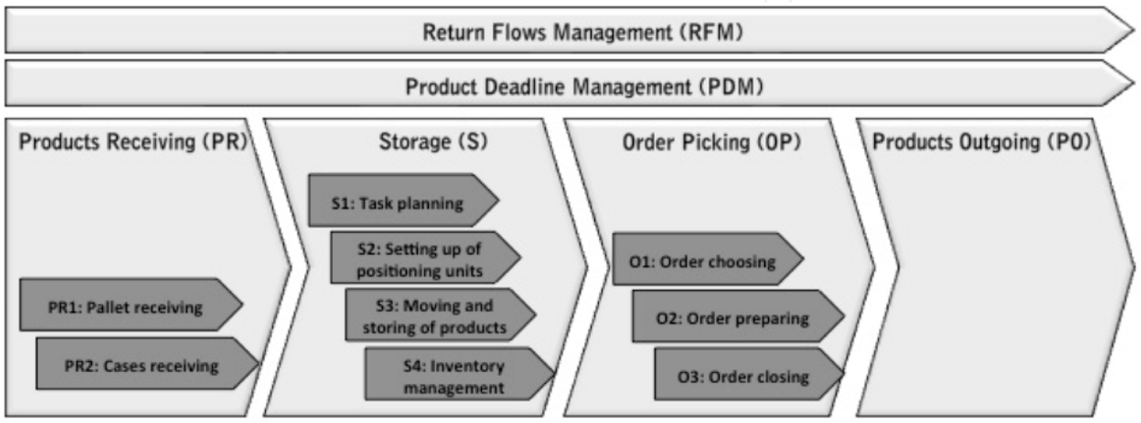

Fig. 4. Abstract vision of the AS IS model of the wholesaler

Fig. 5 reports an overview of the main business processes of the wholesaler by using the Business Process Modeling Notation (BPMN) (BPMN, 2006). This standard, defined for business process modeling, is able to provide a graphical notation for specifying business processes through a flowcharting technique. The main objective of BPMN is to support business process management for both technical users and business users by providing a notation that is intuitive to business users yet able to represent complex process semantics. It represents an effective choice able to satisfy the main requirements of this kind of analysis based on KPIs.

The BPMN design of the business processes is reported in the next section in order to better appreciate the performance comparison between AS IS model and re-engineered model (TO BE).

Main features of the AS IS model are below reported starting with the analysis of the pallet receiving process.

The Pallet Receiving (PR) process, carried out by the receiving clerk, is composed of the following sub-processes:

- Pallet receiving (PR1): One or more pallets, associated with the same manufacturer, are received from the wholesaler. A worker, through a manual procedure, performs a first check of the received products. This check consists to choose and open, in random way, one case from one of the received pallets. Just one item (single medicine package) is taken and analysed. In particular, the worker reads manually (i.e., without the use of an electronic device) number of lot and deadline date. This data is compared and verified with the information reported on the delivery note. Furthermore, the same worker

counts manually the number of cases contained on this pallet. The value is thus verified with the delivery note. If these two manual and rough tests are validated then all products received are accepted to wholesaler. The BPMN design of the current Pallet receiving subprocess is shown in Fig. 6(a).

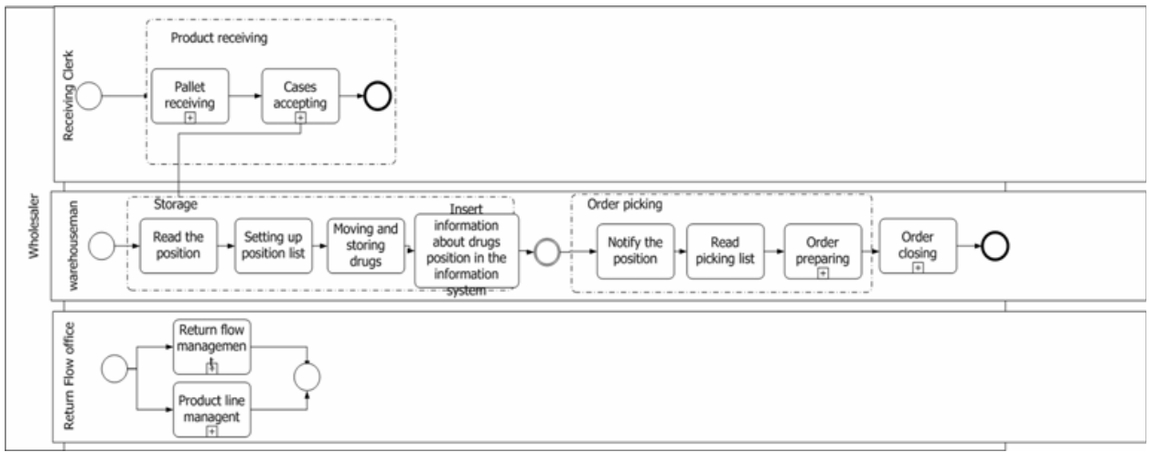

Fig. 5. Overview of the main business processes of the wholesaler by using BPMN

- Cases accepting (PR2): Each pallet accepted is divided in cases. The received cases can be classified into two categories: standard case and mixed case. Each standard case contains medicine packages of the same type, whereas, a mixed case contains different types of drugs within the same case. In the case of standard cases, the worker opens just one case per kind of drug and takes just one single item. This item is identified by using a portable optical device that reads the bar code printed on the secondary package of the drug. This code is transformed into the corresponding lot number and expiration date, which are verified by comparing with the delivery note. Let us observe that this procedure hypotheses that the rest of the case is composed of the same type of medicine product. This might not be true. Instead, for mixed cases, where one case is composed of heterogeneous pharmaceutical products, the worker has to open all these cases and for each he/she has to take one item per kind of drug and verify it by using the previous manual procedure. This kind of verification is not able to guarantee an effective tracing at item level of all received products. This check on all received cases and the validation taking into account the data reported on the delivery note complete the products accepting procedure carried out currently to wholesaler. After this step, all received products are memorized in the Information System (IS) of the wholesaler. The BPMN design of the Case accepting process is shown in Fig. 7(a).

  The *Storage* (S) process, carried out by the warehouseman, is composed of the following activities:

- Tasks planning (S1): this activity is performed by the Information System that prepares the positioning list, where for each type of drug that has to be stored there is a specific quantity and location (i.e., shelf and shelves). The system optimizes the positioning list, taking into consideration different factors: priority of the restoration of the products out of stock (for example the robot line must be always loaded with all high rotation medicines, because the 50% of the orders are dispatched by itself alone), order dispatch priority (often incoming orders are accepted before the medicines are correctly

positioned in the warehouse, even if they are physically already in the goods entrance area). The IS notifies the optimized positioning list to the operator through his/her Personal Digital Assistant (PDA) device where he/she can read all positioning details.

- Setting up of positioning units (S2): the operator takes medicines from the cases in the goods entrance area, that have been previously checked (Cases accepting phase) and set them on one or more carts.
- Moving and storing of products (S3): carts are moved in the area of the warehouse identified by the PDA and the operator place each item in its final position one by one with a FIFO (First In First Out) policy (positioning newer packages at the end of the stack in order to leave at the front those with the most recent sell-by date).
- Inventory management (S4): the operator notifies to IS the number, type and position of the medicines just stored through his/her PDA.

Due to the simplicity of the Storage process, it has been identified in the Fig. 5 using the *group* primitive of BPMN labelled with the name "Storage".

The *Order Picking* (OP) process, carried out by the warehouseman, is composed of the following activities:

- Order choosing (OP1): taking into account several factors (i.e. priority, type of received orders, current status of the storage area, etc.), the IS generates and assigns one picking list for any worker available in that moment. This list is sent to worker that uses a PDA device equipped with a Wi-Fi adapter. The worker takes one case, scans its bar code by using his/her PDA and starts the next activity. The BPMN representation of this sub-process is shown in Fig. 5 inside a group named "Order Picking".
- Order preparing (OP2): this activity can be carried out in three different modes. These are: Automatic (OP2.1), Manual (OP2.2), and Hybrid (OP2.3). The worker receives instructions about the preparing mode directly from the IS. In Automatic mode, the case related to a given order is composed exclusively by using the robot line. In this case, the picking procedure does not use any employee. All medicine packages included in the picking list automatically fall into a plastic box. On the contrary, the second mode (i.e. Manual) does not use the robot line. The worker, following the indications received by the PDA, reaches the suggested location (i.e. shelf and floor), takes the packages indicated in the picking list and scans them by using the optical reader (i.e. PDA). In the Hybrid mode, the plastic box is filled by using both the previous modes. The BPMN design of the order preparing process is reported in the Fig. 8(a).
- Order closing (OP3): when all products specified in a picking list have been deposited in the plastic box, one copy of the delivery note is printed and included in. The box is closed and labelled with destination references (e.g. name and mail address of the pharmacy retailer). The worker again scans the bar code associated with the box in order to close the order. Furthermore, the IS gives instructions on where the closed box is to be moved towards a particular out gate. Let us observe that in the goods outgoing area there are several out gates that take into account the presence of different couriers that cover different geographic zones. The BPMN design of the Order closing sub-process is shown in Fig. 9(a).

  The *Products Outgoing* (PO) process, not represented in the design reported in Fig. 5, is composed mainly to one activity related to last step that characterizes the products flow within of the wholesaler. A courier takes all closed boxes deposited temporarily at the specific out gate.

The *Return Flows Management* (RFM) process, carried out by the Return Flow office, can be classified into two sub-processes. The first impacts on all products returned from pharmacy retailers. In this case, some employers have to carry out several checks on the returned products. This activity aims to verify, for instance, the product integrity, return reason (e.g., errors in the order delivery, deadline date, etc.), and wholesaler origin. Unfortunately, a wholesaler has problems to verify the wholesaler origin of a specific item because currently there is not an effective item-level tracing system on the whole supply chain. The second sub-process manages, instead, pharmaceutical packages with some irregularities such as deadline date, damaged package, etc. The wholesaler has to organize the return to manufacturer or the transport to disposal company. Currently, all these procedures are manual.

The *Products Deadline Management* (PDM) process is carried out periodically (e.g. 2 times per month) in the wholesaler. Currently, this check is split and assigned among several employees. Each of them receives the specifics related to particular portion of the storage area. He/she reads the deadline date reported on the pharmaceutical package and selects all packages expired or near to expiration that will be managed in the RFM process.

Unfortunately, several processes or activities in the wholesaler are performed in manual mode and so they can be a critical issue, especially, in terms of timeliness (spent time for activity) and correctness. To give a smoother reading, the BPMN design of the last two sub processes (Return Flow Management and Product Deadline Management) has been omitted.

6. Processes re-engineering: TO BE model

Starting from the previous analysis summarized in the AS IS model, the TO BE re-engineering consisted of developing new scenarios, where RFID technology, EPCglobal standard, and B2B are exploited to optimize the critical processes of the wholesaler. The re-engineering of the wholesaler processes is only part of a re-engineering procedure that could be applied on the whole pharmaceutical supply chain. Specifically, the TO BE model of the wholesaler has been developed in order to ensure: traceability at item level, efficient management of logistics activities, and improvement of business messages interchange. The TO BE model is defined hypothesising the use of RFID tags, RFID readers, reader antennas, and software infrastructure as follow reported in detail.

The *Products Receiving* (PR) process is re-engineered as follow:

- Pallet receiving (PR1): The use of passive RFID tags is hypothesised to trace both items and cases. In particular, RFID tags for UHF band are considered because they are able to guarantee high performance in item-level tracing systems (Catarinucci, 2010). One pallet will be composed of tagged cases and each case will be composed of tagged pharmaceutical packages (i.e. items). The goods entries of the wholesaler will be equipped with RFID gates. Each RFID gate could be characterized by two RFID readers (e.g. Impinj Speedway) and eight far field reader antennas in UHF band. This gate configuration is able to guarantee high performance in terms of successful read rate of cases. In the TO BE model, a worker only has to move the incoming pallets through the RFID gate. All cases will be identified and automatic validated with data of an electronic version of the delivery note. In this case, the use of an innovative Business-to-Business (B2B) solution, based on an international standard such as ebXML, is also hypothesised. This solution aims to remove the previous problems (i.e. timeliness and correctness) highlighted in the AS IS model.

In order to understand the difference of the complexity between AS IS and TO BE models, Fig. 6(a) and Fig. 6(b) show respectively the current vision and the re-engineered vision of the "Product Receiving" subprocess.

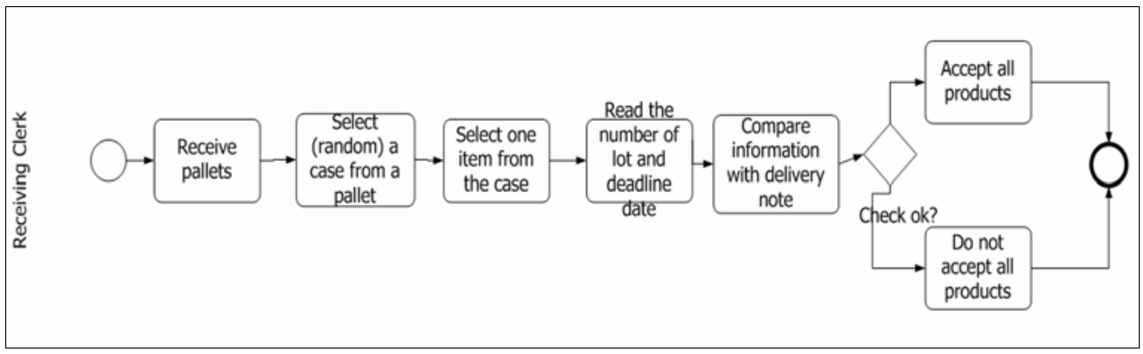

Fig. 6(a). AS IS model of the Product Receiving subprocess

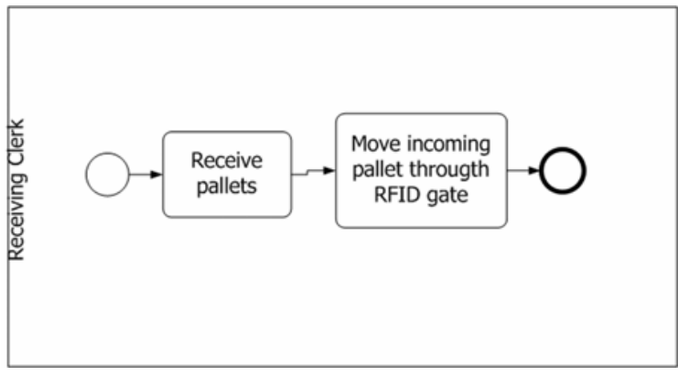

Fig. 6(b). TO BE model of the Product Receiving subprocess

- Cases accepting (PR2): In order to guarantee an efficient item-level tracing system, a particular equipment, similar to that shown in Fig. 3, can be used. It is composed of a conveyor belt, equipped by a line speed regulator, a double containment edge to keep cases in the same position throughout the belt, one RFID reader (e.g. Impinj Speedway), and four near field reader antennas (e.g. Impinj Brickyard) installed within a metallic tunnel. A worker has just to take every case and to put it on the moving conveyor belt. By using this solution, all products contained within each case will be automatic identified. Let us observe that the case remains closed. Furthermore, if a software infrastructure compliant with EPCglobal standard is adopted, the IS of the wholesaler will receive a complete e-pedigree for each received product. Also for this activity, the combined use of RFID and EPC overcome the previous problems and, furthermore, it is also able to optimize also other processes such as the Storage processes.
  The BPMN design of the AS IS and TO-BE model of the Case Accepting sub-process are shown respectively in Fig. 7(a) and Fig. 7(b).
  It has to note that the only operation that the receiving clerk has to do are to take the case and to put it on the moving conveyor belt: the system will do all it is necessary to add the products' information in the information system.

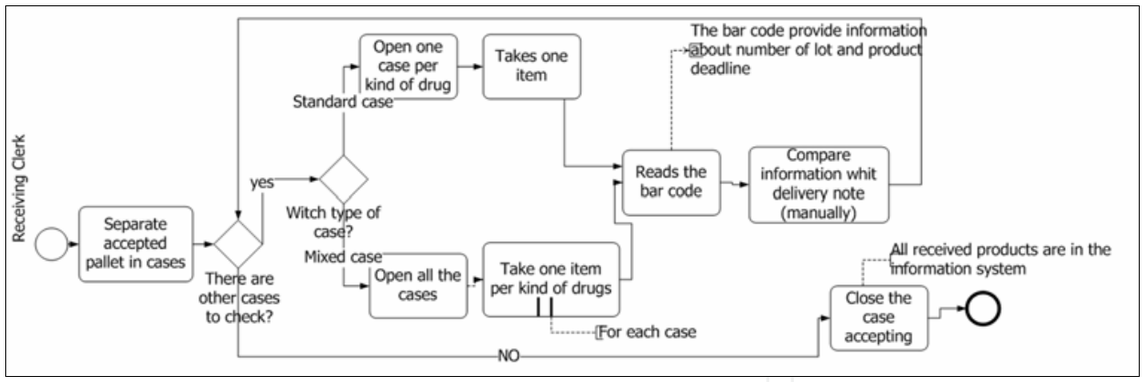

Fig. 7(a). AS IS model of the Case accepting subprocess

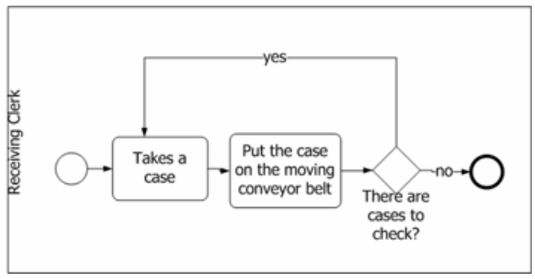

Fig. 7(b). TO BE model of the Case accepting subprocess

The *Storage* (S) process is re-engineered as follow:

- Tasks planning (S1): this activity can use the current knowledge, obtained by RFID and EPC innovations in the previous process, of the information system to optimize the preparation of the positioning lists.
- Setting up of positioning units (S2): This activity could be mainly performed in an automatic way hypothesising the use of different roller conveyors after the RFID tunnel and a software controller that ables to route cases on different carts taking into account the product localization.
- Moving and storing of products (S3) and Inventory management (S4): the worker could wear smart gloves equipped with a portable UHF RFID reader and a near field reader antenna. Let us observe that there are some prototypal models (Muguira, 2009) of these special RFID readers. The use of this special kind of RFID reader allows to optimize storing and inventory management procedures. Another import hypothesis is related to the use of passive UHF RFID tags to identify every location (e.g. every floor of the shelf) of the warehouse. By adopting this technological approach, a simple movement of the worker's hand is sufficient to communicate the exact location and quantities of every product that is in warehouse of the wholesaler. Also for all activities of the process S, the combined use of RFID and EPC is able improve both timeliness and correctness.
  It is important to note that all the random activities made up manually on single item of one case are, in TO BE model, automatic and the only task of the receiving clerk is to move the incoming pallet through the RFID gate. In this case, the IS will be automatically update.
  The combined use of the passive UHF RFID tags applied on every secondary package of medicines and the other enhancements suggested for the activity S3 is able to improve

also the main activities of the *Order Picking* (OP) process. In fact, the activity OP3 may be closed guaranteeing the exact composition (i.e. no errors) of boxes related to orders.
It is important to understand how the business processes change in the reengineered version for the Order Preparing and Order Closing sub-processes of the Order Picking process.
Fig. 8(a) and Fig. 8(b) show the BPMN design of the AS IS and TO BE models of the Order Preparing sub-processes.

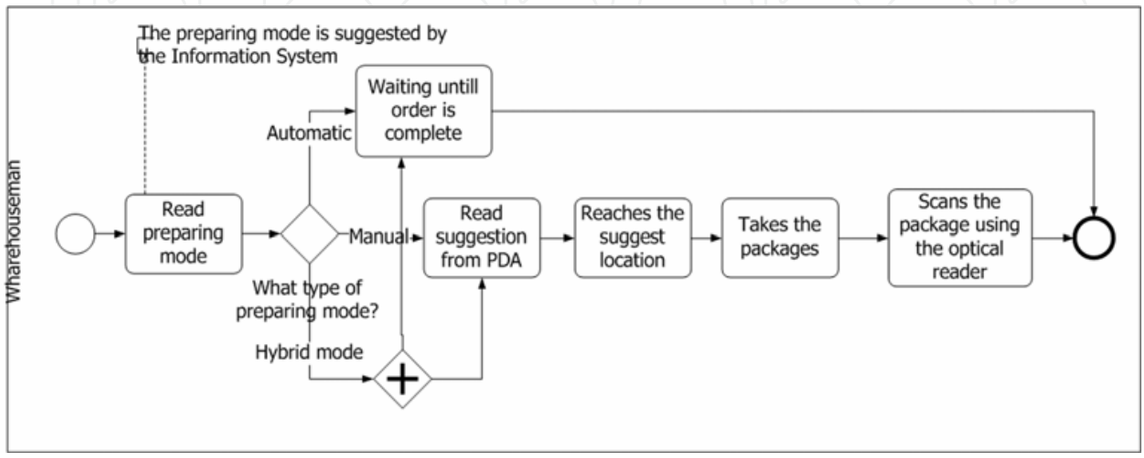

Fig. 8(a). AS IS model of the Order Preparing subprocess

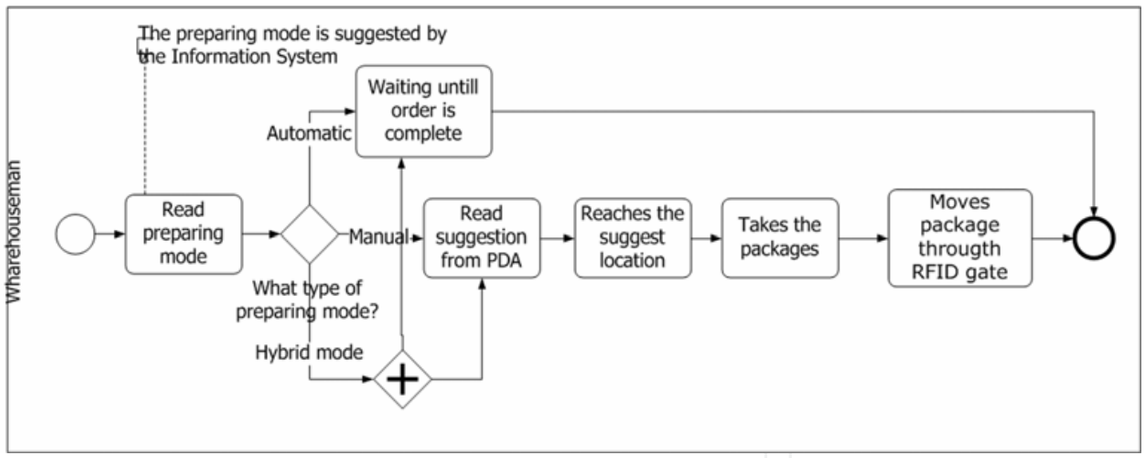

Fig. 8(b). TO BE model of the Order Preparing subprocess

It is important to note that, although, the unique difference between Fig. 8(a) and Fig. 8(b) is related to last task, the effort need to complete this task it is very different: while in the AS IS model the wharehouseman will scan each package in order to add information about the order in the information system, in the TO BE model the wharehouseman has just to put the package through the RFID gate.
Same considerations are valid also for the sub-process Order closing (Fig. 9(a) and Fig. 9(b)). The only difference is in the fourth task that is manual in the AS IS and it is supported by the technology in the TO BE. The wharehouseman has just to move the

box through RFID gate: the execution of the task is more immediate and the information in the information system is more accurate.

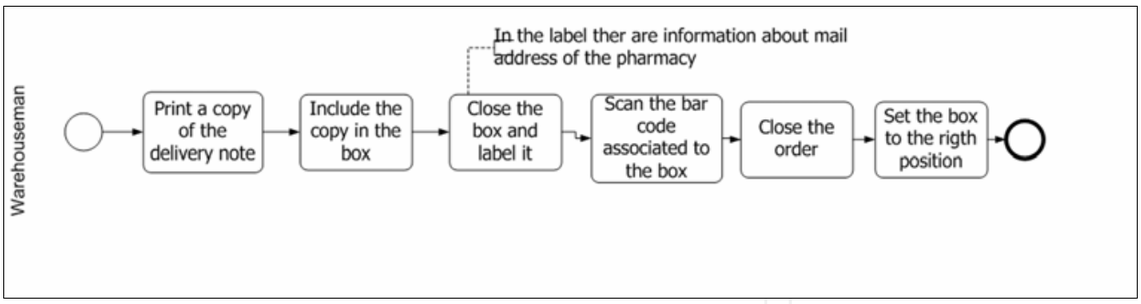

Fig. 9(a). AS IS model of the Order closing subprocess

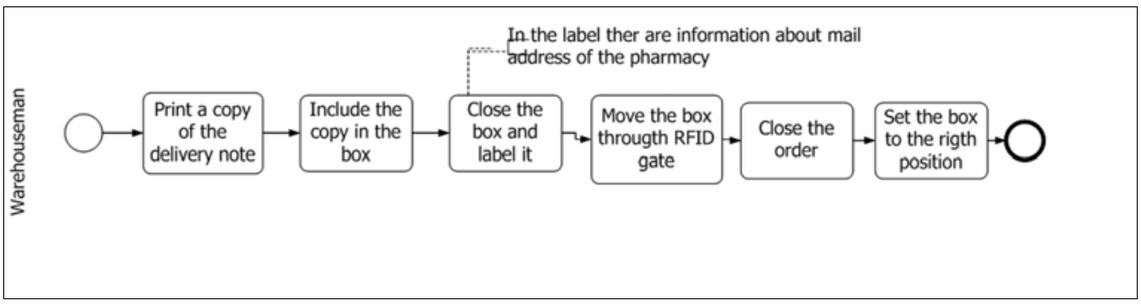

Fig. 9(b). TO BE model of the order closing subprocess

The adoption of the ad hoc re-engineered solutions, able to combine RFID, EPC and B2B, could optimize also the main activities of the *Products Deadline Management* (PDM) process. In fact, the IS should be able to guarantee a complete management dashboard and to minimize the quantity of products that exceed their sell-by date. Furthermore, every manual activity could be avoided.
The use of item-level tracing system based on EPCglobal standard is also able to optimize the main activities of the Return Flows Management (RFM) process. It is sufficient just one instance to demonstrate this. All products returned from pharmacy retailers are easily identified and tracked by using RFID and EPC. A wholesaler could know exactly which products were sold to the same wholesaler. This could improve substantially the RFM process.

7. Discussion about the used performance evaluation method

An analysis based on business processes is a key point to evaluate the effectiveness of modern companies in terms of the added value due to the employment of human and machine resources. The design of the business process is important but not sufficient to appreciate the dynamics that determine how to operate of a company. For this reason, it is also important to be able to measure how the business process is performed.
The measurements of the business process can be useful for several reasons:

- To understand if the business process is effectiveness and, if not, to take some action to improve it (re-engineering);

- To perform comparisons among different companies operating in the same sector (e.g. benchmarking) and thus to study and propose improvements in order to achieve the best practice;
- To evaluate the impact of new technologies in business processes in terms of trade-off between cost and benefits.

The measurement of business process is a delicate task because it is strategic to define indicators and metrics useful for a given applicative scenario. The choice of indicators has to satisfy the following requirements:

- Not many indicators but relevant enough to have a low effort analysis;
- Simple and shared in the whole company in order to make easier the survey and the analysis;
- Unambiguous;
- Able to guarantee a clear and complete vision of the company.

In this chapter, a set of indicators for each business process has been defined in order to evaluate the impact of the use of innovative technologies such as RFID, EPC and B2B. The KPIs (Franceschini, 2009) analysis combined with the CSFs method has been chosen for this kind of study.

The CSF method was presented in (Rockart, 1979). CSF was defined as "few, but important areas where the company must work perfectly in order to have success in business". In other words, the CSFs are defined as the excellence areas where the same company should increase its technological investments in order to reach the business goals. This kind of analysis allows mapping each KPI to one or more CSFs. In this way, main factors where the new technologies could play a very important role are easily identified.

The adopted approach may be synthesized as below reported:

- AS IS analysis of the company aims to identify the main business process of the wholesaler.
- The defined CSFs highlight the key points where the company (in our case the wholesaler) aim to excel in order to obtain its long terms goals.
- Definition of the main KPIs. KPIs are able to show real measurements of efficiency, service level and quality performance of the business processes.
- Mapping between KPIs and CSFs.
- Measurement of the identified KPIs in the AS IS model.
- Design of the re-engineered TO BE model.
- Measurement of the KPIs for the TO BE model.
- Discussion about the potential improvements on the identified KPIs due to the use of the innovative technologies in the business processes.

The cross analysis between KPIs and CSFs is proposed to obtain fundamental information about the quality of the final product and about the effectiveness and correctness of the main business processes.

Taking into account the AS IS analysis reported in Section 5, the main CSF for the wholesaler have been defined in order to understand where the company aims to excel.

An intensive brainstorming and interview activities between the company and the authors allow identification of the following CSFs:

- *CSF 1: to acquire new customers*. In order to acquire new customers it is important to speed up the entry of the drugs into the wholesaler and the management of the recalls;
- *CSF 2: customer's satisfaction*. Customer satisfaction is a priority for all types of companies;

- *CSF 3: quality of drugs delivered to the pharmacy retailers*. This CSF is focused on the activities useful to completing the order;
- *CSF 4: quality of the management of the drugs at the wholesaler*. This CSF is mainly related to inventory procedures and management of the drugs expiration date;
- *CSF 5: human capital*. It is important to make efficient the human capital efficient by minimizing the working hours and maximizing production;
- *CSF 6: interaction with pharmacy retailer*. It is important to answer as soon as possible to the requirements of the pharmacy.

The defined KPI for each sub-process described in the previous sections are reported below in Table 1.

Sub-process name	KPI
Pallet receiving	Item level checking average time
	Case level checking average time
	Pallet level checking average time
	Average errors at drug type level
	Average number of losses at drugs type level
	Item level average errors
	Item level average losses
	Workers for product receiving step
Storage	Item level unit storage average time
	Item level unit preparation average time
	Workers for item level unit preparation step
Order picking	Average fulfilment time per order including release
	Average preparation time per order
	Average number of missing items by using manual picking
	Average number of missing items by using automatic picking
Return flow management	Average number of returned drugs from pharmacy
	Average time for the recall of a drugs
	Average number of returned item for expiration
	Average number of lost drugs
Product deadline management	Average workers to check expiration
	Average number of hours to check expiration
Products outcoming	Average number of incorrect deliveries to pharmacy retailer

Table 1. The defined KPI for each subprocess

The next step of the analysis is to define what KPIs are important in order to obtain each specific CSF. This is a key point for the analysis and was carried out after a brainstorming with the top management and authors. The result of this analysis is showed in the Table 2.
Let us observe that the most indicators related to the sub-process Pallet receiving are mapped with CSF 1 and CSF 2. An efficient management of the pallet receiving sub-process increases the quality of incoming items contributing to improve the quality of the product delivered to the pharmacy retailers. This could impact on the decision of new pharmacy retailers to be served to a particular wholesaler. Furthermore, this could improve the customer.

Sub-process	KPI	CRITICAL SUCCESS FACTORS (CSF)					
		1	2	3	4	5	6
PALLET RECEIVING	Item level checking average time	■	■				
	Case level checking average time	■					
	Pallet level checking average time	■					
	Average errors at drug type level	■	■	■			
	Item level average errors	■	■	■			
	Item level average losses	■	■	■			
	Workers for product receiving step					■	
STORAGE	Item level unit storage average time				■	■	
	Workers for item level unit preparation step					■	
	Item level unit preparation average time		■				■
ORDER PICKING	Average fulfilment time per order including release	■	■				
	Average preparation time per order	■	■				
	Average number of missing items by using automatic picking		■	■			■
	Average number of missing items by using manual picking		■	■			■
RETURN FLOW	Average number of returned drugs from pharmacy		■				■
	Average time for the recall of a drugs		■				■
	Average number of returned item for expiration				■		
	Average number of lost drugs				■		
PRODUCT DEADLINE MANAG.	Average workers to check expiration		■			■	
	Average number of hours to check expiration		■			■	
PRODUCTS OUTCOMIG	Average number of incorrect deliveries to pharmacy retailer		■			■	■

Table 2. KPI – CSF cross analysis

The KPIs related to the order picking are mapped mainly to the CSF 2. As discussed for the pallet receiving case, the order picking sub-process could improve the quality of the product

delivered. The CSF 5 is related to all the indicators that allow measuring the number of workers employed in the related sub-processes. A reduction of the workers effort allows to move the same workers on other activities, more intellectual, and thus to improve the human capital of the company.
In order to evaluate a performance comparison between AS IS and TO BE models exploiting the KPI-based analysis, an intensive measurements campaign is needed. This activity is vey complex because it requires an accurate knowledge of business processes. Furthermore, the estimation of the defined indicators for the TO BE model is often carried out exploiting a simulation approach or past experimental experiences. This comparison is not reported here because its goal was to illustrate a useful approach able to evaluate potential benefits due to the combined use of the three innovative technologies in the pharmaceutical supply chain. Let us observe that the KPI analysis is still in progress when authors are writing this chapter. For this reason, only few experimental results are mentioned here in order to report some examples that are able to anticipate the substantial improvements derivable by a combined use of these innovative technologies (i.e. RFID, EPCglobal, and ebXML) in the pharmaceutical supply chain. For example, the item-level checking time in the AS IS analysis is equal about to 7 min and the Average Errors at level of drug type is about 70 errors on 109 total product types. The TO BE analysis allowed to estimate that the time and errors related to the products receiving process could be significantly reduced. The average time need to carry out the several checks is almost zero because in the re-engineered model workers are involved just in the moving activities. The checks at every level (i.e. pallet, case, and item) are performed by auto-identification systems based on the RFID technology. Furthermore, the combined use of RFID, EPCglobal e B2B will provide the possibility to remove all errors that in the AS IS model have been measured in the Product Receiving process. Also the number of workers needed for the activities in the several sub processes could be significantly reduced. Furthermore, the re-engineered TO BE model is able to guarantee that the orders prepared to be delivered to pharmacy retailers are error-free because the last point to check, characterized by a RFID gate connected to IS, is able to identify any discrepancies avoiding to get out from wholesaler orders not fully comply with the requests done by retailers through the B2B system.
Finally, the comparison in terms of defined KPIs for Return Flow Management (RFM) and Product Deadline Management (PDM) hypothesises that KPIs for the TO BE model converge to zero. A last significant data is related to the number of workers employed to check the expiration date of drugs that passes from 28 to 1 in the re-engineered model. These few examples are useful to confirm the encouraging indications reported in the cross analysis KPI-CSF in Table 2. These innovative technologies, used in combined mode, are able to guarantee a great boost for the company improving the interaction between wholesaler and pharmacy retailer. There is a valorisation of the human capital. The re-engineering activity, in fact, allow to reduce the average numbers of workers both in the pallet receiving sub-process and in the product deadline management and thus there is a reduction of the average time useful to complete the task of each worker. This will provide to the company the possibility to define a requalification programme for workers.

8. Conclusion and future works

This chapter represents a first attempt to evaluate potential benefits of the combined use of the innovative technologies, such as RFID and EPCglobal, in item-level tracing systems in the pharmaceutical supply chain.

In particular, a processes analysis has been performed on the wholesaler that represents a stakeholder very interesting, characterized by many constraints and high product flows. The current vision of the main business processes of the wholesaler has been described through the definition of the AS IS model by using the BPMN notation. This analysis allowed defining a possible re-engineered (TO BE) model based on the assumption of a complete installation of the combined use of RFID, EPCglobal, and ebXML in order to improve traceability and business messages interchange in the pharmaceutical supply chain. Furthermore, significant KPIs and CSF have been defined for the wholesaler in order to make easier a future quantitative analysis of the benefits due to the re-engineering by the innovative technologies described above. At this regard, a combined analysis between KPI and CSF allowed to understand what factors, important for the wholesaler, could be improved. In particular, the analysis carried out promises significantly benefits on the main business processes of the wholesaler, mainly, in terms of increase of correctness and timeliness and reducing of the number of workers.
The next step is to evaluate the performance comparison between AS IS and TO BE models exploiting the defined KPIs. This comparison will be able to demonstrate how the combined use of these technologies is able to guarantee significant improvements of the main business processes in terms of increase of correctness and timeliness and reducing of the number of workers. Realistic estimates of the selected performance indicators will be derived exploiting both consolidated experimental experiences in the use of EPC-aware solutions and ad hoc simulation tool able to reproduce accurately the re-engineered (TO BE) model.

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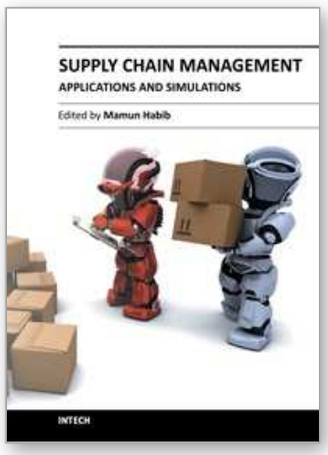

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Supply Chain Management (SCM) has been widely researched in numerous application domains during the last decade. Despite the popularity of SCM research and applications, considerable confusion remains as to its meaning. There are several attempts made by researchers and practitioners to appropriately define SCM. Amidst fierce competition in all industries, SCM has gradually been embraced as a proven managerial approach to achieving sustainable profits and growth. This book "Supply Chain Management - Applications and Simulations" is comprised of twelve chapters and has been divided into four sections. Section I contains the introductory chapter that represents theory and evolution of Supply Chain Management. This chapter highlights chronological prospective of SCM in terms of time frame in different areas of manufacturing and service industries. Section II comprised five chapters those are related to strategic and tactical issues in SCM. Section III encompasses four chapters that are relevant to project and technology issues in Supply Chain. Section IV consists of two chapters which are pertinent to risk managements in supply chain.

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