Easily Deployable Solution Based on Wireless Technologies for Traceability of Pharmaceutical Drugs

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Abstract—**The relevance of time in medical delivery makes difficult to include validation systems into the supply chain. On the other hand, the use of reusable containers duty to transport medicines makes RFid an excellent technology to be used in this application. Not only it is a nonintrusive technology but also cheap because of the reuse of UHF passive tags, attached to medicine containers, paying for itself in the long run. This paper explains the development of a system that uses RFid technology to pursue these purposes, not directly interfering with carriers work.**

Keywords-RFid; traceability; pharmaceutical; supply-chain

I. INTRODUCTION

Pharmaceutical drug supply chain, from an economic and health perspective, requires to control all stages of distribution: since drugs are produced in a laboratory until they reach the pharmacies. This requirement is reflected by the Ministry of Health and Consumption of Spain through the new Royal Decree of drugs traceability, redacted in accordance to Directive 2003/94/EC of the Commission of the European Communities [1].

Adapting to the changes required by regulation, severe changes have to be made in the business model of different actors involved in the pharmaceutical sector. Moreover associated costs are hardly feasible in a highly competitive industry where profit margins often are set by administration [2].

The system described in this paper aims to adapt the distribution system used by pharmaceutical drug warehouses to the requirements demanded by the administration without altering the current business model.

This system, integrated with the WMS (Warehouse Management System) of the distribution company, allows to manage the drugs traceability and to verify the correct delivery of them without affecting the current operating model of the staff or carriers. In a scope of application where reliability and delivery time are the main differentiating factors, installing a system that slows the work of the carriers, forcing them to use handheld RFid or B2B readers is operationally unfeasible. The main advantage of this system is that it is completely transparent not only for carriers but also for warehouse staff.

Besides, in a market where all competitors are offering the same products at similar prices, service quality is a decisive factor because an incomplete or incorrect shipment can result in the lost of a client. The presented system can also detect all issues that arise in the transportation of drugs and minimize the time involved in its management.

II. RELATED WORK

Last years there has been a considerable rise in the global concept of traceability of products and materials. Several research projects have been developed and a lot of research papers have been published. They explore different aspects of traceability of goods [3] [4], applied to different types of industries [5] [6] and needs [7].

The interest shown by companies related to fields where traceability is not only a productive benefit, but a health or safety necessity has been more important, e.g. on areas such as food or pharmaceuticals. Given this social need, the institutions have claimed for traceability systems for those industries.

As a practical example, in Europe, Regulation 178/2002 requires the traceability of all food from farms to the end of the supply chain [8]. While in countries such as Spain, through a traceability pilot [9] which involves the most relevant actors in the pharmaceutical industry, i.e. laboratories and distributors, legislation is being promoted in the same direction for the comprehensive control of drug transport. Moreover, several European projects are being developed, such as BRIDGE FP6 Project [10] in pharmaceutical traceability topic.

As it can be concluded in this kind of projects, adopting a complete system of traceability of goods is a challenge for the industry due to multiple risk factors. In fact, a lot of research papers examining some of these risks have been published. Some of these have been used as reference for implementing the system presented in this paper.

One of the highlights is the need to monitor the drugs traceability at item-level in order to prevent counterfeiting and to guarantee transparency and safety in the drug flow. For a

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better manage of the supply chain, it is also required that all pharmaceutical supply chain participants integrate with each other, resulting in information sharing, consistency checking and anti-counterfeit [11].

Other papers focus on another key issue: the choice of technology that makes possible the identification of products. Technologies such as DataMatrix or RFid has been taken into consideration [12] [13] looking for the best solution for all the participants in the supply chain. This choice is a source of conflict between actors involved: laboratories and distributors. Laboratories cannot bear the cost of RFid tags associated with individual packages, while 2-D printed Barcodes can cause mandatory changes in the operational model of distribution depots involving the alteration of existing distribution system to pharmacies and cause significant delivery delays [14]. Also, it has been conducted in-depth analysis about the type of RFid tags to use [15] [16] to ensure an accurate reading in critical operating conditions (e.g. metals and liquids, misalignment tag and reader antennas, and multiple reading of tags). Other studies have also focused on the evaluation of the potential effects of drugs on RFid systems [17]. The experimental results are strongly encouraging the use of RFid-based technologies for item-level tracing systems in the pharmaceutical supply chain.

The result of our work, therefore, is an ICT solution that considering all the above studies and associated risks provides a functional overall-process platform based on UHF RFid tags in conjunction with a mobile application for support real-time management and complete traceability of the pharmaceutical drugs supply chain.

III. FUNCTIONAL DESCRIPTION

There are three well differentiated parts in this system: the embedded device, the mobile application and the control software solution.

A. Embedded device

It is the main communications device. It detects containers using RFid technology, and communicates with the central server and the mobile unit with its embedded Bluetooth and WIFI modules.

Automated medical dispense robots have to coordinate orders for each pharmacy. This system organizes all requested medicines in containers, and then all of them are sent to the dock ready for loading vans. When the delivery van arrives at the store, a WIFI connection starts between the embedded device, installed into each van, and the Server. The embedded device downloads all needed information and updates the number and EPC (Electronic Product Code) of containers that must be distributed along the next route. It also updates place and number of stops during the route and which container to deliver. With its RFid module, it can detect tags attached to each container, loaded into the van, so that it can warn delivery man with a red or green light if all containers are inside. When the green light is on, the van driver can start containers delivery. If there is a lost container, the embedded device sends by Bluetooth to the mobile application how many containers are missing and their EPCs in order to request for them to the store administration.

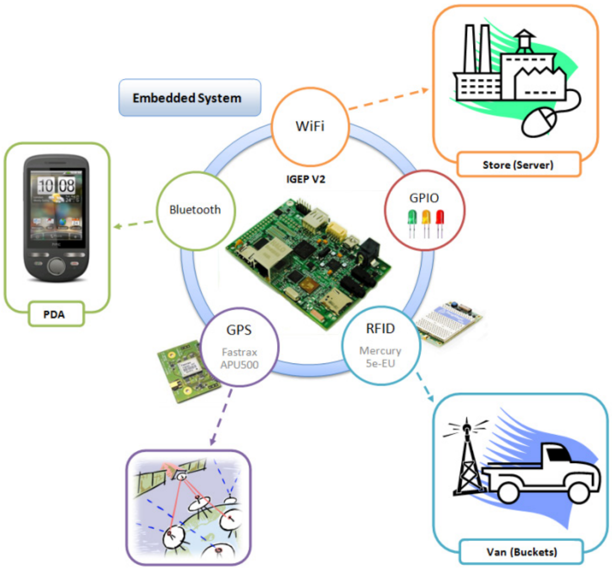

Figure 1. System Arquitecture

During distribution, the communication between the embedded module and the mobile application will warn the driver if he has done a wrong container delivery.

B. Mobile application

It is installed on a Smartphone. The van driver uses it to fill in the work schedule using a user-friendly graphic interface.

Each driver carries a Smartphone to stay connected to the server application in order to know all his needs on every transport service. The big terminal offering and the variety of operative systems has forced us to develop a multiplatform application that works on the majority of newest existing mobiles supporting WIFI, Bluetooth, GPS and GPRS/HSPA.

The application installed on the Smartphone has these features:

1) *Navigation help:* it shows the route, indicating the order in which the driver must make every stop on the planned route. If it is necessary, it assists delivery man in navigating from one point to another in that route. The application also can show information related to each stop included in the route like address, comments of other drivers or temporary deviations from estimations.

2) *Support for transport activities:* in this case, the application shows which action to do on each stop. It validates the correct execution of that action communicating it from the embedded device to the Smartphone. If the number of theoretical containers to download differs from the containers downloaded by the driver, he will receive a warning on his mobile terminal and he will have the opportunity to correct it before sending an incidence to the central server.

3) Incident management: the application has a system to send any incidences to the server like accidents, van breakdowns, containers lost...

C. Control software solution

It is used to monitor medicines traceability, to schedule optimized routes and to position different vehicles of the vans fleet.

This software solution includes the development of a control panel to manage all system. It includes three main features:

1) Medicines traceability: the system has a robust database where all delivery information is stored. That is, pharmacy office in which each medicine unit has been distributed, indicating batch number and expiry date. It allows user to search for a container even if it has been downloaded in a pharmacy office or if it is inside a van during a transport service. The control software also controls containers situation, allowing users to locate them if one of them gets lost.

2) Fleet management: the system can position different distribution vehicles on a map, it can store completed routes and the time spent on each stop. It contributes to the distribution company calculating an approximated time left to deliver a batch on a pharmacy office. It also calculates optimized routes taking into account delivery time, traffic and preemptive supply. And the software solution controls shipping delay, monitoring routes and stops that have been occurred during a penalized transport service.

3) Optimized schedule fleet: taking into account database stored information, using artificial intelligence techniques and generating information by ERP, the application generate routes for each vehicle optimizing time of delivery.

IV. Technical Solution

All features explained in the previous section have been developed thanks to the use of different technologies. At this point, we are going to describe each module of the system from a technical point of view.

Information is structured in the same three parts that correspond to the three main elements on which the solution is composed.

A. Embedded device

This module is allowed to register and validate the route done, cargo changes during delivery and communications. The main device of this system is an ISEE IGEPv2 based on an ARM Cortex-A8 processor stand-alone computer-on-module. The main features of this board are: a micro-SD with OS, WIFI IEEE802.11b/g, and Bluetooth 2.0, GPIO pins, serial ports.

- Micro-SD with OS: it contains a Linaro distribution with a Linux kernel optimized for this specific board.
- WIFI IEEE802.11b/g: implemented on a chipset based on Marvell 88W8686. This WIFI connection is used to update transport service information from the server control system for the new route and to send back a register of the completed route.
- Bluetooth 2.0: it is Class 2 with a power of 2.5 mW (4 dBm). With a range of 10 meters, this sub-module allows each van driver to connect to the main module to control and validate his actions during delivery.
- GPIO pins: these pins are connected to two green and red high brightness LED diodes. These diodes inform the driver if all containers have been loaded or downloaded in the correct pharmacy.
- Serial ports: two of the serial ports are connected to the GNSS receiver and to the RFid reading system.

1) GNSS receiver

Since most of the routes are developed in urban areas where coverage is limited, an ultra high sensitivity GPS receiver module is used. Furthermore, as the module is fed from the main battery of the van it must have low power consumption. GPS receiver supports WAAS / EGNOS / MSAS to improve the accuracy and cold start. The receiver module (fatrax i310) is connected to the embedded device through a UART port.

2) RFid reading system

This sub-module is composed of a Mercury5e-EU RFid Reader, two commercial high gain antennas and a passive UHF tag attached to each container. The reader works at the UHF range of frequency to improve interrogation distance and bears EPC Gen2 protocol, more robust against noise and reading interferences. The working procedure of this system starts with the IGEPv2. It asks for the information of tags inside the van sending a request through serial port. The RFid reader starts generating a continuous wave to power up the tags stored into the van and these tags answer their EPC (96 bits) modulating the continuous wave generated by the reader [18]. To detect all those backscatter signals generated by transponders, two high gain antennas are connected to the reader and are strategically positioned into the van. In this manner the reader improves its reading range against low power answering of transponders and enlarges covering inside wagon. The reader manages those antennas, activating and deactivating alternately, to avoid interferences between them [19]. Once it has completed a read cycle, the reader sends back through serial port all EPCs stored in its internal buffer to the IGEPv2.

B. Mobile application

Android technology has been used for the development of the mobile application. This decision is motivated by the opportunity offered by the pharmaceutical transport company "Cenfarte, Centro Farmaceútico del Norte S.A" with which it has established an active collaboration to enable the implementation of a real pilot of the solution. The company has the means to have an Android terminal for each route or carrier. Our development starts from the premise to make the architecture as open as possible in order to port the application to the largest possible number of mobile platforms, including Apple iOS and BlackBerry OS, in the near future.

To achieve this goal, the development has focused towards an SOA (Service Oriented Architecture), in which most of the functionality is distributed in the central server, freeing the processing load to other devices that will access the logic through SOAP messages to a web service developed for the control software solution.

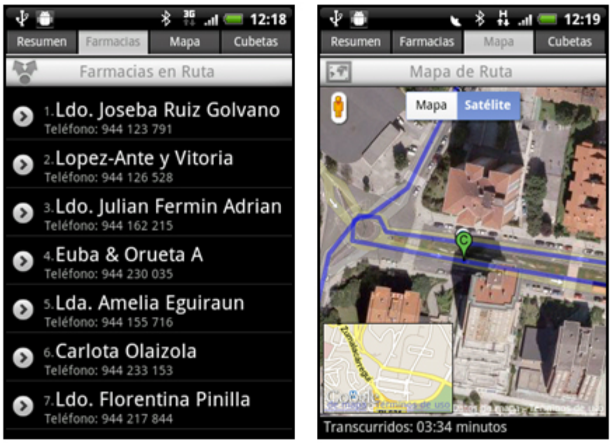

Figure 2. Mobile application interface

The mobile application supports the carrier in the development of daily activities, allowing to significantly reduce operational errors in the process. Thereby this subsystem seeks to improve the overall productivity of transport.

Once transportation is available to perform a service, the application displays the routes that are currently available. It does so through a WIFI connection to the server, accessing the web service responsible for obtaining the daily routes not yet started. In case of failure of the WiFi connection, the system offers continued support in communications through GPRS/HSPA connectivity present in the mobile device itself.

Application makes extensive use of Google Maps API in order to obtain all possible information about the route. Thus, once the route is established, the mobile device obtains data about the full path: distance, estimated duration, number of stops, addresses, etc.

Similarly, for each of the established stops relating to the pharmacies on a route, concrete EPC of containers to download are obtained.

This information is accessible via another web service that fulfills the function of data-oriented middleware enabling the capture of real-time information from the ERP system implemented in the company. The developed system obtains the information in a transparent and non-intrusive manner, not being necessary expensive modifications in the legacy order management system.

All this information is displayed to the carrier through an user interface designed with the intent to facilitate maximum usability.

Once in the course of the route and since these are changing according to the pharmacy establishments involved in them, the mobile device offers integrated navigation service for helping the carrier.

At each stop, the embedded device reads RFid tags and detects changes in the cargo that are sent via Bluetooth to the mobile application. This data relating to the operation of the carrier in the loading or unloading of containers, provides real-time information about possible deviations (human errors in cargo management) allowing warehouse staff to rectify the errors on delivery in minor time.

We consider as incidents significant deviations in the planned route. It has been established that against a greater than 10% deviation in the estimated time for delivery of an order or a non-conformity in the containers to download, an incidence must be generated.

The incidents are managed by the mobile application, simultaneously alerting both the carrier and control center. This will be achieved using communications established via GPRS/HSPA between the mobile device and control software solution.

C. *Control software solution*

Within the control software solution we can find three distinct parts: the data model, web services and web application. The technical characteristics of each of the parts composing the control system are listed below.

1) *Data Model*

Data that should be stored by the application has been conceptually modeled. Microsoft SQL Server 2008 DBMS has been used in this context. Entities are collected as part of the functional structure of the application: drivers, routes, pharmacies, buckets, etc.

The process of storing the operational data of transportation occurs at the end of the route. When this occurs, the onboard device is connected via WIFI to the server and sends a generated XML file which includes both the actual path followed by the vehicle and the incidences that may have occurred.

This file is automatically treated by the system, generating the necessary entries in the DBMS so that the route is recorded at the time of its completion. This route can be accessed later using the historic route.

2) *Web Services*

Information relevant to the application is in the DB; however, as discussed in previous sections, access to such information is done through Web services developed with WCF technology (Windows Communication Foundation.)

This technical decision allows both data and application logic can be accessed from other devices, thereby ensuring the scalability and interoperability of the whole.

Security also is increased because the data access does not occur directly (accessing the DB) but through the services, providing greater control over database queries. The network will be controlled at all times under a firewall that prevents unauthorized access.

The set of services developed therefore allows full interoperability between the different components of the system, which is a major benefit in broadening the number of devices compatible with the system and facilitate their development in the future.

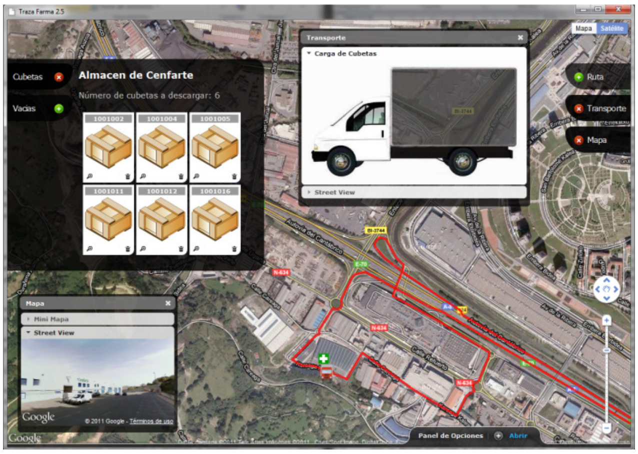

Figure 3. Web application interface

3) *Web Application*

The development of the control solution is completed with the web application which offers features beyond the typical application of fleet management.

This application has been developed taken into account two fundamental characteristics: (1) to maintain a friendly and attractive interface, (2) without prior installation or further configuration.

In these terms this Internet application approaches usability to a modern desktop application but with all the advantages that such implementation offers, being available globally via the Internet to a vast number of devices supported, without prior installation or further configuration.

The Control Panel, based on asp.NET development framework, has been made extensive use of technologies designed for creating Rich Internet Applications (RIA): JavaScript, CSS3, HTML5, Ajax and jQuery, along with the use of the tools offered by Google for displaying and processing of geographic and positioning information.

Thus, the designed user interface lets you use the application as if it were a regular desktop application, making use of in frequent UI elements in an application of this kind, such as dialogues, menus, tabs, etc. This feature improves not only the final visual aspect of the application but also the overall usability.

The whole site is based on a synchronous behavior, so interaction eliminates the sense of loading data and responds instantly to user actions. All kind of choices as routes, stops or containers represent a dynamic and transparent loading of data and an almost immediately response to their interaction.

V. Testing and Evaluation

For the application test, five pharmacy offices offered their services to make the experiment. It should be noted that instead of using RFid system mentioned above, a handheld short range RFid reader has been used.

TABLE I. PHARMACY OFFICES ROUTE

Pharmacy Office	**Route data**			
	Estimated time	***Time spent***	***Containers to deliver***	***Containers delivered***
Etxanobe	18 min	18.5 min	2	2
Olivares Gonzalez	8 min	7.5 min	2	2
Timprenero	3 min	3 min	1	1
Jiménez Linares	4 min	4 min	2	1
Iturriaga Otaño	13 min	13 min	1	1

The delivery studied in this case has been made a total of ten times during a week and just two of them have generated an incidence. The chosen route is 30.7 Km length starting and ending at the distribution store, and the estimated time calculated for that is 45 min. A total of 2h is calculated adding 15 min per stop.

Some of the times measured are shown on Table I. All measurements are from test 3. But the last row of the table has been modified with the one in test 7 to show another incidence. So two incidences are shown on the same table, but they occurred in different tests.

Comparing total estimated time with real time spent on the delivery, an error time is obtained according to expression (1) where tp is the time spent going from one pharmacy office to another, ts is the time spent on each stop, downloading containers, and ξ is the error time caused by differences between estimated time and real time.

$$\begin{aligned} t_T &= \sum t_p + \sum t_s + \sum \xi \\ t_T &= 45\min + 75\min + 13\min = 134\min \equiv 2h13\min \end{aligned} \quad (1)$$

That error time generated an incidence in the system and was registered in the control software solution when the delivery van arrives at the store.

On the other side, an incidence was generated on the 4th pharmacy office and it was caused by a mistake downloading a container. The delivery man shouldn't have continued with the delivery because the red light was on, so the system generated an incidence that was transferred to the control system solution when the van arrived at the store again.

VI. Conclusions

Profits that item-level traceability for pharmaceutical drugs provides to society in terms of public health and ensuring access to medicines enforces governments to require this feature to the different actors involved in the pharmaceutical supply chain in the short term. Many of the studies and initiatives referred on the section related work have been designed taking into account only the requirements imposed by governments but without considering the difficulties of deploying such systems in the storehouses currently working on and supporting the pharmaceutical supply chain. The reduction of profit in the pharmaceutical industry motivated by the imposition of certain public policies hardened because of the economic crisis affects not only laboratories but also distributors of pharmaceutical products that are unable to afford the investment needed for these systems. The system described by this paper aims to meet the requirements set by the Ministry of Health of Spain minimizing the impact of their deployment in existing pharmaceutical distributors.

Therefore, rather than imposing a technology for the item-level identification of medicines, it is proposed to combine the two technologies predominantly used in the pilots carried by the same scope: RFid and 2-D Barcodes.

The "Good Distribution Practices for Pharmaceutical Products" drafted by the World Health Organization states that all pharmaceutical products should be stored and distributed in containers which do not have an adverse effect on the quality of the products, and which offer adequate protection from external influences. Thanks to the reuse of these containers, the transportation of drugs is an ideal scenario for the use of RFid tags. The high current cost of UHF tags used by the system is amortized by an application capable of geo-positioning last location of each lost container.

This system performs container-level tracking since those containers are loaded in a pharmaceutical warehouse until they are delivered in pharmacies. In this way the technology used by pharmaceutical laboratories will not interfere in the process. The system must collect the containers loaded by the automated dispensing robot installed in drug warehouse, validate the loading of each container, using technology agreed upon by the laboratories (2-D barcodes), and carry out the traceability of the last step in the supply chain.

On the other hand, this system offers some additional features of great interest for pharmaceutical warehouses manage: (1) the monitoring system of routes allows the depot manager to identify the causes that have led to irregularities in the execution of a route; (2) the assistant device of the van driver notifies immediately when significant delays are produced or errors in delivery are detected; (3) the device of container tracking indicates the position of all containers that have not been returned to the warehouse enabling their recovery.

VII. FUTURE WORK

The work presented in this paper describes the first part of a project currently underway and is scheduled to end in December 2012. There are three additional challenges to carry out in the future:

- Pilot test of the complete system using commercial wide range antennas for the detection of tags inside the wagons of delivery vans. This pilot will be implemented during the first half of 2011.
- Custom Antenna design to minimize errors in the detection of containers. This part of the project is scheduled to be performed during the second half of 2011.Upon completion of this part is scheduled to deploy the system in the warehouse that the distributor of pharmaceutical products Cenfarte SA owns in the Basque country.
- During the course of 2012 is scheduled to design and implement a validation system able to dump the contents of a container loaded of medicines and pick out its content through the identification of 2D bar codes. This system should be integrated into automated robotic dispensing of pharmaceutical products manufactured by Cenker Robotics, a company that collaborates on the project.

With the development of these parts, the system meets the requirements set by the administration and allows easy deployment in the distribution of stores currently in operation.

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