# Easy to Deploy Solution for Pharmaceutical Drugs Traceability in Distribution Warehouses

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***Abstract*— Enormous profits that item-level traceability for pharmaceutical drugs provides to society in terms of public health and ensuring access to medicines enforces some governments to require this feature to the different actors involved in the pharmaceutical supply chain. Other existing works have been designed without considering the difficulties of deploying traceability systems in the storehouses currently working. The system described in this paper is based on ITS technologies and aims to meet, specifically, the requirements set by the Ministry of Health of Spain, but minimizing the impact of deployment in existing pharmaceutical distributors.**

## I. Introduction

There is a growing need for smart solutions in logistics to improve the supply chain. However, **most existing commercial applications focus on generic needs of transport operators and are not adaptable to the specific needs that arise in certain sectors** which are intended to improve service or adapt to new demands required by law. Through this paper we describe a system that facilitates the adaptation of distribution depots of pharmaceuticals to the new regulations demanded by the Ministry of Health in Spain by combining different intelligent transportation technologies.

Pharmaceutical drug supply chain, from an economic and health perspective, requires control all stages of distribution: from 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 imposes severe changes 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].

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 portable 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 loss 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.

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## 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 which explore different aspects of traceability of goods [3] [4] applied to different types of industries [5] [6] and needs [7].

Even more important has been the interest shown by companies related to fields where traceability is **not only a productive benefit, but a health or safety necessity**: areas such as food or pharmaceuticals. Given this social need, have been the institutions which have claimed 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: laboratories and distributors**, legislation in the same direction for the comprehensive control of drug transport is being promoting. 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, have been published a lot of research papers examining some of these risks. Some of these papers 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 guarantee transparency and safety in the drug flow. To better manage the supply chain 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, has been conducted in-depth analysis about the type of RFID tags to use [15] [16] to ensure an accurate reading in presence of critical operating conditions (e.g. metals and liquids, entre 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. Intelligent Drugs Tracking System Architecture

There are three well differentiated parts in this system: the embedded device, the mobile application and the control software solution. We are going to describe each module of the system from a functional and technical point of view.

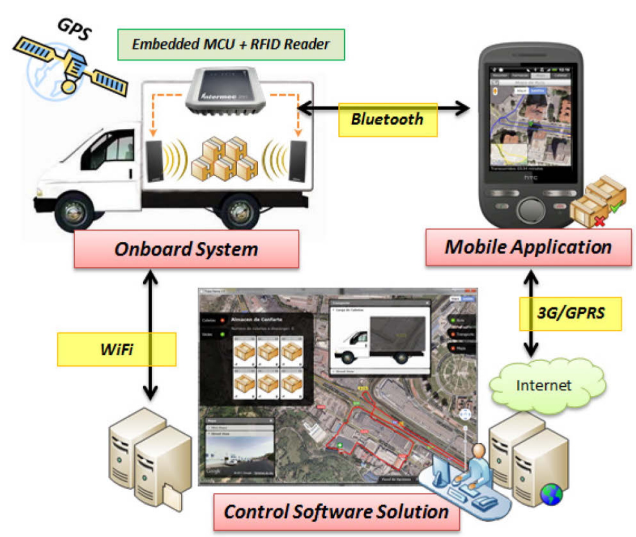


Fig. 1.System architecture

### 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 of containers to be distributed along the next route. It also updates place and number of stops 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. If there is a lost container, the embedded device sends by Bluetooth to the mobile application how many containers are missing in order to request for them to the store administration.

The main device used to implement all these features is an ISEE IGEPv2 based on an ARM Cortex-A8 processor stand-alone computer-on-module. The main characteristics of this board are:

- 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 and used for updating information at the warehouse.
- Bluetooth 2.0: it is Class 2 with a power of 2.5 mW (4 dBm). With a range of 10 meters, it sends information to the mobile application of the driver.
- GPIO pins: these pins are connected to two green and red high brightness LED diodes that inform the driver if the load or unload of containers has been done correctly.
- 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 be low power consumption. GPS receiver supports WAAS / EGNOS / MSAS to improve the accuracy and cold start. The receiver module (Fastrax i310) is connected to the embedded device through an UART port.

*2) RFid reading system.* This sub-module is composed of a Mercury5e-EU RFid Reader, two commercial high gain antennas and passive UHF tags attached to each container. The reader works at the UHF frequency range to improve interrogation distance and bears EPC Gen2 protocol, more robust against noise and reading interferences. To detect all 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.

### *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.*** 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 been 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. As a result of that, 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, including Apple iOS and BlackBerry OS. **To achieve this goal, the development has been focused towards a 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.**

The mobile application helps the carrier in the development of daily activities, allowing to reduce operational errors in the process significantly. 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, are obtained concrete EPC codes of containers to download. 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. As a result of that, the application offers navigation help, support for transport activities and incident management.

*1) Navigation help:* 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. It shows the route, indicating the order in which the driver must make every stop on the planned route and if it is necessary, it assists delivery man in navigating from one point to another in that route.

*2) Support for transport activities:* at each stop, 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.


Fig. 2. Mobile application interface

*3) Incident management:* incidents are considered as, significant deviations in the planned route. It has been established that in more 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*

**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:

- 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 solution provided also controls containers situation, allowing users to locate them if one of them gets lost.
- 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.
- 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.

All this functionalities are developed using this control software solution where we can find three distinct parts: the data model, web services and web application. Below are listed the technical characteristics of each of the parts composing the control system.

*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.

*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 Web 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.**


Fig. 3. Web application interface

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.**

## IV. 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 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 to laboratories but also to 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 impose a technology for the item-level identification of medicines, it is proposed combining 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 the 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, validates the loading of each container, using technology agreed upon by the laboratories (2-D barcodes), and **is responsible for carrying out the traceability of the last step in the supply chain.**

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 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.

## V. 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:

1) 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.
2) 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.
3) 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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