

ONASSET

INTELLIGENCE

MEDICAL

SMARTCONTAINER®

For Pharmaceuticals and High Value Biological Shipments

Executive Summary

Automated identification systems have long been proven to be highly beneficial to the end user. The markets for these systems have continuously grown since their first use in World War II. Since the initial implementation as a friend or foe identification system, auto-id technologies have ventured into every aspect of our lives. Today, auto-id technologies are well known for their contributions in tracking, tracing and authentication. These contributions are being proven around the world and are quickly making auto-id technologies a revolutionary tool in the fast paced business world.

Pharmaceutical and high value biological medications have for a very long time been in need of a supporting framework such as auto-id technologies. Track and trace capabilities will not only revolutionize the pharmaceutical industry, but will also contribute immensely in customer satisfaction, as it will give the user tremendous access to the world of information systems. This new world will not only reduce complications and gain customer confidence, but it will also create a very lean industry that will continuously be more and more efficient. Authentication systems powered by a global information system will enable an incredible amount of confidence in the industry, which would allow for a seamless stream of business opportunities.

This document will enlighten the reader with information regarding the state of art in track, trace and authentication. The reader will be given an opportunity to observe the latest in auto-id technologies being implemented for the pharmaceutical and high value biological medication industries.

The SMARTCONTAINER® was developed by a team of sophisticated scientists and engineers at OnAsset Intelligence. This innovative product was designed with the end user in mind by providing a complete solution for the track, trace and authentication need of this industry. The fundamental working mechanism of this product is detailed, and this document also highlights business benefits and a path to a successful implementation.

Introduction

Automated identification systems today are quickly emerging as an enabler in the fast pace industries we live in. The numerous reasons for this strong emergence are not limited to the fact that these technologies offer an unsurpassed identification scheme that allows for more efficient processes. In fact, auto-id technologies offer so much more to the user although they typically consist of only three major divisions. The three major concepts employed by auto-id technologies are the track, trace and authentication mechanisms. These mechanisms are typically used together to produce highly effective processes that benefit both businesses and the end user. Radio frequency identification or RFID has revolutionized the automated identification realm today, generating enough interest within the public domain to surpass the barcode technological revolution experienced decades ago. Today, we see a market landscape where the merging of technologies are required to enable the adoption of emerging technologies, while maintaining low vulnerability and high security or privacy concerns. These emerging technologies such as RFID require very little human intervention as compared to existing barcode technology. The need for smart devices that adopt these emerging technologies has never been greater. Today, organizations thrive on discovering innovative methods to simplify life using these technologies. Smart devices that can contribute to reliability and offer any of the three concepts described earlier will benefit communities worldwide.

The SMARTCONTAINER® is an intelligent device innovatively designed by OnAsset Intelligence in Irving, Texas. This device was engineered with the end user in mind and targeted at the pharmaceutical and high value biological medication industries. The initial design, spurred by the desire of OnAsset Intelligence to revolutionize the pharmaceutical industry was conceptualized in the Irving facility. The SMARTCONTAINER® is designed to allow for tracking and tracing of high valued pharmaceutical and medical shipments. The need to track these valuables is highly critical and a breadcrumb system would enable real time asset tracking and would give power to information systems and thus the user. The tracing capabilities of the system would enable historical information to be passed down, allowing authenticated users to visualize the drug flow chain and gain knowledge on the pedigree. Finally, the authentication is provided to limit interventions by unauthorized handlers and hence reduce the level of vulnerability to which the end user is exposed.

All in all, the SMARTCONTAINER® is a track, trace and authentication system that increases automation and security, while reducing risks and vulnerability to all participants.

In the following pages, light will be shed on the working mechanisms of this smart device. A non-technical (yet detailed) view of the hardware will be given to enlighten the reader about the fundamental concepts and functionality of the system. Then, a rigorous information capture system is presented to tackle the extensibility of this smart system while maintaining simplicity to the user. Finally, deployment recommendations and conclusions toward the future of this industry are presented in a concise format.

Workings of SMARTCONTAINER®

To explain the workings of the SMARTCONTAINER®, one must understand the capabilities of the system. The SMARTCONTAINER® was designed to be highly modular and rich in functionality. In doing so, the design included the ability to support multiple technologies and offer compatibility for further upgrades and future technologies. A key design constraint was initiated to incorporate a total plug and play (PNP) system. The ease of functionality offered to the user by the PNP approach will reduce errors involved with user participation. Similarly, the system was designed with smart software that minimizes errors. Automation at this level would reduce error rates by narrowing the thought process for the user. The smart software

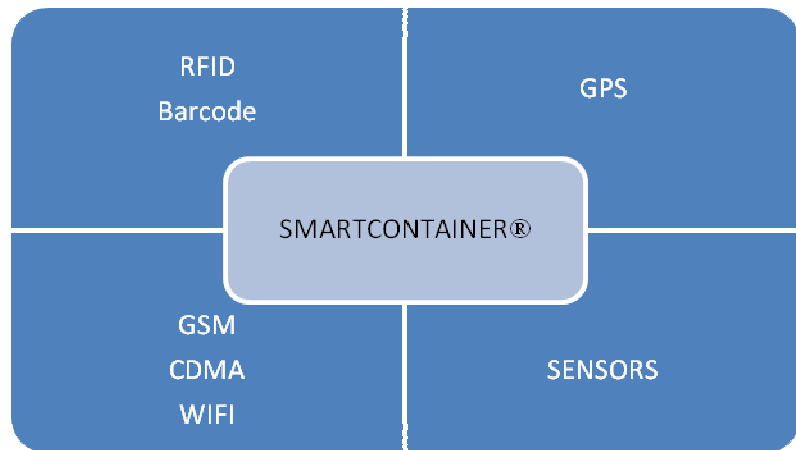


Figure 1: Constituents of the SMARTCONTAINER®

system adopts a very intuitive feel and helps the user use the technology without the problems created by unmanaged devices. A systems approach to the SMARTCONTAINER® allows a good holistic view from the software design perspective. The software architecture employed utilizes an innovative approach by anticipating future upgrades and expanding platform technologies. Figure 1 shows a typical SMARTCONTAINER® and its constituents. The four fundamental building blocks of this system are the Readers/Scanners, Real-Time Location Platform, Cell-Phone/Messaging Connectivity and Sensor Modules. The Readers or Scanners typically consist

Motivation for the SMARTCONTAINER® stems from the need for a pedigree approach in the pharmaceutical and high value biological medication industry. A pedigree approach allows a holistic view on the track, trace and authentication mechanisms required today by the industry.

of a near-field RFID reader and mobile barcode scanning solution. A near field RFID reader is implemented to enable an automated event notification system for both incoming and outgoing materials. Real-Time Location Platform is used in the

SMARTCONTAINER® to enable tracking at the package level. Global Positioning Systems (GPS) are used to alleviate the issues regarding missing units while providing guided delivery, location-based delivery confirmation and also real-time location through virtual maps. The Cell-Phone Messaging System is equipped with a Global System for Mobile Communications (GSM) unit that enables both incoming and outgoing messages. The GSM unit allows the authenticated user to send incoming messages that could potentially change specific user or system level settings. On the other hand, the outgoing messages schema is used for communicating alerts, confirmations and delivery updates both to the end user and to appropriate authenticated agents. The last major block of the system is the Sensor Module. This module is a PNP system that allows anything from temperature sensors to humidity, pressure and vibration sensors. Although these four are noted as highly desirable for the operations of the SMARTCONTAINER®, other high sensitivity sensors are easily incorporated into the SMARTCONTAINER®.

Figure 2 is a detailed view of the information gathered during the first phase of user participation. This process of information gathering is prepared before the loading of material is complete. The purpose of this process is to outline details regarding the client, the pharmacist, the person or entity delivering the drugs and thorough information regarding the drug itself. This information is gathered from the host computer through a platform designed by OnAsset for connectivity to the SMARTCONTAINER®. This software application allows the pharmacists to insert or update the fields as depicted in figure 2. The critical process information is then used to update the information system database, which securely stores all information. This database is easily accessed with authentication for all future queries. On the other hand, the downloading of the critical process sheet is accomplished during host connectivity with the SMARTCONTAINER®. It is easily visible that information relating to the delivery location is denoted during the download process. Basically, the download process initiates a secure database connection to the SMARTCONTAINER®, which then uses this information to guide each successful event. After a successful download, the SMARTCONTAINER® will be ready for its mission.

An event is denoted by any occurrence of human participation in the process, after completion of the download phase.

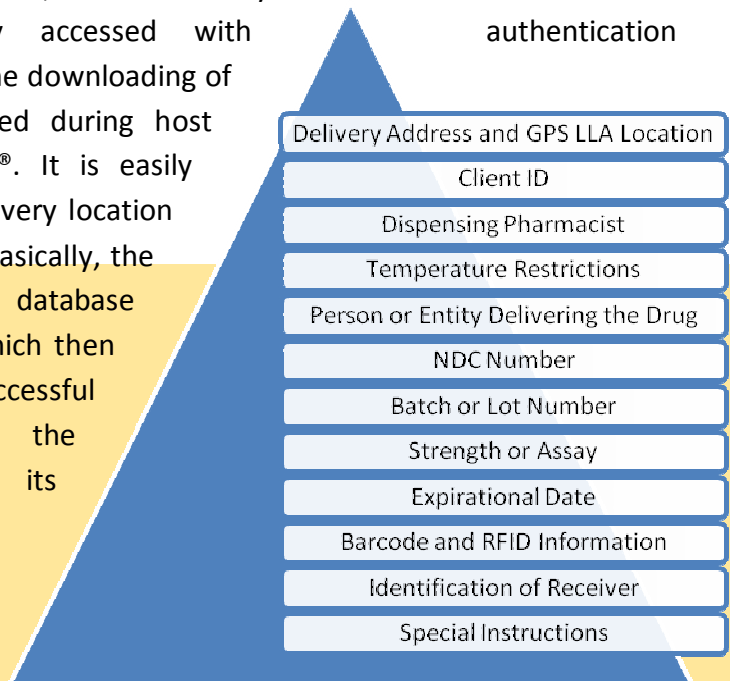


Figure 2: Critical Process Information

The NDC number, also known as the National Drug Code number is a universal product identifier required by FDA under The Drug Listing Act of 1972 for human drugs

During this mission, it will most likely endure more than one task. In a multi-task situation as such, the critical process information as denoted above would exist for more than one delivery. This multi-task mission will be available for the person or entity delivering the drug. A choice of an overview for each mission can be provided

or otherwise a first-in-first-out queuing system (FIFO or similar approach) could be initiated to allow more stringent control on the delivery during these multi-task scenarios. Regardless, the next step of events would guide the mission to ensure a successful delivery.

Figure 3 depicts the ideal event flow process that occurs from the post-download phase until

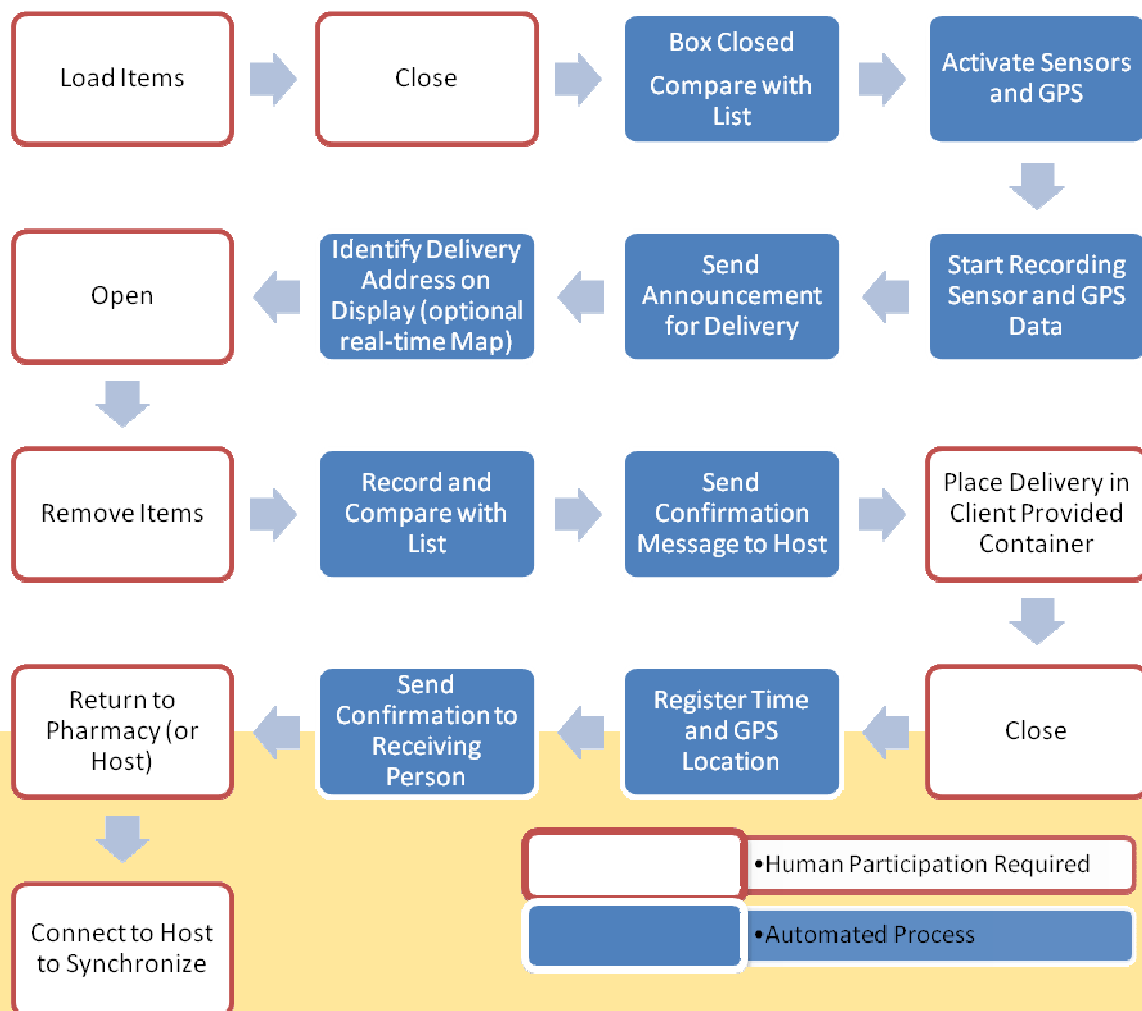


Figure 3: Ideal Event Flow Chart

delivery completion and host synchronization at the end of every mission.

After the items are loaded, the user will close the SMARTCONTAINER®. This initiates an automated process that compares the items inserted (into the Inbox) with the critical process

information from the host download. Assuming a perfect match, the system will initiate all appropriate sensor modules and the GPS unit. These units would begin collecting data, and depending on user requirements would either display or log this into a database. Immediately thereafter, a delivery announcement is initiated to both the host and client using appropriate Cell-Phone/GSM Messaging techniques. This is an important first step in the assurance process, where knowledge about the track and trace is conveyed to both the authenticated users and the client. After this initial startup phase, the user will be provided with either the delivery address or a GPS linked virtual map, via the liquid crystal display (LCD). This will provide the person or entity delivering the drugs with information regarding the driving destinations and locations. A simple algorithm implemented with software would point out any deviance from the preferred path to both the person delivering the drug and the host computer and generate appropriate alarm messages. The specific drugs for that delivery would be removed from the container. A comparison with the database would indicate if a wrong drug was removed and via this process of feedback, a completely secure delivery is now plausible. Assuming a correct drug removal event has occurred, a confirmation message is initiated and sent to the host computer. This confirmation would verify and record the timeliness of the delivery process. The SMARTCONTAINER® would then be closed and important information such as delivery time and GPS coordinates would be logged into a database. Immediately thereafter, a second delivery confirmation is sent to the client or customer. Repeating this process for subsequent deliveries, the person or entity delivering these drugs would (at point of mission completion) return to the pharmacy (or host computer location). Finally, the databases and generated events list from the SMARTCONTAINER® would be uploaded into the host computer through a direct connection at the pharmacy. This synchronizing process would also simultaneously download new critical process information and delivery databases for any subsequent new missions. At this juncture, the first SMARTCONTAINER® mission is officially completed. This view although holistic in nature, is suitable but does not completely describe the events that occur during the mission. This is so because the typical mission will likely involve some level of mishandling from the user (person or entity delivering the drug) or the environment. The issues that require enlightenment include a non-ideal sensor environment (i.e.: temperature sensor out of specified operable range), a non-ideal destination event (i.e.: GPS location out of specified delivery range) and a non-ideal load (or unload) event.

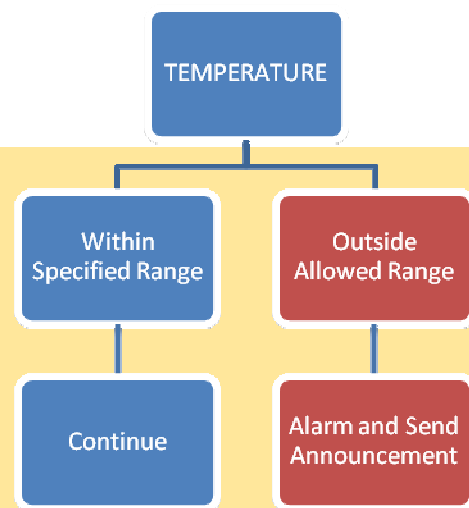


Figure 4: Non-Ideal Temperature Event

During a non-ideal temperature event, if the sensor indicates that the environment temperature is outside the specified allowable range, an alarm is immediately activated and an announcement is made via GSM Messaging to the host computer. In this scenario the alarm would generally be both visual (on the LCD) and audible (through a built in speaker system). If all other temperature environments are within the operable range, the data logging process is resumed along with the normal operations of the system. These occurrences are depicted in figure 4 (note that the red box indicates abnormal activity or event, whereas a blue box indicates normal activity). Similarly, figure 5 illuminates a non-ideal destination event. During this event, a GPS comparison that specifies a location outside the allowable radius would be construed as a wrong location.

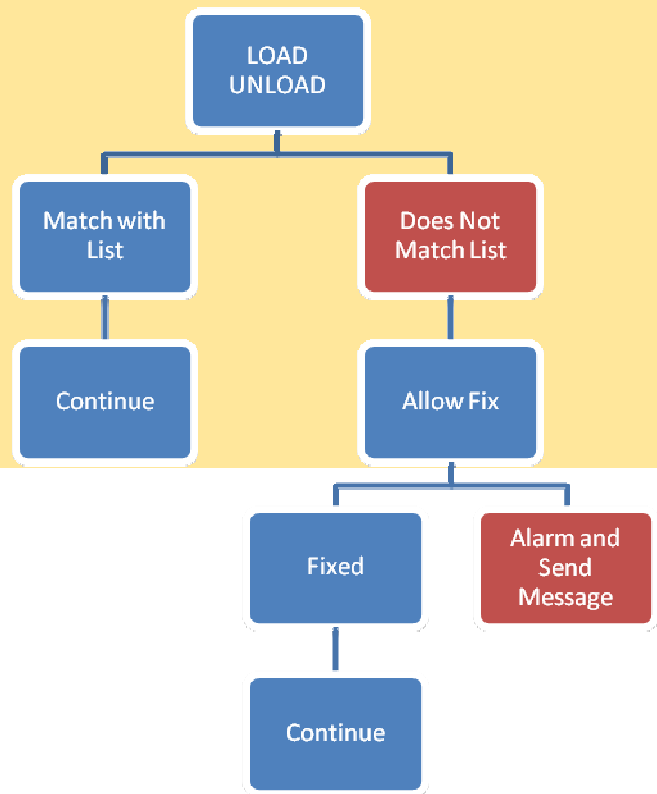


Figure 5: Non-Ideal Loading/Unloading Event

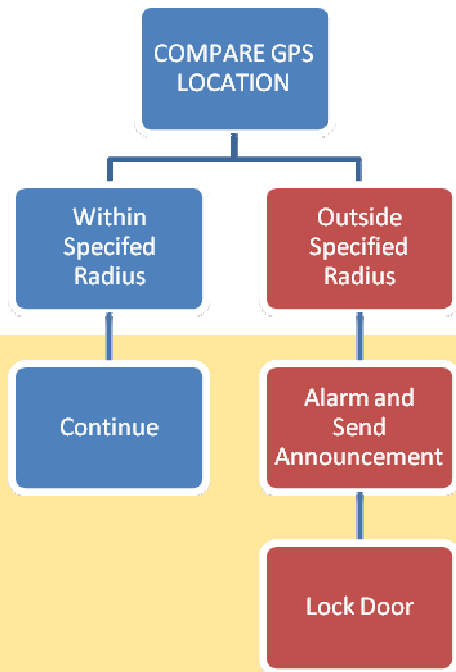


Figure 6: Non-Ideal Destination Event

This comparison although typically done during arrival at the destination, could also be initiated during the delivery to check for path deviations. In a wrong location condition, the system would initiate an alarm and send announcements similar to the non-ideal sensor event. The difference in this process is that the wrong location event would also enable a lock door function that would negate any attempts to open the container. This along with both the audible and visible alarms should deter the user (person or entity delivering the drug) from making wrong deliveries. Finally, figure 6 depicts the non-ideal load (or unload) event. During the loading or unloading phase, if there exist a mismatch with the expected items or drugs, the system would prompt the user to a “fix event”. This fix would allow the user to return a wrongly removed drug and/or remove the appropriate drug. Any attempts by the user to negate this fix would be construed as a fault and an alarm and announcement will

be generated in a similar fashion to the previous events. In a situation where the event is fixed, the user will be allowed to resume normal activities.

This summarizes the workings of the SMARTCONTAINER®. This non-technical view is essential in understanding the general concepts behind this system.

SMARTCONTAINER® Hardware

The presentation approach used thus far enables the reader to view the process, chain of custody, track, trace and authentication. This process view is used in a holistic manner to allow for a broader perspective on the usages of this system. In this section, a component level view of the SMARTCONTAINER® is provided. This section will convey the hardware components of the system as well as the factors involved in choosing the components used in the SMARTCONTAINER®.

Construction and Components

The hardware construction of the SMARTCONTAINER® is dominated by a number of critical components. As listed in figure 7, it is easily seen how a modular design would be a key requirement for this flexible system. Modular architecture enables the operation of multiple technologies simultaneously. This is done using a highly nodal analytical design methodology. The nodal method appropriates each group as shown in figure 7 as a node of itself. In doing so, every node is independent of each other and only communicates through nodal participation.

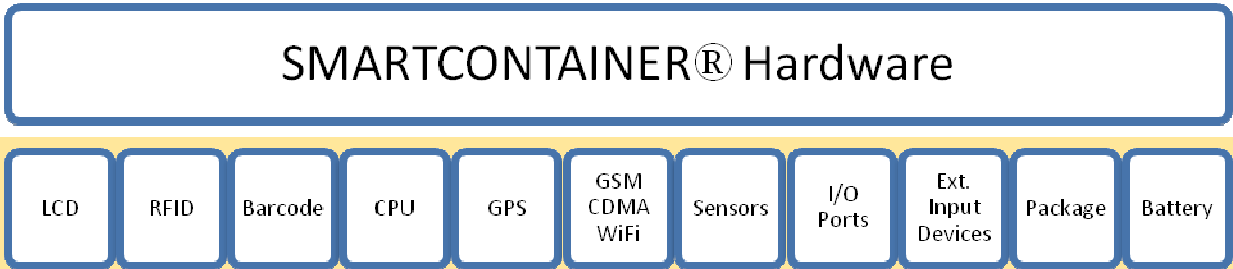


Figure 7: Hardware Construction and Classification

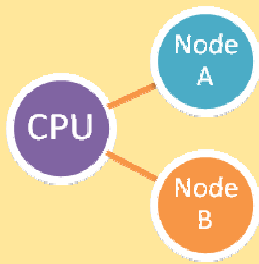


Figure 8: Nodal Method

Figure 8 gives a simplistic view of how modularity works using nodal methods. Considering node A and node B as two separate entities that have different functionality and purposes, a communication link between the two is never initiated directly. Instead a completely independent entity, in this example a CPU, is utilized as a medium for communication. This medium is not required to understand the operation of either node, only the format of the data. This approach allows greater integration amongst multiple nodes (using constant multithreading) and reduces errors stemmed from collisions.

Returning to figure 7, it is worth pointing out that the key components in the SMARTCONTAINER® are the LCD (for display and user interaction purposes), a 13.56MHz ISO 15693 RFID Reader Module with an array antenna technology (patent pending), a slim portable barcode scanner, high performance CPU, GPS system, Cellular (optional CDMA and GSM) system, PNP sensor modules (temperature, humidity, vibration or pressure), input/output ports for future technological additions and upgrades, external input devices (such as a keypad), a smart packaging system and a long-lasting rechargeable battery. The smart packaging system is OnAsset's way of customizing the package size and dimensions to fit various types of applications in the industry. This has proven to be highly valuable, especially in the pharmaceutical and high value biological medication industry, since there exist a variety of needs and variability of usages or operations. Finally, the battery used for the SMARTCONTAINER® is a rechargeable battery designed specifically for this product and has a life of up to 7 days depending on usage conditions. This lifetime can be extended for certain types of packaging that trade size for longer battery life. OnAsset is currently working with their strategic partners to design cutting edge batteries that reduce packaging dimensions and weight while increasing battery life.

Factors of Choice

During the selection process, a very idealistic view was preserved for the mechanism of the SMARTCONTAINER®. In doing so, the choices for the modules and systems or sensors were taken into consideration. These choices were important because they would both implicitly and explicitly determine the workings of the system. Besides the general workings, the choices made in the software design and architecture would be highly dependant on the factors taken into consideration when selecting the different nodes (i.e.: LCD, RFID Reader Module). Figure 9 is an outline of the key features of each system (or node) in the SMARTCONTAINER®.

LCD	•65k Colors Touch Screen Extra Bright
RFID	•13.56MHz ISO 15693 RFID Reader with array antenna package
Barcode	•Slim and portable barcode scanner with plug and play capabilities
CPU	•ARM7 based microprocessor with up to 600MHz of processing speed
GPS	•Low power GPS unit built-in with accuracy of up to less than 3 meters
GSM	•Low power GSM unit built-in with messaging queing and SMS support
Sensors	•Temperature, Humidity, Pressure and Vibration with high accuracies
Input/Output Ports	•Up to 40 external input/output ports for future sensor upgrades
External Input Devices	•Keypad, USB devices such as thumb drives for multiple platform communications
Packaging	•Smart packaging made with the customer and application in mind and fully customized
Battery	•Long life of up to 7 days depending on operating conditions and longer lifetimes for custom solutions

Figure 9: Features of the Modules or Nodes

Each module in this list is chosen with detail and caution. This is done to reduce errors with compatibility, to increase performance and life and to ensure the smooth and seamless nature of the operation. During this process a list of key considerations were generated to allow for a knowledgeable decision. Figure 10 depicts a few of the key factors that were taken into consideration.

LCD	•Bright, Low Power and Touch Screen
RFID	•13.56MHz ISO 15693, Low Power
Barcode	•Slim, Portable, Plug and Play
CPU	•High speed processing, Sizable On-Board Memory, Low Power
GPS	•High Accuracy, Low Power
GSM	•SMS Support, Low Power
Sensors	•High Accuracy, High Precision, Low Power, Medical Grade
Keypad	•Slim, Portable, Convenient, Plug and Play
Packaging	•High Packing Ratio, Convenient Design, Reliability, Sturdiness
Battery	•Long life-time, Rechargeable, Quick charge, Slim, Low in Weight

Figure 10: Key Factors

Using these selection criteria, the requirements of the system were molded into a very solid architecture. This architecture would then reveal the work of both art and science in a designed system called the SMARTCONTAINER®.

SMARTCONTAINER® Implementation

Recommendations

The SMARTCONTAINER® was designed with simplicity of operation in mind. Therefore, its implementation is particularly straightforward and requires very little modification to processes already in place. However, similar to other auto-id and RFID technological implementation, there exist certain pertinent choices that must be made before an implementation can be successful. Figure 11 shows three simple yet important considerations to take into account during the pre-implementation process. The three groups that are of interest are the business aspect, implementation situation and the criticality on the existing information technology (IT) infrastructure.

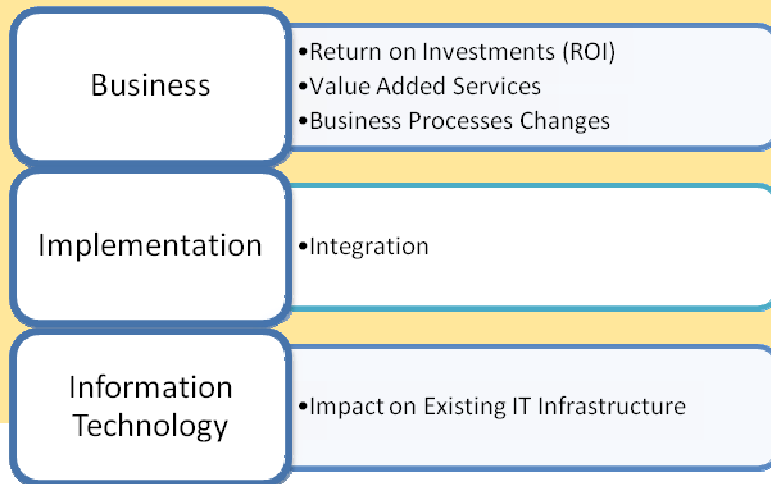


Figure 11: Pre-Implementation

When discussing the business aspect, ROI must be the reason for the use of this product and technology.

Besides ROI, the SMARTCONTAINER® also has the capability of expanding value added services that could be provided. Because of the modularity in its architecture, the value added services are endless and hence could cater to a huge variety of

customers. Business process changes must also be taken into account to ensure any successful implementation.

Next, any implementation must take into consideration the impact from an integration perspective. In a world where systems and systems integration are predominant, a key outlook on integration with the existing processes is highly desirable (if not compulsory). During such an analysis, one must consider the integration process and its extensibility, benefits and drawbacks to current processes in use.

Finally, the impact of the system on the existing IT infrastructure must be analyzed. This analysis will reduce many potential risks during and after the implementation that could prove painful and expensive.

Conclusion

Auto-id technologies have come a long way since their first use as a friend or foe system during World War II. Since then RFID has emerged as one of the fastest growing technologies. The growth in this field stems from the various capabilities that this technology provides. The most dominant role of this technology lies in its ability to track, trace and authenticate. OnAsset's SMARTCONTAINER® was invented to tackle the needs within the pharmaceutical and high value biological medication industries. Industries like these are in need of not just a technological breakthrough, but also a system level solution to the pedigree problem. The SMARTCONTAINER® will help these industries move ahead with their need for an “all-in-one” product, as it offers both a technological and system level solution. Because of its modularity, many tasks that are currently multi-process can be handled using a single product with a

modular architecture. On the other hand, the functionality and adaptability offered by the system level approach allows for upgrades and is open to future architectures as well as future technologies. This adaptability is a key design issue incorporated in the SMARTCONTAINER®.

About the Author

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OnAsset Intelligence

OnAsset Intelligence is an industry-leading innovator of unique, low-cost wireless products for today's dynamic global marketplace. Our goal is to offer adaptable products that serve industry requirements while still providing ease-of-use and a rapid return on your investment.

In today's business world you cannot afford to waste valuable time and resources on new technology that is difficult to use and integrate. OnAsset Intelligence has developed a unique product-oriented approach that centers around one key goal: Provide the customer with the best possible solution at the best possible price by using only what you need to get the job done, which is the basis for our global RFID interrogator platform Connect & Communicate.

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