Summary

Minimally invasive, pharmaceutical item-level serialization is an attractive option for manufacturers looking to incorporate RFID and security measures into their production process without affecting operational efficiency.

Background

Many pharmaceutical manufacturers placed their item-level serialization efforts on hold after numerous FDA-based and state-based ePedigree initiatives were delayed. The lack of solid requirements and misconceptions surrounding ePedigree technologies has left many manufacturers in a holding pattern. One of the common misconceptions pharmaceutical manufacturers have is that money could be saved by delaying the implementation of these technologies. Another is related to the maturity and stability of the radio frequency identification (RFID) components and systems. RFID technology has advanced tremendously in the last two years; the standards are high enough that the key components in a solution and interoperability between manufacturers can effectively be addressed. In reality, manufacturers are leaving money on the table by allowing their present processes to remain in place.

While there hasn’t been a clear definition of what the FDA or California, for instance, would require, implementation dates could continue to be pushed out as a result. One thing is clear: any initiative will include item-level serialization. The generally accepted methods for achieving item-level serialization are:

- Printed media-based 1D/2D barcode technology
- RFID technology
- Hybrid solutions, incorporating aspects and advantages of both technologies.
When it comes to the integration of an ePedigree solution a couple of key concepts must be considered. First, are you going to integrate the technology in order to comply, or are you going to keep advancing your complete supply chain and its overall visibility? In the former case, the first thing that springs to mind is that the manufacturing team will only do what is necessary to comply. In the latter case which accepts that the future will contain an element of item-level serialization, the thought becomes, “How can we realize some elements of what those technologies could provide, while also enabling the organization to lay a foundation for compliance in the future?” RFID technology enables pharmaceutical companies to make use of far more than compliance-based serialization.

Traditional methods for integrating RFID serialization can take days or even weeks to integrate into a manufacturing line, affecting production, causing validation issues and resulting in significant additional expenses to the manufacturer. However, there is a technique to integrating item-level serialization without disabling production lines: mobile serialization.

**Mobile Serialization**

At its core, mobile serialization is minimally invasive and provides the flexibility to process and program the finished/cased product at the end of the production line. In most pharmaceutical production environments the usual type of automation is fast, complex and often difficult to integrate. The mobile serialization process is based on the migration and movement of key products that need to become RFID enabled by using an RFID label or package that can be implemented using existing labeling or packaging systems, requiring little or no modification. By using a label supplier capable of producing RFID-enabled product labels, or packaging tested to meet performance needs, a manufacturer can use these solutions with confidence that the RFID component will operate with the final product.

Mobile serialization can be achieved by placing a highly adaptable station at the end of the line, which, with minimal intervention and setup, can accommodate a variety of packaging. Systems have been fielded that are capable of handling a range of products, from a 10 pack of 5cc vials to a case of 8-500 ml bottles. Being able to accommodate a wide variety of packaging forms, as well as make use of existing labeling equipment to apply smart RFID labels that are programmed at the end of the line, minimizes the impact to existing line operations.

A system such as this one can easily accommodate item-level and case-level presentation within the same physical configuration. The system’s ability to either program a single bottle of medication, or a case of 10 of the same or different product, allows the planning team to deal with a variety of production scenarios. In addition, the ability to provide visibility and traceability as to whether each case of a given product had 10 functioning uniquely programmed IDs after the case is sealed, further enhances confidence in the supply chain. When coupled with other overt and covert security features, a tamper-evident case of RFID enabled items (which were scanned after they were packed for shipping and can be confirmed by scanning upon receipt), produces a solution that is very difficult to corrupt. Some of the advantages to the mobile serialization approach include:
A single system moved from line to line, which can potentially cover all RFID demands (depending on RFID product volume)

- Production flexibility, achieved by continued use of the present, flexible, point-of-use printing for lot and date coding
- RFID inlays, which don’t require programming prior to or during their application on a high speed portion of the production line, potentially affecting cycle time
- Fewer concerns about factors surrounding the final packaging form than with full production line integration
- Synchronize production lot RFID programming with appropriate date code and lot information without the need to work with an RFID label integrator
- Significantly less management and parts tracking for both the supplier and production floor planning teams
- Realizing and recovering value stream opportunities on key products with a limited scope implementation, while increasing a team’s RFID expertise

As an organization begins to move ahead towards item-level serialization, what may initially seem to be inexpensive and the least complex method (2D) could in fact be more expensive and intricate. Consider the line validation effort required if those resources were used to validate a minimally invasive hybrid system capable of supporting both the 2D and RFID methods of serialization; the team will have accomplished much more.

In any attempt to improve the efficiency or visibility in an organization’s processes the team must have confidence in the technologies being proposed. Between 2007 and 2009, a lot of attention was being given to the federal and California ePedigree initiatives and manufacturers were claiming instability in RFID technology. In contrast, today’s RFID solutions are significantly more robust than even the best solutions being used during that period. Integrated RFID solutions are more readily available, better established and understood, cost-effective, and involve much less risk to an organization today when compared to even a few years ago. Stabilization in RFID technology allows an organization to consider the value an RFID solution might add to their complete manufacturing and supply chain, rather than just a traceability and ePedigree support component. This technology is now established and considered reliable in the pharmaceutical field, as it has been for a while in other highly regulated industries such as foreign material exclusion and control within nuclear power generation.

After a solution has begun to be implemented, further items to consider for their potential effect include:

- Efficiency-based supply chain opportunities - increased delivery accuracy empowered by comparing an order’s line items with the items which were being boxed or loaded
- Creation of advanced shipping notices containing what was actually scanned during the load operation
- Automated receipt and reconciliation of goods
- Product authenticity – based on the product and use case, a manufacturer could choose to protect their consumable products and implement a complete authentication scheme which ensures their product is used

**Beyond Serialization**

Recent studies have recorded significant reductions in the time required to complete an accurate inventory process. Whether this is in the retail product arena, counting of items in manufacturing WIP or controlling a critical process within a manufacturing facility, significant insight and savings can be realized with the empowerment of an RFID-based solution.

In addition to inventory visibility, the use of RFID has had a tremendous impact on data recording and reconciliation. In highly regulated environments, staff often manually record everything from yield, to inspection, to traceability information. The recording process alone can experience efficiency improvements, but when used in situations where the data is manually entered or reconciled, the accuracy and value increase exponentially.