

No Compromise Necessary

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

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Many pharmaceutical manufacturers placed their item-level serialisation efforts on hold after numerous FDA- 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 serialisation. The generally accepted methods for achieving item-level serialisation 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 that accepts that the future will contain an element of item-level serialisation, the thought becomes, "How can we realise some elements of what those technologies could provide, while also enabling the organisation to lay a foundation for compliance in the future?" RFID technology enables pharmaceutical companies to make use of far more than compliance-based serialisation.

Traditional methods for integrating RFID serialisation 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 serialisation without disabling production lines: mobile serialisation.

Mobile Serialisation

At its core, mobile serialisation is minimally invasive and provides the flexibility to process and programme 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 serialisation 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 labelling 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 serialisation 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

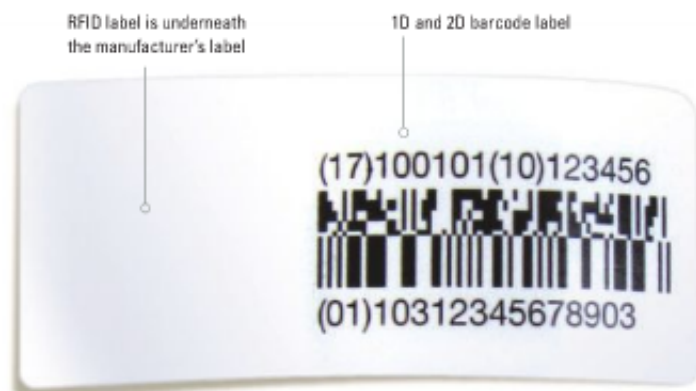




Image: Northern Age

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, minimises the impact to existing line operations.

Such a system can easily accommodate item-level and case-level presentation within the same physical configuration. The capability of the system to either programme 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 serialisation 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
- Synchronise 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 the production floor planning teams

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- Realising and recovering value stream opportunities on key products with a limited scope implementation, while increasing a team’s RFID expertise

As an organisation begins to move ahead towards item-level serialisation, 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 serialisation; the team will have accomplished much more.

In any attempt to improve the efficiency or visibility in an organisation’s processes, the team must have confidence in the technologies being proposed. Between 2007 and 2009, so much 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 organisation today when compared to even a few years ago. Stabilisation in RFID technology allows an organisation 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 Serialisation

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 realised with the empowerment of an RFID-based solution.

In addition to inventory visibility, the use of RFID has had a tremendous impact on the recording and reconciliation of data. In highly regulated environments, staff are often found manually recording 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.

About the Author



Rick Raber is Chief Technology Officer with Northern Apex Corporation, based at Fort Wayne, Indiana, US. Rick has been involved in successful manufacturing and field support systems design and

development for more than 20 years, including over 13 years of specific experience in complete RFID solution integration at Northern Apex. Rick’s experience with fielded solutions include the first UHF-based, RFID-enabled, item-level production line for bottles and case level reads. Rick’s style has led him to speak or contribute for many venues and environments, including serving as a subject matter expert for the US Congress on the use of RFID in the pharmaceutical supply chain. Email: rraber@northernapex.com