Are There Business Benefits to Serialization Beyond Compliance?

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This may seem a complex question to answer as you begin your serialization journey. It is difficult to look beyond the significant challenges that lie ahead in this undoubtedly complex project - initial funding and stakeholder engagement, vendor selection and delivery adherence, uncertainty in the regulatory environment and of course the numerous changes that will impact your packaging, warehousing and supply chain processes. However despite lots of challenges, serialization can deliver valuable business benefits to your organization. The core objectives of your organization’s serialization strategy are fundamentally to provide enhanced product security and thereby provide safe, unadulterated medicines to patients, whilst ensuring business continuity and safeguarding your right to continue to supply medicines that meet regulatory requirements.

Patient Safety

At the very heart of the legislative and regulatory processes driving the need to serialize medicines lies patient safety, too many tragic incidents have occurred and are still occurring whereby patients have suffered adverse effects and even death due to unknowingly being exposed to counterfeit medicines. A visit to the WHO website provides shocking statistics and documents just how lucrative the “business” of supplying counterfeit medicines is to the criminal gangs behind this practice. Serialization provides perhaps the most effective weapon the pharmaceutical industry has yet adopted to fight against counterfeiting and ultimately protect patient safety. Combined as part of your brand protection strategy, serialization, alongside your existing safety features, not only protects the patient but also from a business perspective protects your brand. Publicity associated with any incidents of counterfitting-counterfeiting creates a significant threat to even the strongest brand.
Reducing Recalls

Serialization has a significant impact on reducing the risk of product recalls from a labelling perspective which has traditionally been the biggest causal factor behind recalls. Errors can sometimes arise with artwork but also in cases of the printing of variable data (lot number, expiry date, manufacturing date etc.) which may, in rare instances, go undetected through the quality system internally, or which may occur due to fading/rubbing/loss of data due, for example, to faulty inks or carton quality, making it illegible as the product moves through the supply chain.

Generally serialization demands tighter in-process controls, documented risk mitigation strategies, enhanced technology, and tighter validation controls which all play their part is preventing recalls by increasing the likelihood of uncovering a labelling error whilst the product is still under your control. Typically when introducing a serialization program there will be increased focus on in-process checks at a packaging level, ensuring that defect levels are reduced. A detailed approach to validation of the printing & vision equipment associated with serialization should provide a series of robust challenges (print quality, readability & legibility, testing of the 2D code quality, similarity testing - where the vision system is challenged to detect between similar numbers & letters for example 6 & 8, 8 & 9, a, c & e etc).

In the event that a product is in the market and has to be recalled, with a serialized system in place, your organization will be able to respond much more rapidly to this situation. Timeliness is key in dealing with such events in order to protect the patient, demonstrate control of the supply chain and your quality management system procedures to the regulators, and ultimately limit the damage to the organization’s reputation.

Positive Impacts

The positive impacts of serialization will be felt right through your entire supply chain;

- Product shrinkages/ losses will be reduced due to much better product visibility as the product moves through the supply chain,
- Expiry date management will become much more efficient and stock write-offs can be minimized, meaning regular stock controls such as cycle counts can be performed with greater efficiency by utilizing the system generated data in the form of serialized numbers, enabling data to be reviewed with greater ease and at a frequency that suits the business, thus minimizing stock write-offs.

(Traditionally this may have been performed by manually counting stock),
- Sales forecasting accuracy will improve as more real time data flows into your supply chain. While serialization will not provide companies with any specific sales data that relates to patient confidential, as the product moves through the supply chain and touches various points (distributors, 3PL, warehouse, and finally is prescribed by pharmacies) greater visibility of product movements will become apparent which will enable smarter sales forecasting,

- Product diversion incidents whereby genuine product is fraudulently diverted to be sold in a different market than it was intended for will be greatly reduced with serialization. It is an aspiration of the global regulatory controls being implemented that diversion will be greatly reduced and even eliminated. Serialization makes it infinitely more difficult for the people behind diversion activities to move product between markets,

- Inventory management of both finished goods and consumables, e.g. inks, wrapping materials, cardboard and pallets, will be enhanced.

Seek Improvements

As you embrace the changes that serialization brings on site, seek process improvements, particularly at an equipment level on your packaging line - fix things that need to be fixed, engage with operators and technicians, listen to their feedback, involve a wide team of people and communicate well and frequently. Don’t just view serialization as an “add on” to your existing process - challenge the status quo, encourage innovation, think about how things can be improved, become leaner and smarter. Greater automation & data management associated with serialization equipment have allowed companies to use this information to save time on line changeovers by utilizing the automatically generated data as opposed to having to perform manual counts. Many companies have utilized this additional focus on their packaging function to implement 5S & other lean tools, as it provides an opportunity to take a holistic view of your production area and implement improvements. There are several teams that should be considered part of any serialization plan. At a site and packaging level, personnel from Supply Chain, Production, Automation, Engineering, IT, Quality and Regulatory Affairs will all be impacted by the introduction of serialization.

Serialization provides a great many challenges to even the most dynamic organizations but it also provides opportunities, particularly in terms of colleague engagement and team working - from a cultural perspective this can lead to a behavioral and mind set change. Fundamentally serialization is a mandatory, or soon to be mandatory requirement in most of the world’s biggest markets. The message is simple, to continue doing business, you must comply. At the core of this is patient safety- arguably the biggest business benefit of all to be gained from serialization.
About ESP

Enterprise System Partners (ESP) is a leading global consulting and project engineering company - supporting manufacturing IT solutions for the life science industry since 2003.

We offer specialist support and consulting services exclusively for manufacturing and supply chain operations in biotechnology, pharmaceutical and medical devices, with core focus on Manufacturing Execution Systems (MES) and serialization.

ESP has a unique blend of knowledge specialists from level 0 to level 4 and across the supply chain. This gives us a distinct advantage in the delivery of serialization solutions.

We have worked with many of the early adopters within the life science industry, developing and executing their serialization strategies so they are internationally compliant for the future.

Contact us to discuss how we can assist you in reaching your local and global obligations and optimizing your serialization strategy.

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About The Author

Yvonne is a highly experienced pharmaceutical and biotechnology professional with specialist knowledge of packaging and GMP systems. She has worked for leading global companies and delivered results in areas such as project management, packaging hall design, process development, packaging validation, operations management, lean six sigma, implementing 2D coding and serialization on packaging lines.