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PHARMACEUTICAL SERIALIZATION

The End of the Beginning—Moving Beyond Compliance

Over ten years ago, the pharmaceutical industry embarked on a journey. One that was intended to protect the global pharmaceutical supply chain. An effort still in progress, founded on high aspirations, but falling short of the end goal—to protect people from the dangers of pharmaceutical counterfeiting.

This journey set in motion an initiative driven by regulators and other stakeholders that sent the industry on a firefighting mission of sorts—one fueled by smoldering suspicions of patient peril, damaged company reputation, compromised brand integrity and stolen profits by counterfeiters. The initiative was ignited by various issues and forms of outcry such as counterfeit prevalence estimates from the World Health Organization, Interpol press releases on the profitability of "bad actors" and most notably by the book *Dangerous Doses* which shed light into the dark corners of the pharma supply chain for allowing less than acceptable trading practices.

The much thought about and debated answer to these issues was implementing serialization to give each and every drug package its own unique identifier. But the reality is, serialization is not a global solution but a local one. In other words, individual geographies around the world mandated specific serialized labeling requirements for medicines to be distributed in THEIR country/countries only.

This has most certainly not been a globally consolidated and consistent effort. Generally, the process requires placing a product code (NDC, GTIN or similar), serial number, lot number and expiration date in both machine-readable and human-readable format onto pharmaceutical packages. Each geography that has introduced serialization has required something similar but in each case different.

Mission Accomplished?

The industry seems poised to step up onto the first plateau of their mountain climb to the summit—compliance towards unique product identification. This part of the journey was certainly a Herculean task given the level set required for subject matter expertise, problem identification, standards development and the enablement of resources. However, just as the industry gets ready to raise their arms in a "V" for an initial victory and accomplishment, we all need to step back and ask the question: What has truly been accomplished?

Having multiple formats and disparate guidelines transformed pharmaceutical serialization from an anti-counterfeiting and patient protection initiative into a "compliance" mandate for manufacturers. More than that, the counterfeiters out there quickly realized that:

- These systems are not globally integrated
- Copying and fabricating serialized barcodes is easy
- There are plenty of geographies around the world with no serialization requirements whatsoever.

A shortcoming is best highlighted at this juncture. In order to achieve compliance, the industry has lost sight of the issues that put this dedicated effort in motion. The regulatory requirements that have driven serialization enablement to this point are mainly directed at the United States and the European Union—two of the safest and most secure pharmaceutical supply chain markets in the world. Meanwhile bad actors remain unchallenged in areas such as counterfeiting and product diversion that the industry sought to thwart. These threats continue to endanger patient safety, damage company reputation/brand integrity and steal industry profits.

Intrinsic Value from Serialization: Efficiency of Internal Operations

Under batch production methodology, the reconciliation of physical product information and the associated data record is a complex and often impossible practice.

The process of moving towards item-level traceability through serialization enforces data integrity through a series of strict process rules and adherence. Serialization provides manufacturers with the potential to gain improved visibility and control over internal operations, leading to efficiencies that can generate significant cost savings.

Addressing Inventory Leakage

A multitude of factors impact leakage as products move from manufacturing to packaging and on to shipment—these include labeling issues, quality sampling, human error and employee theft. Under batch packaging, reconciliation of production and shipped product is an arduous and often impossible task.

The process of creating product identity through serialization offers manufacturers a means of tracing a product's journey through each stage of the packaging process and internal movement. In capturing this information, manufacturers can gain the requisite insight to quantify the root causes of product leakage. Once these causes have been identified corrective action can be taken.

Automating Inventory Control

The automated inspection and verification that forms parts of the serialization process allows manufacturers the ability to reduce—if not eliminate—the need for manual counting and data entry. Thereby, driving a higher level of accuracy and timeliness in inventory reporting and reconciliation.

Print and Template Management

Mislabeling is a common cause of product recalls. Printer management and inspection as part of the serialization process allows manufacturers to ensure that each product is appropriately labeled.

Managing Packaging Assets

Data collected through serialization can be utilized to accurately capture and manage the economy, efficiency and capacity of different packaging lines' internal and outsourced assets. In addition, the overall equipment effectiveness (OEE) can be monitored with a much greater level of accuracy by using the serialized data for root cause analysis.

Post Serialization: Product Identity Challenges

Serialization was introduced by governments as a mechanism to protect the pharmaceutical supply chain. Whether it actually does, is up for debate. While there is little doubt that serializing each salable unit of medications will be a good thing overall, will it truly end global counterfeiting and supply chain diversion? That answer is likely “no”. But is there a way to leverage this significant investment for greater value and protection?

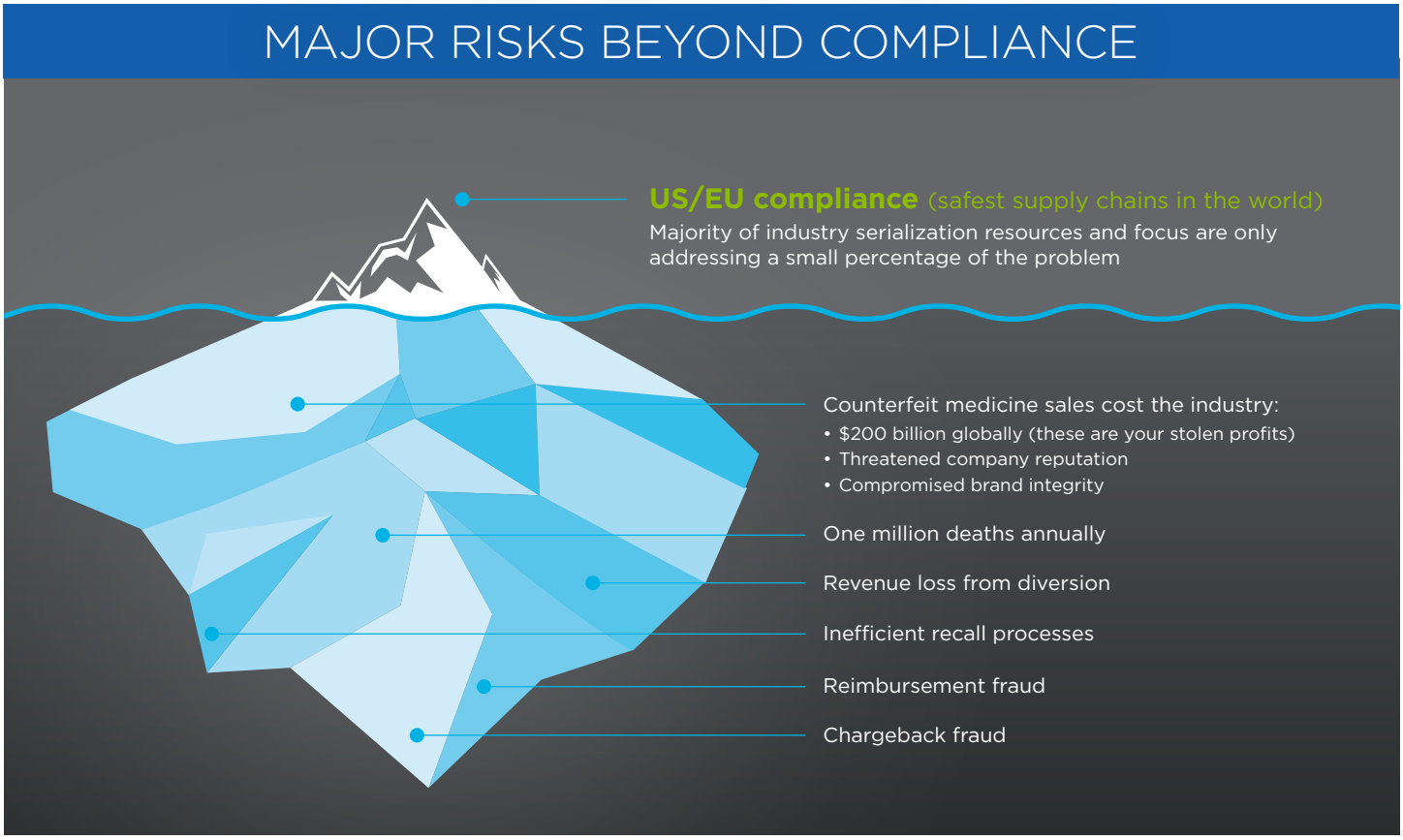
Serialized barcodes are easily copied. There is comprehensive data contained in serialized 2D barcodes that when scanned can be used to find much more pertinent product information. Unfortunately, counterfeited products with a replicated barcode read the same and provide the same information as the legitimate item.

If we look at the EU Falsified Medicines Directive, for example, it utilizes a “bookend” model for drug authentication. First, each drug is identified with its product code and serial number and commissioned upon packaging. These numbers are communicated to a central repository or “hub” for storage. The medication then passes through the supply chain without ever being scanned. Then it is scanned upon dispense to the patient. This is bookend authentication.

If a counterfeiter obtains, then replicates, a legitimate serialized barcode that is already in the central hub, they will have a fake product that completely mimics the legitimate product when scanned. Meaning, if they inject their counterfeit product into the legitimate supply chain, and the counterfeit is scanned before the legitimate product, it will be authenticated as legitimate. Subsequently, when the legitimate product comes through later and is scanned, it will be recognized as “dispensed” and flagged for investigation and removal.

Additive and overt mechanisms like foils, seals and holograms are also easily available to counterfeiters. With the profit margins seen in the counterfeit industry, along with the innovations and cost reductions in commercial printing technology, counterfeiters have an easy time of making their illegitimate products look legitimate.

This is especially true in markets where there is no serialization mandate. No serialization equals minimized focus on regional pharmaceutical supply chain security and safety.



Establishing Individual Product Identity Goes Beyond Compliance

As with human identity, the concept of product identity relates to the combination of characteristics that make one product uniquely recognizable over another. Establishing a product's identity involves the collection of multiple data points throughout its lifecycle to render it unique. The shift towards item-level traceability coupled with the development of intelligent consumer interfaces and smartphone technology offers manufacturers the opportunity to drive competitive differentiation from the personification of their products.

Initial industry investment in establishing product identity has been largely driven from a defensive perspective—in response to consumer safety issues or concerns about brand protection. While the value created by product identity varies by industry and brand, it goes far beyond this defensive positioning.

Product identity can be used to solve real business problems and offer tangible returns through cost reduction, revenue protection and revenue generation. It is important to consider the totality of these benefits when determining the value of product identity to a given brand owner.

Identity Simplified: Maximizing the Serialization Investment

Earlier this question was posed: “Is there a way to leverage this significant investment for greater value and protection?” The answer is yes. Pharmaceutical companies can leverage what already exists on their drug packages—serialized 2D barcodes—to derive a unique digital identifier (e-Fingerprint®) for every product that can be used for item authentication.

But how? The printing process is a dynamic. There are environmental factors such as line speed, humidity and substrate that create micro-differentiations in printed output. For example, you may have one million of the same printed UPC barcode on a product. With e-Fingerprinting technology, you can individually identify each and every product uniquely.

In theory, serialization gives us uniquely identified products. But innovative solutions like e-Fingerprinting can help truly accomplish what regulatory bodies set out to do with serialization. That is, give each drug package a unique digital identity that can be used to confirm product authenticity, combat counterfeiting and prevent product diversion.

This approach leverages the power of smartphones and mobile networks to image the barcodes wherever the package is in the world, and uses it to authenticate that product immediately. With e-Fingerprinting, the product becomes instantly “connected”to the Internet of Things. The non-additive nature of this technology also represents a substantial cost saving on capital purchase, artwork redesign and change management as compared to additive solutions like RFID.

Does this mean you have to authenticate every item individually throughout the supply chain? Obviously, that wouldn’t be a scalable solution. The good news is, pharma companies can mirror what many are already doing with serialized product—use aggregation. Individual e-Fingerprinted items can be placed and scanned into a case, which is also e-Fingerprinted. Multiple cases can be packed onto a pallet, which gets e-Fingerprinted as well. Now, one authenticated scan of the pallet label is an authentication event for all cases and “eaches” on that pallet. This makes supply chain traceability and authentication simple.

Digitally e-Fingerprinting barcodes on pharmaceuticals establishes serialization-like uniqueness and individuality—totally secure and impossible to replicate. This might be the answer for brands fighting counterfeit goods and product diversion in minimally regulated markets.

SERIALIZATION VS. E-FINGERPRINTING

Serialization

- Does not provide visibility down stream in the supply chain
- UPI transfer data is not accessible, not owned
- Barcodes can be manipulated
- Has required a large investment
- Can't provide an authenticity check in the field

Digital e-Fingerprinting

- Provides visibility to the patient level
- Data is accessible because it's owned by the manufacturer
- Cannot be replicated or reverse engineered
- Requires a much smaller investment
- Confirms authenticity with a simple smartphone app

Enabling the Future of Serialization

Serialization is definitely at the forefront of improving the most granular track and trace you can have—the individual item level. Global regulatory mandates all have different flavors of data integration requirements that have tracking capabilities built in. So, having corporate repositories of serialized product information and even government hubs of serialized data are transforming the pharmaceutical supply chain.

But again, the integrity and security of the entire integrated serialization ecosystem are reliant upon a printed barcode that is so easy to replicate which fuels counterfeited and diverted products in the supply chain. Why not leverage an extra—yet non-additive—layer of security? What if you could use existing packaging and labels to create a solution that helps fight counterfeiting and product diversion? Just imagine the intriguing possibilities when you turn the that serialized barcode into a robust digital e-Fingerprint, adding value well beyond basic serialization compliance.

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