Pharma Serialization: Regulations Summary

“By 2018, over 40 countries and more than 75% of global medicine supply will be covered by one or more serialization track and trace regulations”, according to few reports.

Bio/pharma players have to postulate with challenges halting from supply chain security which goes by (product recalls, diversion) counterfeiting and rigidly accurate regulations. Moreover apprehension of safety pertains; these challenges also vitiate the health of the drug industry by adversely hitting brand believability and research go-aheads of the companies or industry as a whole.

Both the biopharma players and regulatory bodies recognizing the importance of implementing product serialization, makes it compulsory for all companies within the pharmaceutical supply chain to abide by legislations concerning to the locations in which they function.

Seeing secure product track and trace capabilities through various lines along the supply chain process-medicine product serialization implementation is all important to deal the challenges confronted by industry. Apart from furnishing quality, visibility and complete traceability within the supply chain, successful serialization programs will be a key differentiator and a clear competitive reward for bio-pharma companies.

Serialization is both global and highly local, creating diversity in companies need to plan for operational process and IT architectures.

- Coding requirements [2D vs. linear, GTIN vs. NTIN, different data ordering on package, etc.]
- Serialization formats [GS1, China EDMC, Brazil IUM, etc.]
- Sources of serial numbers [Pharmaceutical company, Government (China)]
- Serial number generation attributes [Randomized vs Sequential, 1 in 10,000 Uniqueness, Uniqueness Across All Products]
- Packaging hierarchies, aggregation [Unit, Bundle, Case/Transport Container]
- Master data [Company, Partner, Product]
- Record retention [6 yrs. Past expiry, 1 yr. past expiry]

Typically thinking, regulations require each product package be labeled with an unique serial number, as well as other details such as:

- Batch Numbers
- Lot Numbers
- Country Registration code
- Product Expiration Date

Specific requirements for presenting this information vary from country to country.
The fashion in which serialization is enforced has the potential to be very tumultuous.

Smaller contract manufacturing organizations (CMO) may not be able to bear the serialization implementation cost while those bio or pharma companies that are willing to confront some of the costs to their CMOs may resolve to focus their investment in just a few packagers. The result is likely to be that many smaller CMOs will find themselves out of the packaging business and potentially be displaced of business altogether.

Meeting serialization track and trace regulations not just make your facility ready but also link or align with your diverse supply network – contract manufacturers, wholesalers, retailers and regulatory agencies.

Other countries have followed suit, doing great steps in the fight against counterfeit medicines; Includes China, South Korea, France, and Turkey have enforced some type of serialization program in the past few years.

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