

## Dec Group White Paper shows how effective aggregation can maximize serialization benefits

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Dec (Dietrich Engineering Consultants) Group, the leading global provider of contained material handling systems, has produced a White Paper guide on effective serialization strategies for pharmaceutical producers.

The White Paper *Leveraging Serialization Investments with Aggregation* is published as a response to increased regulation but also shows there are powerful benefits to comprehensive aggregation strategies. These include enhanced supply chain efficiencies, traceability, control in production and distribution and easier compliance.

### **Combating counterfeiting**

Traceability has become a keyword for the pharmaceutical industry over recent years, with serialization as the enabling concept in providing each individual product with a unique identity in data, including manufacturing source, Global Trade Identification number (GTIN) and expiration date. This is the most effective counter-measure to counterfeiting, which now accounts for more than 10% of all medicines in circulation according to the American Food and Drug Administration (FDA). Accordingly, all EU-based organizations producing or distributing pharmaceutical products are now required to apply serialization in accordance with the Falsified Medicines Directive 2011/62/EU (FMD), keeping step with North America where the Drug Quality and Security Act (DQSA) has made serialization obligatory within the pharmaceutical supply chain in the USA and the newer Drug Supply Chain Security Act (DSCSA) will require full unit level traceability, including not only serialization but also aggregation by 2023.

### **Aggregation: logical next step**

The Dec White Paper presents aggregation – linking individual products to their secondary and even tertiary packaging – as the logical next step in the move to full serialization and traceability. It presents the ‘what, why, where, who, when and how’ of aggregation in theory and practice.

The White Paper covers:

- **Basic Principles of Aggregation:** creating parent-child relationships between primary, secondary and tertiary packaging levels, all interlinked in metadata to make the whole supply chain visible.
- **Global requirements for Aggregation:** showing how the impetus towards full aggregation is extending worldwide
- **Benefits:** implications of effective aggregation for GxP compliance and smarter small batch production
- **Timing and implementation:** the benefits of early adoption and technological solutions
- **Impact of Aggregation:** The business opportunities that aggregation opens up for individual businesses

The White Paper concludes that although regulation focuses on serialization, aggregation is actually the more important concept in both enabling full traceability and also in vastly increasing efficiencies along the whole pharmaceutical supply chain.

White paper available under the login section