



## Learning UDI Community Work Group Summary Statement

### **WORK GROUP TOPIC: UDI Single Use Device (SUD) Packaging Exception and Distributor Low Unit of Measure Programs**

The work group will explore cost effective and sustainable solutions around labeling at the lowest unit of measure/unit of use —where technically feasible—devices that meet the UDI final rule’s SUD packaging exception.

#### **WHY THIS TOPIC IS IMPORTANT:**

The FDA’s final rule establishing a unique device identification system created a packaging exception wherein all classes of individual SUDs that are distributed together in a package and intended to be stored in that package until use do not need a UDI on the individual device itself. Rather, the UDI can go on the next higher level of packaging. The SUD expectation does not take into consideration the role of healthcare distributors in the supply chain, as many distributors operate low unit of measure (LUM) and just in time (JIT) program where SUDs are broken down to less than “inner pack/package” quantities and delivered directly to patient care areas, minimizing hospital labor involvement in inventory processing.

The FDA requires a UDI at every level of packaging except shipping containers; however, the individual or “each” devices within the “inner pack/package” that meet the SUD exception are mostly exempt from having an individual UDI label because they are assumed to be distributed together in the “inner pack/package” to the healthcare provider.

#### **AFFECTED/REQUIRED STAKEHOLDERS:**

The FDA’s final UDI rule affords manufacturers the option of using the SUD UDI labeling exception (i.e., rather than labeling each device within the package of a SUD, a manufacturer may choose to place the UDI label on the higher level of packaging as long as the devices within the package remain in the package until removed for use, and which are not intended for individual commercial distribution). Its existence is problematic in many cases for distributors, as it does not take into consideration the role of distributors and the value add services distributors provide (i.e., LUM/JIT programs) on behalf of their provider customers who expect certain SUDs to be broken down to the “each”.

#### **EXPECTED OUTCOMES/DELIVERABLES OF THE WORK GROUP:**

Part of the impetus behind the FDA’s Class II compliance deadline extension is to afford distributors, manufacturers and other supply chain partners time to develop best practices around UDI compliance and its impact on distributor LUM/JIT practices.

#### **PROPOSED TIMEFRAME TO DELIVERABLES:**

Spring 2017

#### **INDIVIDUALS PROPOSING TOPIC:**

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