

# RSQM Associates UDI Implementation Consultation Services One-Day UDI Training Workshop

#### **Background:**

FDA's new UDI regulation will have a significant impact to medical device labelers now and in the future. This outline of consultation programs addresses how RSQM Associates can help medical device labelers meet this new requirement and why it should be viewed as an opportunity to help increase revenues, decrease costs and greatly improve their Master Data Management capabilities.

#### **Program 1: One-Day UDI Training Workshop**

Many companies do not understand UDI and its implications for their business. This workshop will educate the attendees on UDI and outline the steps they will need to take to be compliant. It will include:

- An understanding of FDA UDI and how it will impact the company now and in future
- · An understanding why the company should implement UDI sooner than later
- The data elements required to be compliant with UDI and strategies for obtaining and managing
- What steps are needed to perform gap analysis
- Assessment of current capabilities (based on questionnaire completed prior to Workshop)
- The barcode format company should use and impact on current packaging
- Understanding what information/processes/systems need to be validated
- Determination what SOPs will need to be updated to fully comply
- Identify 3<sup>rd</sup> Party to provide Data Synchronization services to GUDID (if required)

## We have the experience...

RSQM has many years experience implementing unique identification systems - from UPC to GTINs. From project management to project design. From analysis to strategic planning.

### Contact us **TODAY** to for your quote on our One-Day UDI Training Workshop!

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<sup>&</sup>quot;Your success in life isn't based on your ability to simply change. It is based on your ability to change faster than your competition, customers and business."