



RSQM Associates UDI Implementation Consultation Services UDI Implementation Management

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.

Programs Outline:

The objective of these programs are to provide our client with several "programs" they can choose from as they endeavor to implement UDI. All of the "programs" except the One-Day Workshop, require meetings and buy-in from Top Management (President/CEO). If Top Management does not buy-in and understand both the benefits of complying and pit-falls for failing to comply, then I would recommend that we do not proceed with this particular company. There are many steps involved in a manufacturer/labeler becoming compliant with the FDA UDI regulation. Therefore, the programs take into consideration the resources a company may have internally to implement this new regulation.

Program 3: UDI Implementation Management

This is for the company that has already performed their own GAP Analysis. If upon review of the analysis, we concur, then this offering would be to oversee and manage the implementation process. It would include the following:

- Identify UDI Champion and Implementation Team within organization.
- Create strategic plan (in conjunction with Implementation Team) and schedule (details, budgets, assignments, partners) to:
 - Address needs in PLM/ERP (based on required GUDID attributes) and supply chain systems, labeling/packaging equipment and procedures, and labels/packaging
 - Define gateway to GUDID
 - Create validation and compliance plans of action
- Identify 3rd Party to provide Data Synchronization services to GUDID (if required)
- Amend label/packaging composition and components; order to be in place and validated by compliance date
- Compose, establish, administer and validate software system changes and integrations
- Acquire new or upgrade existing labeling and packaging equipment and validate
- Rehearse connectivity with GUDID and validate all systems are functioning correctly
- Create/revise SOPs as needed and conduct process validation
- Create training programs for UDI implementation
- Create plan for post-implementation follow-through

(over)



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 for your quote on our UDI Implementation program!

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“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.”

- Mark Sanborn