RSQM Associates, LLC
Regulatory, Quality & System Management Consultants

RSQM Associates UDI Implementation Consultation Services

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 5: UDI GAP Analysis, Recommendation, Implementation Management and Post-Implementation Follow-through

The first step is to determine what a manufacturer/labeler will be required to implement to be compliant with the UDI regulation. A full analysis to determine shortfalls between UDI obligations and current systems will be done including the following:
- ERP/Computer System – Does it have the ability to store UDI, use UDI in documents (sales orders, purchase orders, EDI transactions, etc.)? Does it have the ability to record device class and other regulatory information?
- Labeling/Packaging Equipment capabilities – Do they have the ability to print UDI labels?
- Impact to current Quality Management System
- Supply Chain (customers and suppliers)
- Timelines – Based on product Class(es), what are the timelines they need to meet?

Written recommendations will be provided detailing the above and outlining the next steps and an estimated budget that will be needed in order to be compliant.

Once the Gap Analysis has been completed, the next steps would be to oversee and manage the implementation and post-implementation follow-through processes. 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
- Supervise transition to manufacturing of the first run of each product
- Coalesce UDI requisites into product development process and new models/versions of current products
- List new product and new models/versions of current products with GUDID
- Continual training of UDI requirements

This is an ongoing commitment to the customer to provide ongoing services on a project management/retainer basis.

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 Gap Analysis, Recommendation, and Post-Implementation Follow-through program!

Phone – 617-356-7776
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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