ID #	Task	Dept./Person Responsible	Date Due	Comments
1	Identify UDI Project Team Members & Roles			
2	Create Quality Plan for UDI Implementation, identifying scope of project, risk assessment, documents requiring revisions and timelines			
3	Select FDA-accredited Issuing Agency • Become member & receive Company Prefix			
4	Assign numbers i.e. trade items, legal entities, locations			
5	Establish a regulatory contact, at least one GUDID coordinator, and at least one GUDID labeler data entry (LDE) user[1]			
6	Request a GUDID account[2]			
7	Verify company information listed in Dun & Bradstreet database is correct			
8	Identify GUDID data attributes[3]			
9	Gather data required for GUDID records[4]			
10	Determine FDA 21 CFR requirements applicable to your devices			
11	Perform gap analysis between FDA requirements and your quality system, including labeling, product classification and UDI requirements			
12	Determine method for uploading data to the GUDID: • web interface • internal SPL HL7 • third-party submission[5] *If SPL HL7, establish an FDA ESG account and complete required testing[6]*			

ID #	Task	Dept./Person Responsible	Date Due	Comments
13	Review label printing system to determine ability to accommodate UDI requirements • In-house • Suppliers			
14	Select printing process for labels i.e. Pre-printed label stock, on-demand printing, color, inline, direct on package			
15	Select a barcode format and design the barcode for product and package labels			
16	Design/redesign label templates to incorporate UDI barcode and other label elements as identified in gap analysis			
17	Select and procure barcode verification system (based on determination of need)			
18	Perform validation of labeling and barcode verifier systems			
19	Update quality system documents to support UDI implementation, including procedures for ongoing maintenance of GUDID data • see UDI-4002, QMS & Documentation Considerations handout			
20	Schedule internal audit review of UDI processes			
21	Cleanse & verify GUDID data			
22	Verify/validate the UDI submission process (protocol, execution report)			
23	Confirm implementation readiness per quality plan			
24	Submit data to GUDID			
25	Communicate Device Identifier information to customers			

RESOURCES:

1 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf

2 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/ucm416113.htm

3 GUDID Data Elements Reference Table

4 UDI-4001, GUDID Master Data Template

5 http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396841.pdf

6 http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm2005551.htm