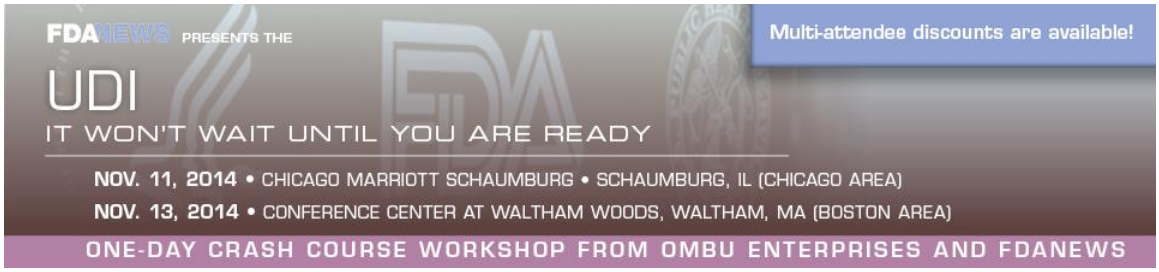

Agenda

8:00 a.m. – 9:00 a.m. **Registration and Continental Breakfast**

9:00 a.m. – 10:15 a.m. Part A – Overview of the UDI Rule

- Distinguishing among Identification, Tracking, and Tracing
- The elements of the system: UDI and GUDID
- Determining applicability
- Determining compliance dates
- UDI locations: device, label, and package
- The GUDID and its data elements
- The required organizational structure
- Loading the data into GUDID
- Change control (when you need a new DI)
- Exercise – Participants review cases to determine if a change requires a new device identifier

10:15 a.m. – 10:30 a.m. **Break**

10:30 a.m. – 12:00 p.m. Device, Label, & Package UDI

- UDI = DI + PI
- Compliance Dates
- Direct Marking
- Device Label
- Package Configurations
- Accredited Issuing Agencies
- UDI Specification by Issuing Agency
- Exercise – Participants review cases to determine the compliance date
- Exercise – Participants apply the packaging configuration rules

12:00 p.m. – 1:00 p.m. **Lunch**

1:00 p.m. – 2:30 p.m. Populating the GUDID

- The GUDID Data Elements
- The organizational structure for GUDID maintenance
- The technical methods for GUDID data loading
- Exercise – Participants determine some GUDID data for example cases
- Exercise – Participants develop GUDID data for one of their own devices

2:30 p.m. – 2:45 p.m. **Break**

2:45 p.m. – 4:00 p.m. Updating the QMS

- Quality System Regulation
- Medical Device Reports
- Corrections and Removals
- Record Retention
- FDA Inspections
- Related Issues
    - 510(k)
    - eMDR