AGENDA

10:00 a.m. – 10:15 a.m. - Welcome and Introduction
Dan O'Leary, President, Ombu Enterprises LLC

10:15 a.m. – 11:00 a.m. - FDA Spotlight Presentation: Understanding the UDI Final Rule and Its Impact on Devicemakers
Now that the FDA has published its final rule for mandatory unique device identification, device manufacturers have 1-5 years, depending on device class, to implement this system. While monitoring and tracking of devices will be easier, planning, executing and implementing a compliant system is still a challenge. Join Jay Crowley, the FDA's point person on the UDI rule, as he discusses the FDA's perspective on the regulation and required elements and standards. Mr. Crowley will reserve a portion of his presentation to answer attendees specific questions.

Attendees will learn:

- First-hand updates on the rule and an understanding of the compliance expectations
- Best practices for implementing a compliant UDI system within your organization

Jay Crowley, Senior Advisor for Patient Safety, CDRH, FDA

11:00 a.m. – 11:45 a.m. - HL7 Standards for UDI Across the World: How to Ensure You Comply
The good news is that there are now clearer standards for UDI submission. The challenge is understanding and implementing them. This session will provide insights on Structured Product Labeling, Common Product Models and other related HL7 standards for FDA submissions, including Individual Case Safety Reports used for eMDR, and Regulated Product Submissions used for electronic market authorization submission and approval. Compiling data on each of a devicemaker's products will require a substantial investment in data management and SOPs that create consistent data management practices. However, if the proper SOPs and practices are not in place, databases could become confusing and sloppy.

Attendees will learn:

- How data entry and exchange are being harmonized across the world
- The global standards required for data entry and exchange
- The four standards set by HL7 and the interrelationship between them

- How to use these standards to implement a system for data entry into the UDI database

Jackie Rae Elkin, Global Process Owner, Medtronic

11:45 a.m. – 12:30 p.m. - Break

12:30 p.m. – 1:15 p.m. - UDI in Medical Facilities — Improving Recall Management
Medical facilities that fail to improve their recall programs under the new UDI rule face new nightmare patient scenarios. Example: Several hospitals in Hong Kong took two weeks to find 30 patients affected by a recall of a hip replacement treatment program. It's a growing problem for domestic medical facilities, too. Hospitals often have to rely upon recall databases using multiple numbering systems to identify products, making it difficult to match devices to patients. Many medical facilities devote far more compliance time to drugs, sometimes at the expense of device recall programs. However, as medical device options proliferate and more devices are used in invasive procedures, risks for patient safety using faulty devices increase. Implementation of UDI will allow providers to know the unique identity and location of any device in their systems and successfully remove them before they are used in patient care.

Attendees will learn:

- Clinical information system changes needed to accommodate the UDI
- Business system changes needed between providers and suppliers
- Internal business system processes needed
- Major operational challenges facing hospitals with UDI implementation

Rosalind Parkinson, Chief Supply Chain Officer, The Ohio State University, Wexner Medical Center

1:15 p.m. – 2:15 p.m. – Lunch

2:15 p.m. – 3:00 p.m. - Practical Implementation Issues for Manufacturers
Manufacturers will face some new, complex issues in implementing UDI. This presentation explains the issues by identifying three essential implementation elements: QMS changes, device changes and submission changes. QMS changes will require changes in procedures required by FDA regulations. In addition to the explicit changes, there are other sections that make changes, e.g., a potential addition to the Design History File. In addition, there are implicit changes, such as designating individuals for roles and training. The QMS will also need new criteria to determine when a design change creates a new version or model, therefore requiring a new UDI. Device changes include the three types of UDI: direct marking, label and package. The presentation addresses the compliance dates, mandatory and optional elements, and GUDID data elements. Submission changes raise the issue of a new 510(k) submission resulting from the UDI. The presentation analyzes the requirement based on the current 510(k) guidance.

Attendees will learn:

- The two elements of the system: UDI and GUDID
- Determining applicability
- Determining compliance dates
- UDI locations: direct marking, labels and packages
- The GUDID
    - Data elements
    - The contact person
    - Providing the data
- Impact on procedures, work instructions and training
- Change control (version or model)
- Revisions to internal quality audits
- Revisions to management review

Dan O'Leary, President, Ombu Enterprises LLC

3:00 p.m. – 3:45 p.m. - Understanding What GUDID Really Is and How It Will Control Your Life for the Next Few Years

The Global Unique Device Identification Database, aka, the GUDID, is the master repository of device information for devices marketed in the USA. The GUDID will contain Device Identifier (DI) information only and other company information but will not contain the Product Identifier (PI) information that makes up the second part of the UDI (UDI = DI + PI). FDA is focused on maintaining high quality standards for the data entered into the GUDID and this will mean increased resources to meet these standards.

Attendees will learn:

- The tools for gathering all the information needed set up a GUDID Account, enter company data and to enter Device Information.
- The two methods of entering data into the GUDID
- The "Part 11" trap of HL7 SPL

Donald Guthner, Principal, Orgenix, LLC

3:45 p.m. – 4:00 p.m. - Closing Remarks