Agenda

Day 1

12:00 p.m. – 1:00 p.m. **Registration**

1:00 p.m. – 1:15 p.m. **Welcome and Introduction by Chairperson**

1:15 p.m. – 2:00 p.m. **FDA's 2020 Medical Device Regulation Agenda: CDRH's Priorities**

Are you addressing CDRH's top strategic priorities for FY 2020 head on? If not, your devices might be left behind.

This session will enable you to get ahead of your competition:

- CDRH reorganization — what it means for your devices and processes
- Comparing QSR v. ISO13485:2016
- Get ready for new software validation guidance documents
- How to address moving to a risk-based inspections approach — and what inputs will influence your results
- MDSAP program — what it means for your processes
- The truth about FDA's new shipment examination program at ports of entry

2:00 p.m. – 2:45 p.m. **Implementing the Clinical Evaluation or Performance Evaluation Process**

Do you know the ins and outs of the clinical evaluation system (EU-MDR) and performance evaluation system (EU-IVDR) requirements? If you're looking to obtain a CE Mark, this presentation is a must.

Gain the tools you need to ensure success:

- Secrets of the new requirements for clinical and performance evaluation
- How to prepare your documents to meet the notified body's (NBs) requirements
- Using the NBs review process to your advantage
- The best way to respond to issues raised by the NBs

- When it benefits you *not* to perform a clinical evaluation or performance evaluation — and how to document and present that decision

2:45 p.m. – 3:15 p.m. **Refreshment Break**

3:15 p.m. – 4:45 p.m. **Panel Discussion: EU-MDR & IVDR QMS**

Is your quality management system foolproof? While the new EU regulations require a quality management system with significant extensions from ISO 13485:2016, chances are it only partially covers the regulation's requirements. In some cases, ISO 13485:2016 might not cover *any* of the requirements. Where does yours fall? Are you compliant?

Attend this session to discover:

- Takeaways of the tools, methods and checklists you must have to implement an effective and compliant quality management system
- The areas where ISO 13486:2016 does not meet the requirements of the regulations — and how to close the gaps using CEN/TR 17223:2018

4:45 p.m. – 5:30 p.m. **Impact of New Economic Operators on You, the Manufacturer**

The EU-MDR has six types of economic operators and the EU-IVDR has four — each with specific and well-defined requirements in their relationship with you, the U.S. device manufacturer. Understanding the specialized roles of each economic operator is vital, while ensuring economic operators' accountability is key to compliance — and key to business success in the EU.

Gain insight on enforcing economic operators' accountability to be compliant:

- Understand the specific role each economic operator plays in bringing a device into the EU and getting it to customers
- The interconnections among the economic operators (verifying activities, information exchange, product liability requirements and insurance obligations)
- How best to map the distribution channels
- Get a handle on the supplier management requirements and contractual obligations
- The essential elements in the contract between you and each economic operator
- The economic operators' obligations to the competent authorities

5:30 p.m. – 6:30 p.m. **Networking Reception**

Day 2

8:00 a.m. – 8:30 a.m. **Continental Breakfast**

8:30 a.m. – 8:45 a.m. **Welcome and Introduction by Chairperson**

8:45 a.m. – 9:30 a.m. **U.S. Medical Device Reporting – Part 1: U.S. FDA Perspective**

If you've noticed a disproportionate number of warning letters for Part 803 – Medical Device Reporting, you're not alone. The bulk of your Medical Device Reports (MDRs) citations are likely due to inadequate procedures — they account for nearly 90% of all MDR citations.

Get a clear explanation of the MDR requirements, common problems and reportable complaints. Reduce warning letters when you identify:

- How to evaluate complaints for reportability
- The criteria for reporting
- The investigation requirements
- The timeline for reporting
- How to keep solid records (the MDR event file)
- How to report using FDA's eSubmitter

9:30 a.m. – 10:15 a.m. **EU Manufacturers Incident Reports – Part 2: EU Perspective**

Don't let yourself get tripped up by EU-MDR's and IVDR's new Manufacturer's Incident Report (MIR). True: the new, more-elaborate form is complicated and requires a great deal of information — everything from an historical analysis of similar incidents to classification using the International Medical Device Regulators Forum (IMDRF) coding system.But when you know how to implement a solid system to identify and report serious incidents using MIR, you'll avoid letters requesting resubmissions, which would otherwise cost you time and money.

Save time and money by avoiding resubmission requests. Attend to find out all about the new EU-MIR:

- How to determine a serious incident, including subsequent classification to determine reportability
- The information required for a successful submission
- How best to complete the MIR
- How to submit the MIR the right way

10:15 a.m. – 10:30 a.m. **Refreshment Break**

10:30 a.m. – 12:00 p.m. **Mock Trial: The Product Liability Lawsuit**

What you don't know could bankrupt you: medical device manufacturers don't always understand the implications of a product liability lawsuit. This mock trial will hit home the points you absolutely must understand to protect your business, all while providing some enjoyable entertainment.

The premise: During an in-patient medical procedure, a patient suffered harm. The patient is suing the hospital where the procedure took place, the doctor who performed the procedure and the manufacturer that made the device. The patient hires an attorney who then hires an expert witness to review the manufacturer's documentation.

The discovery phase can require the manufacturer to produce thousands of pages of historical documents extending over years. A set of scripted vignettes is told from the expert witness point of view as she receives, reviews and comments on the manufacturer's documentation. A "stage manager" will explain each vignette.

You — the audience members — are the jury. Each jury member gets a simple jury form with some choices. At the end of the trial, you'll fill out the form and submit it to a member of the FDAnews team in return for admittance to lunch. During lunch, the FDAnews staff will compile the results and announce the verdict.

Come away not only energized, but with a deep understanding of business best practices to prevent debilitating lawsuits:

- Issues to consider in product development, manufacture and quality
- Product liability concerns — they can present themselves years after shipment
- Issues surrounding record retention and how to counteract them

12:00 p.m. – 1:00 p.m. **Lunch**

1:00 p.m. – 1:45 p.m. **Correction & Removals, Medical Device Recalls and Closure – Part 1: U.S. FDA Perspective**

Do you understand the U.S. process for correction and removals, device recall and closure? With a great deal of incorrect folklore being shared, it pays for manufacturers to be in the know when it comes to the multiple interlocking processes and multiple players involved.

Go through the U.S. process from beginning to end. You'll be able to identify, navigate and use to your advantage the exceptions, the required records and the various reporting methods and their issues. This will help you ensure any corrections, removals, recalls or closures have the minimum impact on your business:

- How to get a handle on the various steps and participants
- Once and for all: the manufacturer *does not* determine the recall class or the depth of the recall

- What to include in a recall plan, should FDA require one
- Periodic reporting — what's required by FDA?

1:45 p.m. – 2:30 p.m. **EU-MDR/IVDR Field Safety Corrective Actions – Part 2: EU Perspective**

If you're not completely clear on new EU-MDR/IVDR Field Safety Corrective Actions (FSCAs), you could be putting your business at risk. For instance, did you know the EU system has no recall classes? But the latest EU regulations do have requirements for a vigilance system that includes situations where a marketed device needs an update or some similar action. Fail to file your FSCA, Field Safety Notice (FSN) or other reports with the Competent Authorities (CA) — or file improperly — and you'll incur unwanted costs.

Attend this presentation to go through the EU process from start to finish, ensuring your business complies:

- The various steps involved, from filing an FSCA, writing a Field Safety Notice (FSN) that tells the user or patient how to handle the situation, submitting the FSCA and FSN to the Competent Authorities (CA), analyzing the reason for the FSCA, implementing corrective action and filing additional reports with the CA
- Exactly who the relevant participants are so you know whom to contact when for maximum efficiency

2:30 p.m. – 2:45 p.m. **Refreshment Break**

2:45 p.m. – 4:00 p.m. **ISO 14971:2019 – Risk Management Systems**

Are you ready to implement ISO 14971:2019? What about EN ISO 14971:2019? With FDA recognizing ISO 14971:2019 as a consensus standard, you must prepare to implement it within your risk management systems to ensure compliance.

Receive an overview of the new international standard and hear about the changes from the previous version. After attending, you'll be able to strengthen your processes to avoid noncompliance with:

- Practical ways to implement the new international standard and the EU variant in one unified quality management system and risk management system
- Understanding the issues involved and how to overcome them
- How to prepare implementation plans to remain compliant

4:00 p.m. – 4:45 p.m. **EU-MDR/IVDR Postmarket Surveillance**

EU-MDR/IVDR's new regulations require a detailed system for postmarket surveillance (PMS). Fail to create a detailed plan and various reports and you could risk fines, seizure of products, imposition of special compliance contracts and worse. When you take a more proactive approach to PMS, your company develops a reputation for producing ever-more-reliable and safer devices, not to mention that it reduces complaint-handling costs thanks to fewer incidents and greater customer loyalty.

Session attendees will gain insight into implementing an effective PMS system:

- Detailed information on PMS
- The associated reports (which change by device class)
- Other processes associated with the PMS system, including risk management

4:45 p.m. **Closing Comments by Chairperson, Steven Niedelman**

Post-Conference

8:00 a.m. – 8:30 a.m. **Continental Breakfast and Registration**

8:30 a.m. – 4:30 p.m.

As a device manufacturer, you must analyze data for product improvement and to satisfy regulatory requirements in Quality System Requirements (QSR) and ISO 13485:2016. But are you completely clear on what the requirements are and, more importantly, what techniques to use?

This workshop identifies methods based on ISO/TR 10017:2003, which describes statistical techniques for a quality management system. While the standard describes methods, it does not provide implementation details. This, coupled with the fact that there are other methods available mean you need guidance on how to make your quality management system work to your best advantage.

Get the exact guidance you need to ensure your products remain viable. Statistical techniques covered include:

- Descriptive statistics
- Hypothesis testing
- Measurement analysis
- Process capability analysis
- Regression analysis
- Sampling
- Monte Carlo methods
- Statistical process control (SPC)
- Statistical tolerancing
- Time series analysis

During the session, receive data sets and descriptions so you can work on examples. The workshop does not use Minitab, because many small companies do not have

it. Participants need to bring a computer, with the current version of MS Excel, to implement the necessary statistical techniques.

Dan O'Leary, President, Ombu Enterprises LLC

4:30 p.m. **Training Adjournment**