Day 1

Wednesday, Oct. 7, 2020

11:00 AM **Welcome and Introduction by Chairperson**

11:00 AM – 11:15 AM EDT

Steve Niedelman
Lead Quality Systems and Compliance
Consultant
King & Spalding LLP
Former FDA Deputy Associate
Commissioner for Regulatory Operations

11:15 AM **FDA's 2021 Medical Device Regulation Agenda: CDRH's Priorities**

11:15 AM - 12:00 PM EDT

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11:15 AM **FDA's 2021 Medical Device Regulation Agenda: CDRH's Priorities**

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Are you addressing CDRH's top strategic priorities for FY 2021 head on? If not, your devices might be left behind.

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

- Operating and maintaining quality during a pandemic
- CDRH reorganization — what it means for your devices and processes
- Comparing QSR v. ISO13485:2016
- Get ready for the planned 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 devices
- The truth about FDA's new shipment examination program at ports of entry

12:00 PM **Implementing the Clinical Evaluation or Performance Evaluation Process**

12:00 PM - 12:45 PM EDT

Jon Gimbel
Executive Director and CER Business Unit Lead
Regulatory & Quality Solutions (R&Q)

Do you know the ins and outs of the clinical evaluation system (EU-MDR) and performance evaluation system (EU-IVDR) requirements?

Also, if you're looking to obtain a CE Mark, this presentation is a must.

Gain the tools you need to ensure success:

- EU-MDR's and EU-IVDR's significant differences from the regulations
- Secrets of the new requirements for clinical and performance evaluation
- How to prepare your documents to meet the notified body's (NB's) requirements
- Using the NB's review process to your advantage

- The best way to respond to issues raised by the NB
- When it benefits you not to perform a clinical evaluation or performance evaluation — and how to document it and present it

12:45 PM **Break**
12:45 PM - 1:00 PM EDT

1:00 PM **Panel Discussion: EU-MDR and IVDR QMS**
1:00 PM - 2:30 PM EDT

Ibim Tariah
Vice President
EU-MDR and IVDR Consulting Services
Regulatory & Quality Solutions (R&Q)

Dan O'Leary
President
Ombu Enterprises

Is your quality management system (QMS) foolproof? While the new EU regulations require a QMS 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 your QMS fall? Are you compliant?

Session attendees will discover:

- Takeaways of the tools, methods and checklists you must have to implement an effective and compliant QMS
- 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

2:30 PM **Break**
2:30 PM - 2:45 PM EDT

2:45 PM **Impact of New Economic Operators on You, the Manufacturer**

2:45 PM – 3:30 PM EDT

Dan O'Leary
President
Ombu Enterprises

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 new insights on enforcing economic operators' accountability to stay compliant:

- Understand the specific role each economic operator plays in bringing a device into the EU and getting it to customers
- The interconnections among 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
- Essential contract elements between you and each economic operator
- Economic operators' obligations to the competent authorities

3:30 PM **Break**

3:30 PM – 3:45 PM EDT

3:45 PM **Virtual Social Event**
3:45 PM – 4:15 PM EDT

Beer and Cheese Tasting – We will send you a sampling of Craft Beer and Fine Cheeses. In a Zoom call an expert will talk us through the pairings you received.

Day 2
Thursday, Oct. 8, 2020

11:00 AM **Welcome and Introduction by Chairperson**
11:00 AM – 11:15 AM EDT

Steve Niedelman
Lead Quality Systems and Compliance Consultant
King & Spalding LLP
Former FDA Deputy Associate Commissioner for Regulatory Operations

11:15 AM **ISO 14971:2019 – Risk Management Systems**
11:15 AM – 12:00 PM EDT

Eric Henry
Consultant
FDA & Life Sciences
King & Spalding

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:

- Understanding how the updates in ISO 14971:2019 impact your current risk management process
- Harmonizing risk management across all risk-based elements of the QMS using ISO 14971:2019 as a guide
- How to prepare implementation plans to remain compliant

12:00 PM **EU-MDR and IVDR Post-Market Surveillance**

12:00 PM – 12:45 PM EDT

Jon Gimbel
Executive Director and CER Business Unit Lead
Regulatory & Quality Solutions (R&Q)

EU-MDR's and IVDR's new regulations require a detailed system for post-market 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.

Learn how to implement an effective PMS system:

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

12:45 PM **Break**

12:45 PM – 1:00 PM EDT

1:00 PM **Medical Device Data Analysis Methods: An In-depth Virtual Workshop**

1:00 PM – 4:15 PM EDT

Dan O'Leary
President
Ombu Enterprises

As a device manufacturer, you must analyze 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? If not, you risk noncompliance.

This workshop identifies methods based on ISO/TR 10017:2003, which describes statistical techniques for a quality management system (QMS). While the standard describes methods, it provides no implementation details. This coupled with the fact that there are other methods available mean you need guidance on how to make your QMS 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
- Process capability analysis
- Sampling

You'll receive data sets and descriptions during the session, so you can work on the examples. This workshop does not use Minitab, because many small companies do not have it.

4:15 PM **Event Adjourn**