
# Agenda

**Pre-Conference Workshop**

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

**8:30 a.m. – 12:00 p.m.** **Correction and Corrective Action — Dissipate the Fog of Confusion**

Correction and Corrective Action work together as improvement tools for products, processes, and the QMS. They are powerful techniques that, when applied correctly, can help eliminate problems and reduce cost.

Each technique uses a separate process; the two different processes link together to achieve their goals. The device manufacturer can develop any process steps as long as they include the required elements from QSR and ISO 13485:2016. Of course, the manufacturer must follow the process steps; this is an often cited problem. Unfortunately, there is confusion about the requirements. As a result, there are often 483 observations or MDSAP audit nonconformances. In fact, warning letters cite §820.100 more often than any other section. Instead of being an efficient improvement tool, correction and corrective action can become another source of problems.

The solution is to understand the correction process, the corrective action process, and the associated regulatory elements. This presentation lays out compliant process steps and illustrates common problems using examples from warning letters. The presentation also incorporates QSIT Inspectional Objectives and MDSAP Audit Tasks.

As improvement processes, both correction and corrective action utilize quality tools. The workshop describes some of the tools available and connects them to the process steps.

Participants learn how to develop and implement correction and corrective action processes that are easy to use, efficient, and effective.

Workshop leader:
**Dan O'Leary, President, Ombu Enterprises LLC**

**Day 1**

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

**1:00 p.m. – 1:15 p.m.** **Welcome and Introduction by Chairperson, Steve Niedelman, Lead Quality Systems and Compliance Consultant, King & Spalding LLP; former FDA Deputy Associate Commissioner for Regulatory Operations**

**1:15 p.m. – 2:00 p.m.** **Update From the Office of Compliance at CDRH: Priorities and Strategies for 2019**

This session will discuss CDRH's top strategic priorities for FY 2019 and will update you on progress so far and what is still left to do. Hear the latest on some of CDRH's regulatory science priorities. Some key areas of interest include:

- Prioritizing digital health
- Advancing device safety and security
- Offering more flexibility and options for premarket submissions
- Sustaining high-quality servicing
- Efficient oversight
- Engaging patients
- FDA's program alignment plan
- CDRH reorganization

**Jeff Shuren, MD, JD, Director, CDRH, FDA (Invited)**

**2:00 p.m. – 2:45 p.m.** **Medical Device Risk Management: How You Need to Update Your Plan**

The international standard is under revision. While the changes in the process are not intended as “major”, the new standard adds and changes definitions, changes the clause numbering, introduces new requirements, changes many of the annexes, and moves them to a new document. In this midst of these considerations is the risk-related language of the new EU Medical Device Regulation. Your risk management procedures may require an overhaul. This session will highlight the significant changes you need to be aware of and the necessary steps to take to keep ahead of the game. In consideration of the 14971 changes, there will also be a short discussion related to the impact on software-related risk management and the potential addition of cybersecurity to your safety risk management scheme.

**Eric Henry, Senior Quality Systems and Compliance Consultant, King & Spalding**

**2:45 p.m. – 3:00 p.m.** **Refreshment Break**

**3:00 p.m. – 4:30 p.m.** **Panel Discussion: Servicing vs. Refurbishing vs. Remanufacturing**

In December 2018, the FDA hosted a public workshop on medical device servicing and remanufacturing activities. This is part of an effort to develop a draft guidance that will distinguish servicing activities from remanufacturing.

This panel will discuss the outcomes of the workshop and provided best practices for the following questions:

- Are there additional considerations that may help entities distinguish between servicing and remanufacturing activities?
- What are acceptable methods of assessing component/part/material specifications during servicing or remanufacturing?
- What are the pros and cons of the risk-based approach discussed in this white paper?

**4:30 p.m. – 4:40 p.m.** **Refreshment Break**

**4:40 p.m. – 5:30 p.m.** **Data Integrity for Medical Device Companies**

Maintaining data integrity is an essential part of maintaining manufacturing quality of your medical device. It should be a critical role in your cGMP. Do you or your employees have the experience and knowledge to properly record and handle data? This session will help you eliminate any data integrity issues.

**5:30 p.m. – 6:45 p.m.** **Networking Reception**

**Day 2**

**8:00 a.m. – 8:45 a.m.** **Continental Breakfast**

**8:45 a.m. – 9:00 a.m.** **Welcome and Introduction by Chairperson, Steve Niedelman, Lead Quality Systems and Compliance Consultant, King & Spalding LLP; former FDA Deputy Associate Commissioner for Regulatory Operations**

**9:00 a.m. – 9:45 a.m.** **Enacting the Case for Quality: Defining Metrics**

CDRH launched the Critical to Quality (CtQ) initiative to strengthen product and manufacturing quality. The CtQ program is meant to overcome the traditional relationship between FDA and industry that is too focused on managing compliance rather than the shared goal of for continuously improving quality. In this session, you'll hear about the CtQ initiative and the CtQ information documents that have been published.

**Francisco Vicenty, Program Manager for the Case for Quality, Office of Compliance, CDRH, FDA (Invited)**

**9:45 a.m. – 10:30 a.m.** **Regulating Software Used by Life Science Manufacturers: Is it a Medical Device or Not?**

Life science companies using software in clinical trials, software developers, and producer of artificial intelligence products need to know what software is a medical device and what's not. Life science companies utilizing AI or buying off-the-shelf software products often don't realize that they're using those products as medical devices and that significant fact impacts the ability to get their device approved and the validity of the data they've collected and compiled. Many life sciences manufacturers

simply don't realize their product will be considered a medical device and don't know what regulations apply. This session will help you understand:

- The process by which to classify an SaMD based on U.S. and international guidance
- How a company's use of a software product impacts the classification of SaMD and
- When a purchased software product becomes an SaMD
- Remediation approaches to resolve SaMD compliance issues
- Best practices on development and validation strategies for SaMD

**James Rogers, Founder, Compass Life Science Solutions**

**10:30 a.m. – 10:45 a.m.** **Refreshment Break**

**10:45 a.m. – 12:15 p.m.** **Panel Discussion: EU-MDR, MDSAP and ISO 13485:2016: How Are They Interconnected and What You Need to Know**

If you want to market your device outside the United States, you need to be aware of the storm of headed our way. This expert panel will make sure you understand how the commonalities and differences of an FDA program; new European medical device regulations and the international standards are going to play into how you operate.

Moderator:

**Robert Ruff, Executive Director of Medical Device Education and Training, NSF Health Sciences; former Medical Device Specialist and Senior Investigator at ORA and International Team Lead at CDRH, FDA**

Panelists

- **Dan O'Leary, President, Ombu Enterprises LLC**
- **Karl Vahey, Vice President Manufacturing Quality, Cardinal Health**
- **Ibim Tariah, Technical Director, BSI Americas Inc.**
- **Marc-Henri Winter, Staff Fellow, Division of International Compliance Operations, OC, CDRH, FDA (Invited)**

**12:15 p.m. – 1:15 p.m.** **Lunch**

**1:15 p.m. – 2:00 p.m.** **Sampling Plans for Quality Audits**

Sampling raises questions for the auditor, such as the number of records to sample, counting nonconforming records and limits on acceptance. If a record has three errors does the auditor count it three times — one time for each error — or one time as a nonconforming record? Some auditors determine the sample size without using statistical techniques. Sampling the records in an audit is not the same as sampling at incoming inspection — the purpose is different, so the method changes. An audit may need to determine the error rate in a process, or least show that it is not too great.

This session will examine the issues in audit sampling and provide the answers you need for planning.

**Dan O'Leary, President, Ombu Enterprises LLC**

**2:00 p.m. – 2:45 p.m.** **FDA's Focus on Risk Management and Cybersecurity for Devices that Contain Software**

Software has become a critical part of medical devices. More and more medical devices have software embedded or interface with another device or healthcare system that has software as an integral part. Given the increased complexity of medical device software, best practices in risk management and cybersecurity are critical and challenging.

Attendees will learn:

- What the FDA's latest initiatives on device software risk management and cybersecurity are
- How a device manufacturer overcomes technical as well as regulatory compliance challenges
- What resources and tools are available
- What the industry's best practices are

**Seth Carmody, Staff Fellow, Office of the Center Director, CDRH, FDA (Invited)**

**2:45 p.m. – 3:00 p.m.** **Refreshment Break**

**3:00 p.m. – 4:30 p.m.** **Panel Discussion: Medical Device Recall or Product Enhancement? Understanding When to Submit a Part 806 Report**

Many companies are struggling to know when to and when not to report an 806 recall. Devicemakers now have to wonder if their product enhancements are:

- An acceptable product enhancement
- A recall
- A product enhancement that's now considered a recall
- Or neither a product enhancement nor a recall

Unclear on how your current or future product enhancements might be viewed by FDA?

The expert panel will help demystify any problem areas you face.

Moderator:

**Steve Niedelman, Lead Quality Systems and Compliance Consultant, King & Spalding LLP; former FDA Deputy Associate Commissioner for Regulatory Operations**

Panelists:

- **Anupama Govindarajan, Recall Branch, Division of Analysis and Program Operations, CDRH, FDA (Invited)**
- **Pamela Furman Forrest, Partner, Covington & Burling**
- **Chris Harvey, Director- Recall Solutions, Stericycle**

**4:30 p.m.** **Closing Comments by Chair Steven Niedelman**

**Post-Conference Workshop**

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

**8:30 a.m. – 5:30 p.m.**

The EU-MDR is a complicated regulation. For example, the regulation distributes requirements through a series of interlocking articles and annexes. The EU-MDR doesn't have a single place that identifies each post-market activity and provides the requirements.

Moreover, the slow implementation of the EU exacerbates the problem. For many of the activities the planned harmonized standards, common specifications, and guidance documents are not available.

The problem is creating an issue for manufacturers. Many companies intend to use the "soft transition" which allows a medical device with a valid MDD or AIMD certificate to remain on the market until May 27, 2024 provided the manufacturer:

- Does not make a significant change in the device design and intended purpose
- Implements the MDR requirements for post-market surveillance
- Implements the MDR vigilance requirements
- Registers the economic operators
- Registers the devices
- Gains agreement from the MDD or AIMD Notified Body

Regardless of the manufacturer's plan, the full set of post-market activities must be in place by the Date of Application, May 26, 2020. This means the manufacturer must understand the requirements, develop the expanded QMS procedures and implement them for every device.

Under the MDR, the manufacturer performs post-market activities after putting the CE Mark on the device and placing it on the market. However, in the soft transition the manufacturer has already made the device available on the market under the MDD or AIMD. This can complicate the post-market activities when there are new pre-market requirements.

The workshop provides necessary information on each required post-market activity. The information uses a process approach to explain the requirements. The process flow identifies the articles and annexes that govern the requirements. In addition, the workshop provides

recommendations and, in some cases, templates to assist in the implementation.

The basic process elements are:

- Develop a PMS procedure that covers all devices
- Develop a plan for each device
- Implement the plan, collect information, and analyze it
- Write a report
- Use the information in the report to update associated plans and reports
- Transmit the report (typically to the Notified Body)
- Iterate the plan's implementation
- Update the report with the specified frequency
- Updated the associated plans and reports
- Transmit the updated report

The workshop covers:

- Clinical Evaluation (pre-market)
- Risk Management (pre-market)
- Post-market Surveillance (PMS)
- Post-market Clinical Follow-up (PMCF)
- Summary of Safety and Clinical Performance (SSCP)
- Vigilance Reporting
- Trend Reporting

Expert Instructor:

**Dan O'Leary, President, Ombu Enterprises LLC**

**5:30 p.m.** **Training Adjournment**