AGENDA

Pre-Conference Workshop (April 3)

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

8:30 a.m. – 12:00 p.m. Effective Complaint Management

A strong complaint management program can help medical device manufacturers make continuous improvements in regulatory compliance, patient safety and customer satisfaction. Unfortunately, many don't manage the process well. Medical device manufacturers receive more Warning Letter citations for complaint management than for anything else save corrective and preventive action. And it's not just domestic concerns. Regional compliant management requirements from the directives and regulations in the EU have to be dealt with as well.

This pre-conference workshop provides information to ensure your complaint management processes can survive an FDA Inspection without a 483, and provides the tools you need to write robust procedures, analyze complaint data, and perform rigorous internal audits that can satisfy domestic and international authorities. These are not simply principles listed on a power point slide, but real workshop exercises that can help illuminate the issues, and make sure you feel ready to improve your program when you return to the office.

And, although the QSR complaint management process is extensive, it still doesn't meet all of the ISO 13485:2016 requirements. Complaint management also is an essential part of ISO 14971:2007. The workshop will explain how to implement a broad system to satisfy these quality management and risk management requirements too, including how to use inspection and audit tools such as QSIT and the MDSAP Audit Model.

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

Day 1 (April 3)

12:00 p.m. – 1:00 p.m. Registration

1:00 p.m. – 1:15 p.m. Welcome and Introduction by Co-chair Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and 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 2018

A can't-miss session, where William Maisel will discuss CDRH's top strategic priorities for FY 2018. He will update you on progress made on the 2017 priorities and what is still left to do. He will also touch on some of CDRH's regulatory science priorities. Some key areas of interest include:

- Establishing a national evaluation system for medical devices by increasing access and use to real-world evidence to support regulatory decision making
- Partnering with patients by promoting a culture of meaningful engagement by facilitating CDRH interaction with patients while increasing patient input as part of the decision making.
- Promoting a culture of quality and organizational excellence
- A Summary of the Regulatory Science Subcommittee's assessment of regulatory science needs within CDRH
- FDA's program alignment plan

William Maisel, Acting Director, Office of Compliance, CDRH, FDA (invited)

2:00 p.m. – 2:45 p.m. ISO 13485:2016 – Starting The Final Countdown

Last March, ISO issued the new version of ISO 13485:2016. All existing ISO 13485 certificates must be transitioned to the new version of the standard by February 28, 2019 – when the MDQC conference meets, the deadline will be less than a year away! Failing to meet this deadline can be costly, so it's in your interest to be ahead of the curve. Device quality expert Robert Ruff will walk you through the best practices to ensure you are on the right track in your transition plan.

Attendees will learn:

- The transition plan for certificates
- The transition plan for the EU Harmonized Standard
- The role of ISO 13485:2016 in the MDSAP and Canada's plan to adopt it
- The major differences between ISO 13485:2003 and ISO 13485:2016

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

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

3:00 p.m. – 4:30 p.m. Panel Discussion: 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.

Moderator:

Stephanie Christopher, Program Director, CfQ & PCBR, MDIC

Panelists:

- **William MacFarland, Director, Division of Enforcement, Office of Compliance, CDRH, FDA (invited)**
- **Francisco Vicenty, Program Manager for the Case for Quality, Office of Compliance, CDRH, FDA (invited)**
- **Al Crouse, Sr. Quality Director, CVRx Inc.**

4:30 p.m. – 4:35 p.m. Refreshment Break

4:35 p.m. – 5:20 p.m. Preparing for the MDSAP Audit Process: A Case Study from the Manufacturer's Perspective

Manufacturers entering the Medical Device Single Audit Program undergo an assessment performed by a single third-party inspector that proves compliance in the US, Canada, Australia, Brazil, the EU and Japan. The audit process is not what you're used to compared to an FDA or ISO audit. Cynosure has successfully certified two manufacturing sites in the last year. The Cynosure facility in MA (1,000 people) was audited as part of the MDSAP in October 2016 and their facility in NY (40 people) was audited to the MDSAP in March 2017. Both facilities passed the audit with only minor findings.

Executive Vice President of RA/QA Connie Hoy will take you through the preparation process from the manufacturing perspective. You will also hear what lessons they learned along the way, what they would have done differently and how it compares to a corporate audit versus a small manufacturing plant audit.

This presentation will cover:

- What they did to prepare for the audit
- The audit flow and how it differs from QSIT and ISO audits
- The differences and similarities between preparing the two plants
- What they would do differently to prepare now that they have undergone the process.

Connie Hoy, Executive Vice President of RA/QA, Cynosure

5:20 p.m. – 6:30 p.m. Networking Reception

Day 2 (April 4)

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

8:45 a.m. – 9:00 a.m. Welcome and Introduction by Co-chair Elaine Messa, President of the Medical Device Practice, NSF Health Sciences; former Director of the Los Angeles District, FDA

9:00 a.m. – 9:45 a.m. Voluntary Medical Device Manufacturing and Product Quality Program

Should you participate in the Voluntary MD Manufacturing and Product Quality Program? Captain Sean Boyd from the FDA will explain the program's features and why he thinks medical device firms can really benefit themselves by helping move the conversation away from compliance to how well the quality system is delivering value to customers and business.

CAPT Sean Boyd, Deputy Director for Regulatory Affairs, Office of Compliance, CDRH, FDA (invited)

9:45 a.m. – 10:30 a.m. Keeping Your Quality System Trim: Lean Principles for GMPs

Some of the most successful medical device manufacturers are using the Lean Principles it to improve their bottom line while ensuring quality. You may already be using some of these principles but just have not heard of the names before, such ask "kanban, heijunka and muda." In this session, you'll learn how to use lean management principles to increase quality, reduce waste (and costs), and increase output – all without losing sight of your compliance responsibilities.

James Shore, President, Quality Lean Solutions

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

10:45 a.m. – 12:15 p.m. Panel Discussion: European Medical Device Regulations — Preparing for the Storm

Like a line of thunderstorms developed on a weather front, various regulatory agencies will move through your company to check up on the Quality Management System. Each visit will be different because they will look at different aspects. The FDA will check your adherence to US regulations. The MDSAP will help prepare you for Canada, Australia, Brazil and other jurisdictions in the program. The unknown factor is the status of the MDR Notified Bodies (NB). There aren't any yet, as the regulation moves through its transition process. We do know that qualifying NBs will conduct audits that are more rigorous than under the directives. The MDR Annex VII, Section 4.5. Conformity Assessment Activities, lists specific requirements for the NB to cover during an audit.

This expert panel will take you through the changes and what you need to know to be prepared to continue to market or bring your product to market in Europe.

Moderator:

Maria Fagan, President, Regulatory and Quality Solutions (R&Q)

Panelists:

- **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**
- **Dan O'Leary, President, Ombu Enterprises LLC**
- **Karl Vahey, Vice President Manufacturing Quality, Cardinal Health**
- **Ibim Tariah, Technical Director, BSI Americas Inc. (invited)**

12:15 p.m. – 1:15 p.m. Lunch

1:15 p.m. – 2:00 p.m. Meet NEST: Building a National Medical Device Surveillance System

FDA has been working since 2014 to build a sustainable national system to evaluate the risks and benefits of medical devices. Enter the National Evaluation System for health Technology (NEST) with a mission to "support optimal patient care by leveraging the experiences of patients to inform decisions about medical device safety, effectiveness, and quality in order to promote the public health." In this session, FDA Associate Director for National Devices Surveillance Gregory Pappas outlines the program's evolution and goals, and presents opportunities for devicemakers to get involved in the data-sharing initiative.

Gregory Pappas, M.D., Ph.D., Associate Director for National Devices Surveillance, Office of Surveillance and Biometrics, CDRH, FDA (invited)

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: MEDDEV 2.7/1 revision 4 and Clinical Evaluation Reporting (CER)

From frequency of reports to specific requirements for authors and evaluators, the fourth revision of MEDDEV 2.7.1 provides more explicit guidance on conducting and reporting on clinical evaluations. It is critical that manufacturers understand the requirements to gain market access to countries relying on the CE Mark. Key takeaways from this session include strategies for literature evaluation, scoping "the right" research questions and perspectives on leveraging data from equivalent competitive products.

Moderator:

Carol Ryerson, Sr. Principal Advisor, Regulator Affairs, RCRI

Panelists:

- **Lisa Casavant, Founder, VP, Regulatory and Quality Solutions (R&Q)**
- **Stephan Buttron, Principal Medical Research Manager of Regulatory Affairs at NAMSA (invited)**
- **Ruthanne Vendy, Principal Specialist, Regulatory and Quality Solutions (R&Q) (invited)**
- **Anne Le Rouzo, West Coast Regional Director & Certification Project Manager/Lead Auditor, LNE/G-MED North America, Inc. (invited)**

4:30 p.m. Closing Comments by Co-chairs Steven Niedelman and Elaine Messa

Post-Conference Workshop (April 5)

Post-market Surveillance

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

8:30 a.m. – 5:30 p.m. Medical device manufacturers can't just design, manufacture, and ship product – they must learn how the device performs and identify any patient or user issues too once it is out in the real world. This process has many names, but it is most commonly called post-market surveillance or PMS.

To meet these obligations, device manufacturers must have a system to collect data, process information, create knowledge, update the quality management system, update the risk management system, and report to regulators. Although many systems have a common framework, the details on what is required vary widely by regulatory region. This workshop employs the framework and provides the details for the US, the EU under the directives, and the EU under the regulations. **PLUS**, we provide tools to help you manage your program!

A starting point is risk management. The PMS information helps detect any weakness in the risk control measure's ability to keep a harm's severity and frequency at an

acceptable level.

For the US, the workshop describes the requirements and methods for complaint management, how to use FDA's Total Product Life Cycle (TPLC) database, Part 803 Medical Device Reports, Part 806 Corrections & Removals, Part 821 Medical Device Tracking, and Part 822 Post Market Surveillance.

For the EU-MDD, the workshop describes Clinical Evaluation, Post-market Clinical Follow-up (PMCF), Vigilance Reporting, Field Safety Corrective Actions, and Trend Reporting.

The EU-MDR expands the PMS system and adds additional reports to regulators (including Notified Bodies). The workshop describes Benefit-Risk Determination (BRD), Benefit-Risk Ratio (BRR), Clinical Evaluation (CE), Post-market Surveillance Report (PMSR), Periodic Safety Update Report (PSUR), Post-market Clinical Follow-up (PMCF), and the Summary of Safety and Clinical Performance (SSCP). Many of these provide information to others, creating an interesting web.

Attendees will learn:

- The risk management process to update the risk management file using the PMS system
- Statistical methods for signal detection
- Using complaints to learn about your device
- Using the TPLC database to learn about other manufacturer's devices
- The systems to report adverse events to regulators
- The systems to revise devices already shipped
- The linkages between clinical evaluation, risk management, and post-market clinical follow-up
- The new set of plans and reports in the EU-MDR and how to implement them
- How to implement the EU-MDR's trend analysis for non-serious incidents

BONUS: Attendees will receive implementation tools including checklists for procedures, plans, and reports.

Expert Instructor:

Dan O'Leary, President, Ombu Enterprises LLC

5:30 p.m. Training Adjournment