Eleventh Annual
Medical Device Quality Congress

Agenda

PRE-CONFERENCE WORKSHOP: TUESDAY, JUNE 24, 2014

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

9:00 a.m.

9:00 a.m. – 12:00 p.m. Harness the Power of Text Mining: Using FDA Data to Analyze Medical Device Recalls

Most pharmaceutical and medical device organizations are analyzing structured numerical (and categorical) data, such as clinical trials, R&D, process development, process monitoring, sales and marketing, product supply and commercial manufacturing. Structured numerical data is, well, numerous and used throughout most organizations. However, the majority of stored data is not numerical; it is in the form of unstructured text in reports and documents, such as nonconformance reports.

Nonconformance reports are written by different people in different areas of the organization; therefore, these reports often contain different words or phrases to report the same problem. The solution? Develop a document-term (word) matrix for the unstructured data. Use proven statistical tools and methods to "rank" words based on importance and frequency, then "translate" these ranked words and phrases into a "word cloud" that very often displays true root problems for systematic nonconformances. Drug and device companies can also use this information to “cluster” seeming unrelated nonconformance reports, providing a much more thorough analysis of nonconformances as part of a comprehensive CAPA program.

During this workshop, the instructor will use data taken directly from the FDA website to teach attendees how text mining can be used to determine how their products (and other products in their class) are being reported. The example used shows how analysis of recall reports from one medical device company established the words "ventilator," "infusion" and "simulator” as true root causes for one company’s medical device recalls. Additionally, the instruction will show how analysis of this unstructured data may provide information on unknown trends and potential problems.

Attendees will learn:

- Understand how to analyze FDA recall data to narrow root causes down to key words
- Know how to develop and populate a matrix of raw data needed for text mining
- Understand how proven statistical tools and methodologies are used to perform text analytics

Your biggest data can be your best data if analyzed efficiently and correctly.

Heath Rushing, Principal Consultant, Adsurgo LLC

DAY ONE: TUESDAY, JUNE 24, 2014

12:00 p.m. – 1:00 p.m. Registration

1:00 p.m. – 1:15 p.m. Welcome and Introduction by Co-chair Steven Niedelman, King & Spalding

1:15 p.m. – 2:00 p.m. CDRH Update on Design Control: Improving Quality Assurance and Engineering Principles in 2014

Design control is one of the industries biggest obstacles that repeatedly troubles device firms. In this presentation you will hear the latest about the FDA's major areas of concern. This session will discuss the importance of design and development planning, design input and output, design verification and validation, and design transfer and changes. Also, recent trends in 2013 warning letters citing design control deficiencies will be used as examples.

2:00 p.m. – 3:30 p.m. Panel Discussion: Best Practices in Implementing an Effective Risk Management System

As technologies and innovation push the boundaries for new medical devices, there is an increased emphasis and expectation that such devices shall be free from unacceptable risk to the patient and end user. In addition, many standards and guidance documents point to ISO 14971:2007 as the standard for medical device risk management. An effective risk management strategy, now more than ever, is a necessity for medical device manufacturers.

Attendees will learn:

- Organizational factors that lead to an effective risk management system
- How companies integrate their product life-cycle processes with risk management
- What constitutes an effective risk management file
- Methods companies use to review, validate and improve their risk management systems
- What companies need to do to address the latest in ISO 14971:2007

enforcement — including how devicemakers are struggling with EU compliance.

3:30 p.m. –Refreshment Break
3:45 p.m.

3:45 p.m. –Tools for Efficient Design Control: Best Practices for Lowering Costs
4:30 p.m. and Improving Schedules While Remaining Compliant

Throughout the design control process there are opportunities to improve efficiency through technology. Personnel involved in product development, manufacturing, quality assurance and regulatory affairs all have a stake in the design control process, and there are tools available for every design control phase. At the same time, 21 CFR Part 11 governs how electronic records and signatures are handled, so we need to choose our technology tools carefully.

Attendees will learn:

- How specific technologies can be used at various stages of the design control process
- When 21 CFR Part 11 applies and how to validate OTS software for design controls
- What tools are actually being used in the industry,\ and how these systems hold up during an audit

4:30 p.m. –Panel Discussion: Managing Operations Effectively: Deliver Quality
6:00 p.m. Devices and Always Be Audit Ready

As the FDA's field staff continues to grow, that long overdue inspection is more likely than ever to occur. In alignment with the recent reorganization of the Office of Compliance, CDRH, the FDA will be prepared to effectively follow up and act on potentially volatile situations to reassure the public that they are providing the public health protection they expect and deserve.

Attendees will learn:

- 5 key elements to have in place to control your manufacturing processes
- How to build an effective CAPA system to take corrective action quickly when a problem arises
- How to create an effective listening system to know how your product is performing and the steps to take when something goes awry

6:00 p.m. –Networking Reception
7:00 p.m.

DAY TWO: WEDNESDAY, JUNE 25, 2014

8:30 a.m. – 9:00 a.m. **Continental Breakfast**

9:00 a.m. – 9:15 a.m. **Welcome and Introduction by Co-chair Elaine Messa, Becker & Associates**

9:15 a.m. – 10:00 a.m. **Medical Device Recall 2014 Update**

The chief of the Recall Branch of CDRH will guide attendees on the FDA's recall policy and provide some highlights of the new draft guidance on Distinguishing Medical Device Recalls from a Product Enhancement and Associated Reporting Requirements. In this session, you'll get an inside look at how the FDA classifies recalls and what triggering events suggest a potential recall. Learn how field service corrections can become recalls and how using prior information can facilitate earlier vigilance, outreach and action.

10:00 a.m. – 10:45 a.m. **Medical Device Recalls: Unique Challenges and Opportunities**

No company enjoys conducting recalls and most view them as a necessary evil. Done efficiently and effectively, however, even a product problem can give your company an opportunity to demonstrate high quality standards and concern for customers. A well-developed and tested methodology for conducting recalls is an important first step.

Attendees will learn:

- The best ways to turn a problem into a unique opportunity
- A successful and efficient model for recall decisionmaking that will satisfy the FDA
- How to assure the effectiveness of recalls — three steps to make it happen quickly

10:45 a.m. – 11:00 a.m. **Refreshment Break**

11:00 a.m. – 12:30 p.m. TBD

12:30 p.m. – 1:30 p.m. **Lunch**

1:30 p.m. – 2:15 p.m. **Closing the Loop on Corrective and Preventive Action (CAPA): A Call to Action**

CAPA problems continue to be one of the most cited FDA Form 483 deficiencies, generating the single largest number of warning letter citations. A recent industry report breaks down the FDA's 2012 inspection findings into five categories: CAPA (30 percent); production and process controls (30 percent); design problems (15 percent); management issues (14 percent); and

other (11 percent). Getting CAPA right remains incredibly important. This session will discuss the importance, requirements and elements of a best-in-class CAPA program, as well as describing how to use CAPA data to help mitigate risk and drive quality in a holistic manner.

Attendees will learn:

- New and updated regulatory requirements and expectations – and how to interpret the latest warning letter enforcement trends.
- How to implement a repeatable, standardized and complete process that can tackle CAPAs and ensure compliance
- The importance of developing closed-loop systems that detect existing potential quality problems and facilitate rapid problem resolution and closure

2:15 p.m. –3:00 p.m. FDA Final Rule and Guidance Makes eMDRs Mandatory Next Year — Are You Ready

Devicemakers should take steps now to secure a production account for submitting electronic Medical Device Reports ahead of an Aug. 14, 2015, deadline for compliance with mandatory eMDRs. The FDA set the deadline in a final rule issued recently, along with Q&A guidance aimed at easing the transition. Devicemakers have two choices for preparing eMDRs. One option is the FDA's free eSubmitter software, which allows manufacturers to manually enter case data for transmission to the agency. The other option is Health Level Seven (HL7) Individual Case Safety Reporting, which allows for batch report preparations. This presentation will help attendees understand best practices for submissions and to assure they are ready for the August deadline.

Attendees will learn:

- What within the recent final rule and associated guidances is most important
- How to choose whether to use the FDA's eSubmitter system or HL7 solutions
- What are likely to be "pinch points" when submitting reports and how to be better prepared

3:00 p.m. –3:15 p.m. Refreshment Break

3:15 p.m. –5:15 p.m. Complaint Handling and Medical Device Reporting: *Where Inspectors Look First*

Customer complaints will never go away. The FDA continues to show more and more enforcement interest in identifying flaws in the complaint handling

programs of regulated companies. FDA inspectors quite often start with complaints and medical device reporting systems, as they provide a clear indicator of how well a devicemaker focuses on quality management and compliance. Year in and year out, at least 65% of FDA warning letters include citations for complaint handling.

Attendees will:

- Understand when an event or field action is a complaint and when it's not — the differences will surprise you
- Learn what FDA investigators will look for when they enter your shop
- How to handle complex, potentially dangerous MDR events
- Prepare service reports that will meet FDA expectations

5:15 p.m. – 5:30 p.m. Closing Comments by Co-chairs Steven Niedelman and Elaine Messa

DAY THREE: THURSDAY, JUNE 26, 2014

Supplier Quality Management Training

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

8:30 a.m. – 5:30 p.m. Medical Device Supplier Qualification and Management — Practical Approaches to Cost-Effective Implementation

The development of extended supply chains raises major issues in risk management. While regulators are looking more closely at device supplier management issues, companies are recognizing the value of risk management in meeting the regulatory requirements. In addition, risk management can help device manufacturers protect themselves against problems, develop more effective management systems and control costs. You can start to prepare with important GHTF guidance documents: Control of Suppliers (GHTF/SG3/N17:2008), Control of Products and Services from Suppliers (SG3/N17/2008), Risk Management Principles in a QMS (GHTF/SG3/N15R8), and Corrective Action & Preventive Action in a QMS (GHTF/SG3/N18:2010). These guidance documents provide the foundation, but lack practical details. This workshop gives you the tools and methods you need for a cost effective implementation.

Attendees will learn:

- The supplier management process and the major steps involved
- The issues of supplier risk management – product risk, business risk, and recalls & liability risk
- How to conduct an on-site supplier audit applying risk management
- How to qualify suppliers that are virtual companies
- Understanding business issues in the supply chain and their risk challenges

- Medical device corrections & removals (recalls)
- How to select and apply supplier metrics and their role in the QMS
- Dealing with FDA record-keeping issues — sponsor vs. supplier

BONUS: Attendees will receive copies of implementation tools, including a process map, sample questionnaire, reevaluation form, audit checklist and more.

Expert Instructors:
John Avellanet, Managing Director & Principal, Cerulean Associates LLC
Dan O'Leary, President, Ombu Enterprises

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