THIRD ANNUAL

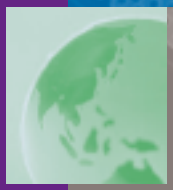
Medical Device Quality Congress

Leading the Way to Better Performance with Quality Systems Compliance

May 2-4, 2006
San Diego, CA

- Industry and FDA guidance on how to achieve compliance with the Quality Systems Regulation and gain value from the process
- Detailed information and case studies on specific QSR requirements
  - Corrective and Preventative Action (CAPA)
  - FDA Inspections
  - Medical Device Reporting
  - ISO 14971/Risk Management
  - Design Controls
  - Software Verification and Validation
- Lessons learned: Understanding the types of FDA enforcement actions and implications of recent litigation

Medical Devices in China



With the growth of the Chinese medical device market, the Chinese government is tightening up its controls and regulations. Chang-Hong Whitney will share her extensive experience in managing regulatory compliance and registration process on the Chinese market. Learn more about product registration, type testing, labeling, industry standards, manufacturing compliance, vigilance and more...

KEYNOTES:

FDA's Outlook for Quality in Device Manufacturing

Timothy Ulatowski, Director, Office of Compliance, Center for Devices and Radiological Health, U.S. FDA

The Six Ds of Design Control Compliance

Georgia Layloff, Consultant, former FDA expert investigator and core member of FDA's Quality System Inspection Technique (QSIT) Team

hosted by

The Management Roundtable

FDANews

www.managementroundtable.com 800 338 2223

THIRD ANNUAL

Medical Device Quality Congress

Leading the Way to Better Performance with Quality Systems Compliance

May 2-4, 2006
San Diego, CA

The pieces of the quality compliance puzzle — CAPA, design controls, inspection, enforcement, risk management — are complex and interdependent. Medical Device firms that understand how the pieces fit together and leverage the interdependencies are leading the way to better performance through safer products and faster time to market.

The Medical Device Quality Congress has become a "must attend" for everyone responsible for assessing the impact of FDA policies regarding QSR and understanding the implications of international regulatory requirements for quality and product registration.

This year's congress provides the most up-to-date, "talked about" information on QSR including design control procedures, management responsibility and requirements, complaint handling and medical device reporting and how to prepare for and host an FDA inspection. It also features in-depth coverage on regulatory requirements in China.

Two pre-conference workshops provide in-depth coverage on: 1) CAPA Warning Letter Prevention, and; 2) Complying with FDA and ISO Software Verification and Validation Requirements. The workshops, keynotes, case studies and interactive sessions are opportunities for you to gather the guidance you need from FDA, attorneys, manufacturing executives, compliance authorities and product development teams to build the essentials into your firm's effective quality system.

Key Deliverables:

- What to expect from FDA and worldwide regulatory bodies with regard to managing patient risk
- Common pitfalls inherent with many risk management programs
- Implement a complete life cycle approach to ISO 14971 and ISO 13485 and gain internal value
- Understand FDA enforcement actions including warning letters and certificates to foreign governments
- Comprehend what happens when the FDA sues: 1) the sign or sue letter; 2) settlement options; 3) consent decree/disgorgement
- Grasp the Federal Rules of Civil Procedures in litigation
- Medical Device Reporting Requirements: understand what is and isn't reportable and why
- Hear examples of effective medical device reporting activities
- How to avoid pitfalls in decision making criteria for what to report
- Methods to achieve compliance with the design control requirements of the QSR
- How to document design changes
- Understand design inputs and outputs — what to include and not to include
- Realize and communicate how QSR affects corporate strategy

WHO SHOULD ATTEND

Vice Presidents, Directors and Managers of:

- **Quality**
- **Regulatory Affairs**
- **Product Development**
- **Compliance**
- **Validation**
- **Reporting**
- **Corporate Counsel**

PRE-CONFERENCE WORKSHOPS

Tuesday, May 2, 2006

7:30-8:30	**Registration and Continental Breakfast**
8:30-11:30	**Complying with U.S. FDA and ISO Software Verification and Validation Requirements** *Dennis Rubenacker, Senior Partner, Noblitt & Rueland*
11:45-12:45	**Luncheon**
1:00-4:00	**CAPA Warning Letter Prevention** *John Malloy, Malloy and Associates, Inc.*
4:00	**Close of Workshops**

CONFERENCE DAY ONE

Wednesday, May 3, 2006

7:00	**Registration and Continental Breakfast**
8:00	**Welcome and Introduction** *Ernest Carabillo, Conference Chairperson*
8:15	**KEYNOTE:** **U.S. FDA's Outlook for Quality in Device Manufacturing** *Timothy Ulatowski, Director, Office of Compliance, Center for Devices and Radiological Health, U.S. FDA*
9:15	**Risk Management – A Complete Life Cycle Approach** *Harvey Rudolph, Ph.D., Global Program Manager-Medical Devices, Underwriters Laboratories, Inc.*
10:00	**Refreshment Break and Exhibit Viewing**
10:30	**Gaining Value From Implementing ISO 14971/Risk Management for Medical Devices – U.S. and Worldwide Expectations** *Scott Cohn, QA Compliance, Stryker Orthopaedics*
11:15	**Trends in Medical Device Reimbursement** *Jeffrey Bush, Corporate Director, Reimbursement, Becton, Dickinson and Company*
12:00	**Luncheon**
1:15	**Panel Session on Product Recalls**
2:15	**Lessons from Litigation: Utah Medical Products, Inc. and Good Manufacturing Practices** *Larry Pilot, Partner, McKenna Long & Aldridge*
3:15	**Refreshment Break**
3:45	**Everything You Need to Know About FDA Enforcement Actions** *Mark Brown, Partner, King & Spalding LLP*
4:45	**China Regulatory Compliance for Medical Device Companies – Challenges & Opportunities** *Chang-Hong Whitney, President, Whitney Consulting Limited*
5:30	**Networking Reception**

CONFERENCE DAY TWO

Thursday, May 4, 2006

7:00	**Continental Breakfast**
8:00	**KEYNOTE:** **The Six Ds of Design Control Compliance** *Georgia Layloff, Consultant*
9:00	**Design Inputs and Design Outputs** *Harvey Weintraub, Manager Design Control, System Development Core R&D, Abbott*
9:45	**Refreshment Break**
10:00	**Strategies for Effective Medical Device Reporting** *Mary Brady, Deputy Division Director, Division of Surveillance Systems, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, U.S. FDA* and *Debbie Yoder, Nurse Consultant, Reporting Systems Monitoring Branch, Center for Devices and Radiological Health, U.S. FDA*
10:45	**Medical Device Reporting: Problem-Solving Exercise in a Team Environment** *Mike Crader, Vice President Regulatory Affairs, Hill-Rom*
11:30	**Ensuring Success in Application Submission and Approval – Major Considerations in GCP, QSR and GLP** *Charma A. Konnor, R.Ph., RAC, Senior Manager/Consultant, Devices and Drugs, Phoenix Regulatory Associates, Ltd.*
12:15	**Close of Medical Device Quality Congress**

AM WORKSHOP

Complying with FDA and ISO Software Verification and Validation Requirements

Dennis Rubenacker, *Senior Partner,* ***Noblitt & Rueland***

Implementation of Software Verification and Validation (V&V) is important for ensuring the safety and reliability of medical device and manufacturing software. The U.S. FDA in 21 CFR Part 820 with related guidance and ISO 13485:2003 require Software V&V. Medical device manufacturers need to understand and address these quality system requirements. This workshop will focus on methods and strategies for applying appropriate and efficient software V&V strategies for a wide variety of software used by medical device manufacturers for the device, device production and implementation of the quality system.

What you will learn:

- FDA and ISO software V&V requirements
- FDA software guidance documents — impact on V&V strategies
- Manufacturing software requirements for V&V
- Software and risk management
- Requirements for 3rd Party and OTS software
- V&V documentation required for device submissions
- How to determine appropriate software V&V strategies

Benefits of Attending:

- Complying with FDA & ISO V&V requirements
- Reduce 510(k), IDE, PMA, CE Mark submission delays
- Implementing efficient V&V strategies
- Prepare for FDA inspections and ISO audits

Dennis Rubenacker *is co-founder and Senior Partner of the consulting firm of Noblitt & Rueland, specializing in FDA electronic recordkeeping, design control, risk assessment, software development and software quality management for the medical device industry. He has extensive experience dealing with product development, software development and software quality assurance for medical device instrumentation. Mr. Rubenacker has held software engineering, software quality assurance, electronics engineering, project management, and management consulting positions in the research and development of medical devices, aerospace systems, and consumer electronics.*

PM WORKSHOP

CAPA Warning Letter Prevention

John Malloy, ***Malloy & Associates, Inc.***

Examples of warning letters will be used throughout this workshop to help participants understand how to avoid receiving a warning letter and how to respond to one when received.

Understanding the CAPA requirements

- Overview of the requirements
- Different approaches to compliance

How to design your CAPA system

a. Process design
b. Communications methods

Inputs to CAPA

a. Nonconforming product
b. Complaints
c. Process monitoring
d. Environmental monitoring
e. Audits other quality data sources

Getting down to the specifics

a. Analysis
b. Investigation
c. Actions
d. Verification or validation
e. Notifications to personnel
f. Management communications
g. Documentation

John Malloy *is President of Malloy & Associates, Inc., a consulting firm specializing in quality systems that meet the U.S. FDA, ISO 9000, ISO 13485 and European Medical Device and In Vitro Diagnostic Directive requirements. He has more than thirty years of experience within the medical industry, having served as an FDA Investigator and having held industry management positions in manufacturing, regulatory, quality and marketing.*

PEOPLE ARE TALKING ABOUT THE MEDICAL DEVICE QUALITY CONGRESS...

"As a repeat attendee, I highly recommend this conference. The workshops, interactive sessions and insights from reputable speakers are very useful and applicable information to take back and share with my company and colleagues."

Heather Jalisi, Quality Assurance Manager, DexCom Inc.

"Compilation of insightful presentations, covering issues faced by every device manufacturer, presented by industry leaders."

Chris Lake, Manager Quality Assurance and Regulatory Affairs, Epimed International

FDA's Outlook for Quality in Device Manufacturing

Timothy Ulatowski, *Director, Office of Compliance, Center for Devices and Radiological Health, U.S. FDA*

The Office of Compliance, Center for Devices and Radiological Health at FDA, continues its efforts toward improving quality by focusing upon employees, processes, and its customers or stakeholders. Training and development of employees has transitioned to a coordinated effort to improve staff competencies at all levels. The internal quality system has been reinvigorated, and the agency is driving toward systematic, disciplined control of our processes. The office is constantly working to achieve better quality in and timeliness of its products. It has reorganized some key functions, focused its decisions based on critical data and risk analyses, and are optimizing its resources all in an effort to help ensure the public health. Mr. Ulatowski will provide an update on the FDA's outlook for quality in device manufacturing.

Timothy Ulatowski *is the Director, Office of Compliance, Center for Devices and Radiological Health. He manages four divisions tasked with promoting consumer health and safety, promoting product quality, and enforcing the medical device and radiological health laws and regulations. Mr. Ulatowski has been with FDA since 1974, and with the Office of Compliance since January 2003.*

The Six Ds of Design Control Compliance

Georgia Layloff, *Consultant, retired U.S. FDA Regional Field Medical Device Expert Investigator*

U.S. FDA has stated that the intrinsic quality of medical devices, including their safety and effectiveness, is established during their design phase. It is the U.S. FDA's stated belief that unless appropriate design controls are observed during preproduction stages of development, a finished device may be neither safe nor effective for its intended use. Learn effective methods to achieving compliance with the design control requirements of the Quality System Regulation.

Topics covered will include:

- Understanding the requirements and establishing procedures
- Documenting your efforts
- Using CAPA to your benefit
- Learning from the mistakes of others
- Effectively interacting with the FDA investigator

Georgia Layloff *is a subject matter expert consultant to the U.S. FDA, contributing to the development of web based training courses relating to medical device regulations and inspection techniques. She also provides consulting services to medical device firms with special emphasis on Quality System Regulation compliance strategies, design controls and FDA inspection techniques. She is a retired FDA regional field medical device expert investigator. She was a core member of the U.S. FDA's Quality System Inspection Technique (QSIT) team making significant contributions to various aspects of the project including development of the QSIT* Guide to Inspections of Quality Systems *and CD and web based training courses.*

Risk Management — A Complete Life Cycle Approach

Harvey Rudolph, Ph.D.

Global Program Manager - Medical Devices
Underwriters Laboratories, Inc.

There is no question that risk management is required in all major medical device markets. Regulatory authorities worldwide expect manufacturers not only to manage risks during the design phase, but also to apply risk management principles throughout the product life cycle. To accomplish this, manufacturers must utilize all of the quality data generated within their quality management system. Using ISO 14971 and ISO 13485 as models, this presentation will examine how to integrate risk management principles into a quality management system so that the complete life cycle approach to risk management can be realized. Common mistakes made as well as hurdles to overcome in accomplishing this will be discussed.

Gaining Value From Implementing ISO 14971/Risk Management for Medical Devices — U.S. and Worldwide Expectations

Scott Cohn

QA Compliance, ***Stryker Orthopaedics***

Risk management is rapidly gaining focus as an integral part of medical device design. Learn how to incorporate an effective risk management system into your design and development programs. This presentation will cover the expectations of the FDA as well as other worldwide regulatory bodies with regard to managing patient risk, as well as the common pitfalls inherent with many risk management programs. The information presented will help your organization not only meet industry expectations, but also discover how to gain internal value from an effective risk management system.

Lessons From Litigation: Utah Medical Products, Inc. and Good Manufacturing Practices

Larry Pilot

Partner, ***McKenna Long & Aldridge***

- Inspections and administrative follow-up
- Warning letters and certificates to foreign governments
- Suing the U.S. FDA
- When U.S. FDA sues
  - The "sign or sue" letter
  - Settlement options
  - Consent decree/disgorgement
- Litigation — federal rules of civil procedures
- Trial and opinion

Everything You Need to Know About FDA Enforcement Actions

Mark Brown

Partner, ***King & Spalding LLP***

- Types of FDA enforcement actions
- How to avoid enforcement actions
- What to do if you are the target of enforcement actions
- How to recover from FDA enforcement actions

China Regulatory Compliance for Medical Device Companies — Challenges & Opportunities

Chang-Hong Whitney
President, ***Whitney Consulting Limited***

With the growth of the Chinese medical device market, the Chinese government is tightening up its controls and regulations on the medical device products. The State Food and Drug Administration (SFDA) is the top government agency that formulates and implements policies and regulations for this industry. Since 1998, the SFDA has been gradually improving its regulations. The policy issued in Year 2000 formalized product registration, safety testing and management of medical device manufacturers. This seminar explores the SFDA functions and regulations that pertain to U.S. medical device manufacturers and their products on the Chinese market. The speaker will share her extensive experience and expertise in managing regulatory compliance, registration process, the challenges and opportunities in China. Topics will include product registration, type testing, labeling, industry standards, manufacturing compliance, vigilance, and other related subjects that affect medical products in China.

Participating Companies at Past Medical Device Quality Congresses

Davol Inc. ■ Genzyme Corporation ■ Integra LifeSciences Corporation ■ Medrad Inc. ■ Respironics ■ American Red Cross ■ McKenna Long & Aldridge ■ Buchanan Ingersoll ■ MEDMARC ■ LifeNet ■ Andersen Sterilizers ■ Ipas ■ IFUJU Photo Film ■ Pedicraft ■ GMP Companies ■ Medex ■ Reliance Medical Products ■ Cook Urological ■ Boston Scientific ■ MicroBiologics ■ Mallinckrodt Tyco Healthcare ■ CMS Inc. ■ Whiteside Biomechanics Inc. ■ Perkins Electronics ■ Alliance Medical Corporation ■ Karl Storz Endoscopy America ■ Amphastar Pharmaceuticals ■ Safety Syringes Inc. ■ ResMed Corp ■ Gen-Probe Inc. ■ DexCom ■ Plus Orthopedics ■ Medimexico ■ Guidant Corporation ■ Endologix ■ B Braun Medical ■ Quintiles ■ Synergy Biomedical ■ Abbott Laboratories ■ Micrus Corporation ■ Biorad Laboratories ■ Insound Medical ■ Bayer Diagnostics ■ Dow Pharmaceutical Sciences ■ Welch Allyn ■ ResMed Australia ■ Orion Canada ■ GlaxoSmithKline Canada ■ Xillix Technologies Corp Canada ■ Inion Oy Finland ■ Aventis Germany ■ AB Biodisk Sweden ■ Unipath Ltd UK ■ MacroPore ■ DexCom ■ ALARIS ■ Medtronic ■ Baxter ■ Sybron ■ LabNow ■ Gambro BCT ■ Nelson Laboratories ■ Diagnostic Products Corporation ■ Blue Sky Medical ■ Breg Inc. ■ Smiths Medical ■ Medrad ■ Medical Graphics ■ Nanosphere ■ Becton, Dickinson and Company ■ Stryker ■ Philips Medical Systems ■ Biogen Idec ■ Johnson & Johnson ■ Medrad ■ Neuronetics ■ Celgene Cellular Therapeutics ■ ApoPharma ■ sanofiaventis ■ Ansell Kedah Sdn Bhd ■ Steris Corporation ■ Reliance Medical Products ■ Terumo Heart ■ Kyphon ■ Affymetrix ■ Sciemetric Instruments ■ TM Bioscience

Design Inputs & Design Outputs

Harvey Weintraub
Manager Design Control, System Development Core R&D, ***Abbott***

- Who the customer is
- Definition of Design Inputs and what else to include
- Definition of Design Outputs and what else to include

Strategies for Effective Medical Device Reporting

Mary Brady
Deputy Division Director, Division of Surveillance Systems, Office of Surveillance and Biometrics, ***Center for Devices and Radiological Health, U.S. FDA*** and
Debbie Yoder
Nurse Consultant, Reporting Systems Monitoring Branch, ***Center for Devices and Radiological Health, U.S. FDA***

- Explanation of MDR requirements
- What is and isn't reportable and why?
- Key terminology
- Examples of effective MDR activities
- How to avoid pitfalls in decision-making criteria for what to report
- The risks of failing to report
- When and how FDA communicates with foreign governments

Medical Device Reporting: Problem-Solving Exercise in a Team Environment

Mike Crader
Vice President Regulatory Affairs, ***Hill-Rom***

Utilizing problem-solving exercises in a team environment, attendees will learn to apply their technical expertise in the application of Medical Device Reporting principles to real life examples. Attendees will be challenged to understand issues that commonly face industry, such as:

- Determining user error, misuse, or abuse
- Timely reporting and when the clock starts ticking
- Serious injury and what is meant by medical or surgical intervention
- How many reports to file for multiple incidents, multiple products used in an incident, or multiple products implicated in an incident

Ensuring Success in Application Submission and Approval — Major Considerations in GCP, QSR and GLP

Charma A. Konnor, R.Ph., RAC
Senior Manager/Consultant, Devices and Drugs, ***Phoenix Regulatory Associates, Inc.***

Key points for success in application submission and approval. How to avoid pitfalls and systemic mistakes that can lead to failure, such as:

- No application approval
- Delay in approval
- Application integrity problems

Thanks to Our Sponsoring Companies

CAMSTAR

Sparta Systems, Inc.
Quality Management Solutions

Do you have a product or service that benefits medical device companies? Here is the place to meet your market...

Here's a golden opportunity to meet the people who buy your products and services, far from the distractions of email, phones and day-to-day responsibilities.

You'll have their attention for two full days as you demonstrate your wares and capabilities. Your tabletop display is located in the area where all continental breakfasts, breaks and cocktail receptions are held. In this intimate setting, there are no bad locations.

Registrations and sponsorships are still available at affordable rates. For details, contact J.T. Hroncich, Sales Director, at 888-838-8578 or 1-703-538-7643 or jhroncich@fdanews.com.

Dates

The conference will be held May 2-4, 2006. Registration and continental breakfast begin at 7:00 am. Sessions begin at 8:00 am on Wednesday, May 3, and conclude at 12:15 pm on Thursday, May 4. Pre-conference workshops are offered Tuesday, May 2, 8:30 am -11:30 am (Software Validation and Verification) and 1:00 pm-4:00 pm (Preventing CAPA Warning Letters). Registration and breakfast begin at 7:30 am.

Venue and Hotel Accommodations

The conference will be held at the Paradise Point Resort and Spa, 1401 West Vacation Road, San Diego, CA 92109. Please call 800-344-2626 and be sure to mention that you will attend the Medical Device Quality Congress. A limited block of rooms is available at our group rate of $175/night until March 31, 2006. Please reserve early to ensure your room.

Program Fees

2 day conference only $1695
2 day conference plus 1 half day workshop. $2090
COMPLETE PACKAGE SAVINGS:
2 day conference plus 2 half day workshops. . . . $2295
1 half day workshop (stand alone) $695
2 half day workshops (stand alone) $1190

Team Discounts

Groups of 3-4 may deduct $100 per person. Groups of 5-10 may deduct 15%. Groups of 11 or more may deduct 20%.

No-Risk Guarantee

Your satisfaction is 100% guaranteed — money back or credit. If you are not satisfied with the quality of this program, let us know in writing and we'll refund your registration fee.

Cancellations/Substitutions

You may send a substitute attendee in your place at any time with no penalty (please inform us in advance if possible). Cancellations made within 5 business days are subject to a $200 cancellation fee or the full fee can be credited toward a future purchase. No-shows are liable for the full fee.

About The Management Roundtable

The Management Roundtable

The Management Roundtable, Inc. (MRT) is the leading knowledge and networking resource for product developers. Practitioner-oriented and unbiased, our focus is on providing actionable about new innovations, processes, tools, and technologies that improve quality and regulatory compliance and enable faster time to market, increased profitability, and overall competitive advantage.

Founded in 1980, Management Roundtable produces newsletters, conferences, workshops, audio sessions and onsite training. Its premium web-based service, Knowledge Roundtable, was launched in 2004 to advance product development, innovation and collaboration.
www.managementroundtable.com

About FDAnews

FDAnews

FDAnews is the premier provider of domestic and international regulatory, legislative and business news and information for executives in industries regulated by the U.S. FDA and The European Medicines Agency. Medical device and pharmaceutical professionals rely on FDAnews' print and electronic newsletters, books and conferences to stay in compliance with international standards and FDA's complex and ever-changing regulations.
www.fdanews.com

FOUR WAYS TO REGISTER:

CALL: **1-800-338-2223 or 781-891-8080** (weekdays, 9:00am-5:30pm EST)
Fax: **781-398-1889**
Internet: **www.managementroundtable.com**
Mail to: **Management Roundtable, 92 Crescent Street, Waltham, MA 02453**

☐ **Yes! Register me for the Medical Device Quality Congress**
(please use photocopies for additional people)

Select the events you plan to attend:

Pre-Conference Workshop (May 2, 2006)

☐ **A. Software Validation and Verification** (half day AM)
☐ **B. CAPA Warning Letter Prevention** (half day PM)
☐ **Conference (May 3-4, 2006)**

Total fee *(See page 7 for pricing)* $ _____

Name Mr./Ms. _____

Title _____

Company _____

Division/Dept _____

Address _____

City/State/Zip _____ Country _____

Phone _____ Fax _____

Email _____

Payment information

☐ Check enclosed, payable in US funds to Management Roundtable
☐ Please bill my
☐ VISA ☐ Mastercard ☐ AMEX ☐ Diner's Club

Card No. _____ Exp. Date _____

Name as it appears on card _____

Signature _____

☐ Please bill my company. PO# _____

THIRD ANNUAL

Medical Device Quality Congress

Leading the Way to Better Performance with Quality Systems Compliance

May 2-4, 2006
San Diego, CA

Come to San Diego to learn how to overcome regulatory challenges and align quality with corporate strategy

PRSRT STD
U.S. Postage
PAID
Tampa, FL
Permit No. 3311

Registration Code: Web Download