Second Annual

Medical Device Quality Congress

April 5–7, 2005
San Diego, CA

Expert Strategies for Global Compliance

- ***Preferred techniques for addressing FDA inquiries and observations***
- ***Critical insight into hot-spots cited in recent FDA warning letters***
- ***Steps to compliance with European regulatory (CE Marking) requirements; including developing technical files and ISO 13485:2003***
- ***Valuable explanation of FDA's Application Integrity Policy***

KEYNOTE PRESENTATIONS

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

Julio Rivera
Senior Vice President,
Corporate Compliance,
Medrad, Inc.
Medrad received the Malcolm Baldrige Quality Award in 2003

Chris Chavez
President and CEO,
Advanced Neuromodulation Systems, Inc.

HOSTED BY:

The Management Roundtable
FDANews

PRE-CONFERENCE WORKSHOPS

CAPA: Management and Executive Responsibility
Back by Popular Demand with **John Malloy!**

Software Validation
New! From **Qualified Data Systems,** a division of BioTeknica

www.ManagementRoundtable.com 800 338 2223

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— Expert Strategies for Global Compliance —

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Who Should Attend

Vice Presidents, Directors and Managers of:

Quality
Regulatory Affairs
Product Development
Compliance
Validation
Corporate Counsel

About 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 information about new innovations, processes, tools, and technologies that enable faster time to market, increased profitability, and overall competitive advantage.

Founded in 1980, Management Roundtable publishes newsletters, hosts a variety of specialized conferences, workshops, and audio-sessions and conducts onsite training. Its premium web-based service, Knowledge Roundtable, was launched in 2004 to advance product development, innovation and collaboration. This service offers continuous, unlimited access to competitive insights and facilitates introductions among industry practitioners for benchmarking and partnering. **www.managementroundtable.com**

About 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. Food and Drug Administration and The European Commission. 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**

Participating Companies at the First Annual Medical Device Quality Congress

Davol Inc. ■ Genzyme Corporation ■ Integra LifeSciences Corporation ■ Medrad, Inc. ■ Respironics ■ American Red Cross ■ McKenna Long & Aldridge ■ Buchanan Ingersoll ■ MEDMARC ■ LifeNet ■ Andersen Sterilizers ■ Ipas ■ Fuji 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-Prob Inc. ■ DexCom ■ Plus Orthopedics ■ Medimexico ■ Guidant Corporation ■ Endologix ■ B Braun Medical ■ Quintiles ■ Synergy Biomedical ■ Abbott Labs ■ 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

Do You Have a Product or Service that Benefits Medical Device Companies? Here Is a 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) 838-5578 or 1 (703) 538-7643 or jhroncich@fdanews.com.

AGENDA

DAY ONE / TUESDAY, APRIL 5, 2005

7:30	Registration and continental breakfast
8:30 – 11:30	WORKSHOP A: *CAPA: Management and Executive Responsibility* **John Malloy**, **John Malloy and Associates**
11:45 – 12:45	Luncheon
1:00 – 4:00	WORKSHOP B: *Software Validation* **Armin Torres**, Principal, **Qualified Data Systems** (a division of BioTeknica)
4:00	Conclusion of Day One

DAY TWO / WEDNESDAY, APRIL 6, 2005

7:30	Registration and Continental Breakfast
8:30	Chairman's Welcome and Opening Remarks – Ernest Carabillo
8:45	KEYNOTE: *FDA's Outlook for Quality in Device Manufacturing* **Timothy Ulatowski**, Director, Office of Compliance, Center for Devices and Radiological Health, **U.S. FDA**
9:45	*Strategies to Prepare for and Survive an FDA Inspection* **Mark Brown**, Partner, **King & Spalding LLP**
10:30	Refreshment Break
10:45	*How to Comply with the CE Marking Directive Including ISO 13485* **Rene van de Zande**, **Emergo Group, Inc.**
11:30	*What's New in Europe?* **Maarten Meuhlenbelt**, Partner, **NautaDutilh**, Brussels, Belgium
12:15	Luncheon
1:30	Interactive Roundtable Discussions: *Responding to 483s* **Jim Kozick**, Principal Consultant, Regulatory and Compliance Services, **PAREXEL Consulting**
3:30	Refreshment Break
3:45	KEYNOTE: *Quality and Integrity in a High-Tech, Innovative Environment* **Chris Chavez**, President and CEO, **Advanced Neuromodulation Systems, Inc.**
4:30	*A Process Approach to Quality* **Kenneth Kopesky**, Vice President, Corporate Compliance and Audit, **Medtronic, Inc.**
5:15	Networking Reception

DAY THREE / THURSDAY, APRIL 7, 2005

8:00	Continental Breakfast
9:00	KEYNOTE: *Medrad's Performance Excellence Journey* **Julio Rivera**, Senior Vice President, Corporate Compliance, **Medrad, Inc.**
10:00	*Risk or Risky Management of Your Clinical Studies?* **Charma Konnor**, Senior Manager/Consultant, Devices and Drugs, **Phoenix Regulatory Associates, LTD.**
10:45	Refreshment Break
11:00	*How to Gain Optimal Value from and Overcome the Inherent Problems of Internal Audits* **Russ Davies**, Vice President, Regulatory Affairs and Quality Systems, **Smiths Medical**
11:45	*Measuring the Effectiveness of Your Quality System* **Cecilia Kimberlin**, Group Vice President of Quality Assurance and Compliance, **Abbott Laboratories, Medical Products Group**
12:30	Conclusion of Conference

KEYNOTES

FDA's Outlook for Quality in Device Manufacturing

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

Mr. Ulatowski 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. Prior to his recent appointment he was Director, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices. He served as the U.S. government representative for Study Group 1 (Premarket) of the Global Harmonization Task Force and on several cross-cutting FDA committees dealing with such topics as reuse of single use devices, user fee implementation, and international standards implementation.

Medrad's Performance Excellence Journey

Julio Rivera
Sr. Vice President, Corporate Compliance
Medrad, Inc.
Medrad won the Malcolm Baldrige Quality Award in 2003

Mr. Rivera is responsible for refining Medrad's performance having joined Medrad in 1998 with the responsibility for all quality assurance and regulatory affairs activities for new product development, suppliers and manufactured products, along with the responsibility for regulatory compliance. He has held positions with Sherwood Davis and Geck, and Baxter Health Care. He specialized in directing quality assurance and regulatory affairs with primary focus in international operations. He was responsible for a number of locations world wide, including Europe, Latin America, the Pacific Rim, Central America, and the Far East, with pharmacy operations in Mexico, Brazil and Puerto Rico. Mr. Rivera's international accomplishments include the successful startup of an LVP manufacturing operation in China and a joint venture operation in Indonesia.

Quality and Integrity in a High-Tech, Innovative Environment

Chris Chavez
President and CEO
Advanced Neuromodulation Systems, Inc.

Mr. Chavez joined Advanced Neuromodulation Systems as president, chief executive officer, and director in April 1998. Mr. Chavez has extensive leadership experience and has served with several Fortune 500 companies in the medical device industry. In his sixteen years with Johnson & Johnson Medical, Inc., a major division of Johnson & Johnson, he progressed through several positions in finance, strategic planning, domestic and international marketing, new business development, and general management to the position of vice president and general manager of the infection prevention business unit, one of four worldwide business units with approximately half a billion dollars in sales.

PRE-CONFERENCE WORKSHOPS

WORKSHOP A

CAPA: Management and Executive Responsibility

John Malloy
John Malloy and Associates

- *Understanding the CAPA requirements*
  a. Overview of the requirements
  b. 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
  f. 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

WORKSHOP B

Software Validation

Armin Torres
Principal
Qualified Data Systems, A Division of BioTeknica

- *Understanding software validation*
  a) Defining the scope
  b) Understanding impact to the business
  c) Understanding the systems-engineering perspective
- *Executing a master plan*
  a) Developing and maintaining an applications portfolio
  b) Assessing the need for validation
  c) Defining a risk-based approach to prioritize validation efforts
  d) Identifying the impact of 21 CFR Part 11 on the validation efforts
- *Implementing a robust validation methodology*
  a) Using a life cycle approach
  b) Defining the essential set of supporting processes and procedures
  c) Evaluating cost and resource requirements
  d) Developing a cost-effective approach to execution
- *Implementing compliance strategies for remediation of computer systems*
  a) Performing gap assessments
  b) Using the six-sigma approach for problem solving
  c) Identifying the hidden costs in remediation
  d) Implementing corrective and preventive measures
  e) Monitoring for effectiveness

PRESENTATIONS

Strategies to Prepare for and Survive an FDA Inspection

Mark Brown
Partner
King & Spalding LLP

- FDA's authority to conduct inspections
- Understanding your rights
- Knowing your responsibilities
- Types of FDA inspections
- How to manage inspections and resolve disputes
- How FDA uses information collected during inspections
- Potential consequences after an inspection
- Inspection dos and don'ts

CE Marking for Medical Devices—Basic Steps to Compliance and Regulatory Update

Rene van de Zande
President & CEO
Emergo Group

The objective of this presentation is to (1) provide a succinct overview and explanation of all relevant issues with regard to the European regulatory (CE Marking) medical devices requirements, including developing and managing technical files; labeling, risk management, vigilance and post-market surveillance, and quality management systems in accordance with ISO 13485:2003; and (2) provide an update on the proposed amendments to the Medical Device Directive 93/42/EEC.

What's New in Europe

Maarten Meuhlenbelt
Partner
Emergo Group, Inc.

- Product Liability: Trends in product liability litigation in EU member states. Are courts getting stricter? How do QA and QC compliance affect the manufacturers' position?
- Purchasing and Reimbursement Trends: Prices of pharmaceutical product have been squeezed by central purchasing and national reimbursement systems. Are medical devices going the same way? What scope do national governments have to express preferences for particular brands or manufacturers?
- Trade and Distribution in an Enlarged EU: The enlargement of the EU from 15 to 25 countries in May 2004 has significantly affected trade in medical devices. A closer look at the impact of varying levels of patent protection, distribution systems and parallel imports.
- Better Safe Than Sorry: How the EC Court of Justice has been applying the "precautionary principle" regarding product approvals—and its impact on medical devices.

Responding to 483s

Interactive Roundtable Discussions facilitated by
Jim Kozick, Principal Consultant, Regulatory and Compliance Services, **PAREXEL Consulting**

A brainstorming and problem-solving session in which meeting participants are pre-assigned into groups of 8 to 10 executives. After initial instruction, each group works through a case study scenario on steps to take when a warning letter is received. The following topics will be included in the lecture and roundtable discussions:

- Elements of a good 483 response
- Pitfalls to avoid when responding to 483s
- FDA's review process for 483 responses
- What to expect following a 483 response

Risk or Risky Management of Your Clinical Studies?

Charma Konnor
Senior Manager/Consultant, Devices and Drugs
Phoenix Regulatory Associates, LTD

Risk management is essential to the conduct and oversight of clinical studies. Important components of risk management are study monitoring and auditing, to help achieve successful FDA review of your application. Conversely, risky management can lead to data integrity problems and major hurdles to obtaining FDA approval. FDA's Application Integrity Policy is explained, and examples of risky management and consequences are provided.

How to Gain Optimal Value from and Overcome the Inherent Problems of Internal Audits

Russ Davies
Vice President Regulatory Affairs and Quality Systems
Smiths Medical

The session will cover the inherent problems with treating internal quality system audits as "paperwork exercises" only. Audits should challenge the internal systems and procedures against the regulatory requirements and best practices. It is important to get the information that you need from the audit process even though there may be barriers to achieving this. The session will cover various techniques and approaches that may be used to overcome these types of issues, and enable the organization to use the audit process as an important management tool as part of its overall "health check" process. The session will also discuss auditing across a multi-site operation.

Measuring the Effectiveness of Your Quality System

Cecilia Kimberlin, Ph.D.
Group Vice President of Quality Assurance and Compliance
Abbott Laboratories, Medical Products Group

This presentation will address the challenges of evaluating current quality systems, redesigning them and implementing changes. Walk away with knowledge on how to measure effectiveness and compliance.

16 Key Benefits

You Will Learn:

1. *How risk management including study monitoring and auditing can help you achieve successful FDA review of your application*
2. *Examples of how "risky" management of clinical studies can lead to data integrity problems and hurdles to FDA approval*
3. *Trends in product liability litigation in EU member states*
4. *Impact of varying levels of patent protection, distribution systems and parallel imports on how medical devices are sold in the EU*
5. *Strategies to prepare for and survive an FDA inspection*
6. *How FDA uses information collected during inspections*
7. *About your rights and responsibilities at an FDA inspection and how to best resolve disputes*
8. *Ways to measure effectiveness and compliance of your quality system*
9. *How to implement changes to your quality systems*
10. *How to tie the pieces together and think about your quality system from a process-minded vantage point*
11. *A step-by-step approach to responding to a 483*
12. *Troubleshooting—how to minimize your risk of receiving a warning letter*
13. *Techniques to stop treating your internal audit as a "paper exercise" only*
14. *Ways to harness internal audits to get the information you need to measure internal procedures against regulatory requirements and best practices*
15. *How to design and implement an effective CAPA system*
16. *How to implement software validation and identify the impact of 21 CFR Part 11 on validation efforts*

Conference Faculty Highlights

MARK BROWN
Partner, King & Spalding LLP
Former Associate Chief Counsel for Enforcement in the Office of General Counsel for the FDA.

ERNEST CARABILLO, Conference Chair
Founder, EXPERTech
In addition to founding EXPERTech, Ernest has served in management positions at Baxter Healthcare and C.R. Bard.

RUSS DAVIES
Vice President, Regulatory Affairs and Quality Systems, Smiths Medical
Russ has led the implementation of several quality management systems to meet European and US regulatory requirements.

CECILIA KIMBERLIN, Ph.D.
Group Vice President of Quality Assurance and Compliance, Abbott Laboratories, Medical Products Group
Cecilia provides quality, regulatory and compliance oversight and strategic direction for the Medical Product Group businesses.

KENNETH KOPESKY
VP Corporate Compliance and Audit, Medtronic, Inc.
Ken's responsibilities include managing the overall compliance of quality, regulatory and clinical activities through establishment of initiatives and compliance auditing.

CHARMA KONNOR
Senior Manager/Consultant, Devices and Drugs, Phoenix Regulatory Associates, LTD
Directed regulatory and compliance issues for 25 years at the FDA.

JIM KOZICK
Principal Consultant, Regulatory and Compliance Services, PAREXEL Consulting
Enjoyed a 29-year career with the FDA in the Los Angeles District.

JOHN MALLOY
John Malloy and Associates
Internationally recognized expert consultant formerly with FDA.

MAARTEN MEUHLENBELT
Partner, NautaDutilh, Brussels, Belgium
Maarten has extensive litigation experience in the EC Commission. He is recommended in European Counsel's Life Sciences Industry Report.

ARMIN TORRES
Principal, Qualified Data Systems, a division of BioTeknica
Amin has led total quality management of in-process quality control inspection and has developed process validation standards and training programs.

RENE VAN DE ZANDE
President and CE, Emergo Group
Rene specializes in the regulatory issues confronting manufacturers and distributors of medical devices and in-vitro diagnostics desiring to export their products to Europe or North America.

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REGISTRATION

CONFERENCE

INFORMATION

FOUR WAYS TO REGISTER:

CALL: **1-800-338-2223** or **781-891-8080** (weekdays, 9:00am – 5:30pm EST)

FAX TO: **781-398-1889**

INTERNET: **info@roundtable.com** or **www.ManagementRoundtable.com**

MAIL TO: **Management Roundtable**, 92 Crescent Street, Waltham MA 02453

SELECT YOUR CONFERENCE WORKSHOP PACKAGE:	Before 12/30/04	After 12/30/04
COMPLETE PACKAGE – BEST VALUE:		
☐ **2-day conference + both half-day pre-conference workshops**	$2095	$2295
☐ **2-day conference + 1 half-day pre-conference workshop** Select: ☐ ***CAPA*** (am) or ☐ ***Software Validation*** (pm)	$1895	$2095
☐ **2-day conference only**	$1495	$1695
☐ **1 half-day workshop** (stand-alone) Select: ☐ ***CAPA*** (am) or ☐ ***Software Validation*** (pm)	$695	$695
☐ **Both half-day workshops** (stand-alone)	$1190	$1190

Name Mr. / Ms. / Dr. _____

Title _____

Company _____

Division/Dept. _____

Address _____

City/State/Zip _____

Phone _____ Fax _____

Email _____

PAYMENT INFORMATION (Amount $_____)

☐ Check enclosed, payable in US funds to *Management Roundtable, Inc.*

☐ Please bill by ☐ Visa ☐ Mastercard ☐ AMEX ☐ Diner's Club

Account # _____ Exp. Date: _____

Name as it appears on the card _____

Signature _____

☐ Please bill my company PO# _____

Registration Code: Web Download

DATES:

Pre-conference workshops begin at 8:30 a.m. (registration and continental breakfast at 7:30a.m.) on Tuesday, April 5 and close at 4:00p.m. The conference will begin at 8:30 (registration and continental breakfast at 7:30a.m.) on Wednesday, April 6 and will adjourn at 12:30p.m. on Wednesday, April 7.

LOCATION AND HOTEL ACCOMMODATIONS:

The conference will be held at the Hyatt Regency Islandia, Hotel and Marina, 1441 Quivira Road, San Diego, CA 92101. Please call 800-233-1234 or 619-224-1234 directly for room reservations and be sure to mention the Medical Device Quality Congress. A limited block of rooms is available for $179 a night until 3/14/2005.

NO RISK GUARANTEE:

Your satisfaction is 100% guaranteed –money back or credit. If you're 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 administration fee. No-shows are liable for the full fee.

TEAM DISCOUNTS:

Groups of 3 or more may deduct $100 per person. Groups of 6 or more, please call 800-338-2223 for special pricing.

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Get the Latest Quality and Regulatory Intelligence Directly from These Key Players

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Advanced Neuromodulation Systems, Inc.

Russ Davies, *VP, Regulatory Affairs and Quality Systems,*
Smiths Medical

Cecilia Kimberlin, *Group VP of Quality Assurance and Compliance,*
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