



How can spending just a few days away from the office provide immediate benefit to your company, its products and your career?

The MD&M West Conference delivers all the information needed to develop both innovative and next-generation medical products within a robust quality management system.

This is the premier conference program for research and development, design, engineering, quality, manufacturing, and regulatory affairs professionals within the medical device industry. Our mission is to provide our audience with application-oriented information, original content and the most valuable networking opportunities.

So whether you are looking for a refresher, or wishing to expand your knowledge and skills to meet a specific project challenge or further your career, our 5 track program allows you to tailor a program which meets your specific educational needs. In fact you will see that our conference offers 20 day-long conferences over 4 days! Our great booking rates mean the more days you book, the more you save.

Attend MD&M West 2012 conference to learn:

- ◆ How today's pre- and post-market FDA regulation, guidance documents, and increased enforcement activities will affect your products
- ◆ Ways to navigate tougher requirements for international medical device approval
- ◆ Managing supplier controls requirements as your partnerships continue to grow
- ◆ Best practices for manufacturing for and within emerging markets
- ◆ New materials, prototyping, and other enabling technologies
- ◆ How innovation and regulatory changes impact the technology development process

As a conference attendee you will have full access to digital presentations of the sessions within your registered track, as well as extended refreshment and lunch breaks to allow you plenty of time to network with your colleagues and peers, but also providing you time to visit the extensive MD&M Exposition.

Take a look at the enclosed conference program to see this year's finely-tuned topics and industry-leading speakers, and don't delay in booking your place. Take advantage of our early booking rates and save up to \$220.

Join us this February, and we guarantee you will walk away with information you can immediately apply to boost job performance.

Conference Sessions Offered

Monday, February 13

- ◆ Preparing Successful Submissions
- ◆ Process Validation
- ◆ A New Era of Supplier Controls
- ◆ Advances in Medical Polymers
- ◆ New Human Factor Requirements

Tuesday, February 14

- ◆ Product Clearance & Quality Systems
- ◆ Design Control Principles
- ◆ Risk Management
- ◆ Move from Good to Great Design
- ◆ Working with Modern Materials

Wednesday, February 15

- ◆ FDA Revelations
- ◆ Product Design Tools
- ◆ Risk Management
- ◆ Product Development & the FDA
- ◆ Medical Devices with Batteries

Thursday, February 16

- ◆ Balancing Your Product Portfolio
- ◆ Product Life Cycle Management
- ◆ Global Quality Management
- ◆ Medical Device Reliability Testing
- ◆ Product Sterilization Selection



Top 5 Reasons To Attend The MD&M West Conference

Real-life warning letters and 510(k) submissions examples presented by FDA representatives—learn what works and what doesn't to ensure that your products are compliant

Network with your true industry peers—a high medical device manufacturer to sponsors ratio means you meet your industry counterparts

Tailor the agenda to meet your specific needs—20 different day long tracks are offered at MD&M West—no where else will you get this volume of information. Attend the sessions that are relevant to you. Session hopping is allowed so that you maximize your day!

Gain tactical insight into how FDA and global regulation affects your daily responsibilities and **what to do about it now**

Take the learning back to the office. Your registration provides you to access to presentations for the sessions you attend. MD&M focuses on tactical solutions to your daily issues – use the presentations for reference when you get back to the office!



Conference: **February 13–16, 2012**

Exposition: **February 14–16, 2012**

Anaheim Convention Center
Anaheim, CA



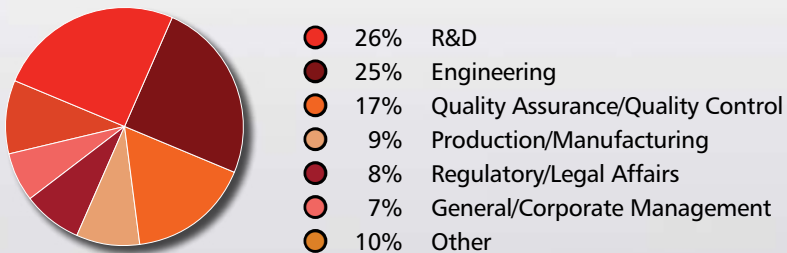
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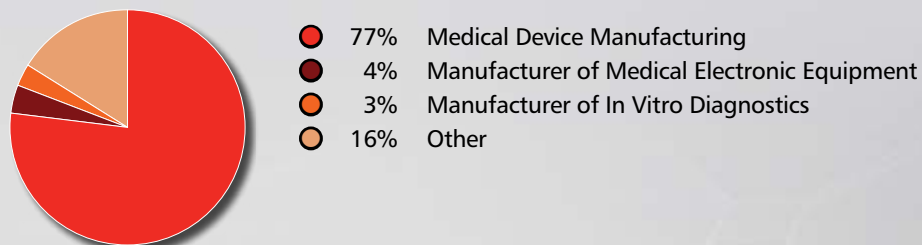
Who Attends the Conference?

R&D, product development, design, engineering, manufacturing, QA, QE and regulatory professionals within the medical device industry

Attendees by Job Function



Industry Breakdown



Event Updates:



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MD&M West Exposition

Find hundreds of world-class suppliers featuring medical-grade materials, automation solutions, design services and more. The exposition also features dozens of supplier technology presentations throughout the three days.

Find complete details, presentation abstracts and easy online registration at

MDMWestConference.com

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Program Agenda—Your Educational Resource for Better Product Development

Monday, February 13 Sessions run from 9:00 A.M. to 4:00 P.M. with an hour lunch break

Preparing Approvable Submissions in Today's Challenging Regulatory Environment – Experts' Tips for Success

Chair: *Richard DeRisio, Divisional Vice President, Regulatory Affairs, Abbott Medical Optics, Inc.*

Meeting FDA's Expectations for High-Quality Submissions: *Christy Foreman, Director, Office of Device Evaluation, FDA Invited*

Achieving the Gold Standard in 510(k) Submissions: *April Veoukas, Director, Regulatory Affairs, Abbott Laboratories*

Rating Deficiency Letters: Assessing regulatory body requests for additional information as a continuous improvement tool: *Richard DeRisio*

How to Optimize Interaction with Your Notified Body: *Jeff Schakenraad, Team Manager US, DEKRA*

Practical Examples of Managing a Submissions Process in Times of Change and Uncertainty: *Michael Morton, Senior Director, Global Regulatory Affairs, Medtronic, Inc.*

How to Navigate FDA's Revised Device Modifications Guidance for Medical Devices: *Christy Foreman*

How Industry is Adapting to the Changes under 510(k) Reform: *April Veoukas and Richard DeRisio*

Speaker panel: *Faculty*

Session: 100

Process Validation: Solutions and Strategies for the Medical Device Industry

Instructor: *Vinny Sastri, PhD, President, Winovia LLC*

Morning:

- FDA Quality System Regulations and Process Validation
- Validation Planning and Validation Master Plans
- Process Validation and Design Control
- Risk Analysis
- Validation and Verification
- Installation Qualification (IQ)

Afternoon:

- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Statistical Tools and Techniques
- Sampling Plans
- Process Control
- Maintaining a Validated State
- Validation Life Cycle
- Documentation, Protocols, Reports and Reviews

Session: 101

Adapting to a New Era of Supplier Controls

Chair: *Steve Niedelman, Lead Quality System & Compliance Consultant, King & Spalding LLP*

FDA Update: Agency feedback and GHTF model: *Melissa Torres, OC, CDRH, FDA*

Managing Supplier Quality in Multinational Corporations: *Craig Nelson, Corporate Purchasing Controls Manager, Stryker*

Supplier Quality Agreements: Structure, enforcement, change control, and SCARS: *Mike Buffington, Executive, Supply Chain Quality, GE Healthcare*

How to Work with a Supplier in an Emergency Situation: *Baxter invited*

What This Means to Suppliers: a Contract Manufacturers Perspective: *Mark McElfresh, Plant Manager, PDS Rockford, The Tech Group*

Enforcement Actions and Warning Letter Examples: *Steve Niedelman*

In Association With: 

Session: 102

Adhering to New Human Factors Requirements

Instructors: *Robert North, Chief Scientist, Human Centered Strategies and Ed Israelski, Program Manager, Human Factors, Abbott Laboratories*

- Overview of FDA's New Human Factors Guidance
- Guidance Workshop I: Preliminary Analysis of User Requirements and Use Related Risks
- Guidance Workshop II: Formative Evaluations and Testing
- Standards Review: Overview of HE-75 and IEC 62366--How do we comply?
- Guidance Workshop III: Validation Testing Essentials for FDA Human Factors Pre-Market Approval

Session: 103

Advances in Medical Polymers for Medical Devices

Co-Chairs: *Margie Hanna, Czuba Enterprises, Inc. and Peter Colburn, Director, Business Development, Innovation & Technology, Evonik Cyro LLC*

Polyolefins for Blow-Fill-Seal Pharmaceutical Packaging: A case study: *Jill Martin, Senior Development Engineer, Dow Chemical Company*

Processing Considerations for Bioresorbable Polymers in Medical Applications: *Lothar Kleiner, Volwiler Associate Research Fellow Abbott Cardiovascular*


Exciting New Extruded Tubing Materials for Medical Applications: *Ed Boarini, Sr. VP and General Manager, Teleflex Medical OEM*

Device Related Hospital Acquired Infections and a Novel Next Generation Antimicrobial Technology: *Arjun Srinivas, CEO, Innova Dynamics*

The Production and Use of Supported Nano-silver Particles in Polymer Systems: *Matt Gande, Principal Technology Specialist II, Medical Device, BASF*

Responsible Approach to Antimicrobials and Materials: *Peter Colburn*

Modification of Silicone Chemistry and its Influence on Release Rates of Active Pharmaceutical Ingredients (APIs): *Brian Reilly, Product Director, Healthcare Materials, NuSil Technology9*

In Association With: 

Session: 104

Tuesday, February 14 Sessions run concurrently from 9:00 A.M. to 4:00 P.M. with an hour lunch break

Morning: CDRH Top Headquarter Officials Discuss Product Clearances and Quality System Compliance for 2012

Moderator: *Nancy Singer, President, Compliance-Alliance, LLC*

Interacting with FDA: *William Sutton, Deputy Director, DSMICA, FDA*

Products Clearances: *Christy Foreman, Director, ODE, FDA*

Complying with the Quality System Regulation: *Melissa Torres, OC, CDRH, FDA*

Afternoon: Activities in the FDA's LA District

Moderator: *Helene Spencer, ClinReg Consulting Services, Inc.*

FDA, Los Angeles District - An Update: *Alonza Cruse, Los Angeles District Director, FDA*

How the LA District is implementing FDA's New Import Program: *Dan Solis, Director of Import Operations, FDA Los Angeles District*

Avoiding Serious Mistakes in Your Quality and Regulatory Records: *Nancy Singer*

In Association With: 

Session: 200

Integrating Design Control Principles into Process Validation

Instructor: *W. Heath Rushing, Principal Consultant, Adsurgo LLC*

This course will demonstrate how you can efficiently integrate design control principles into your quality management system to achieve the desired results:

- Compliance with current regulatory guidance
- Enhanced knowledge of product performance and process variation
- A basis for risk management, process validation, and a control strategy resulting in a product with the desired quality

Learn how to:

- Implement design control principles from discovery through product discontinuation
- Apply statistics to set specifications and validate measurement systems
- Utilize risk management tools to identify and prioritize potential critical process parameters
- Identify critical process parameters and develop a functional relationship between those process parameters and your critical-to-quality attributes (CTQs)
- Establish your process design space
- Develop a control plan as part of a risk management strategy
- Ensure your process is in a continued state of (statistical) control and is capable

Session: 201

Risk Management for Medical Devices: Applying 14971 Effectively Using Risk Assessment and Reliability Tools

Instructors: *Andrew Snow, President, Momentum Solutions, LLC; and Michael Barile, Founder and Managing Partner, Barile & Associates, Inc.*

- Risk Management Concepts and Terminology
- Understanding of the Regulatory Requirements for Risk Management
- An Introduction to the Requirements of ISO 14971:2007
- Fundamental Concepts of Product Liability as it Relates to Risk
- Tips for Integrating Risk Management into the Design and Development Lifecycle
- Basics of How to Conduct a Compressive Risk Assessment for a Device
- Methods for Evaluating Over-All Device Risk Acceptability
- Guidelines for Applying FMEA, Fault Tree Analysis and Other Risk Assessment Tools to Risk Management
- Understanding of How Human Factors Engineering Relates to Risk Management
- Familiarity with How Reliability Engineering Tools (e.g. MIL-HDBK-217) Can Aid the Risk Management Process
- Exposure to Advanced Methodologies Such as Markov Analysis for Predicting and Simulating Hazardous Events

Session: 202

Creativity within Constraints: How to Move from Good to Great Design

Instructors: *Gina Romero, Project Lead, Stacey Chang, Director of Healthcare Practice, Matt Inoyue, Senior Project Leader, and Brian Mason, Medical Products Lead, IDEO; Mary Buchanan Director, User-Centered Innovation*

Life Technologies

Part 1: Framing and the Design Challenge

- What is design thinking?
- Industry guest speaker: how design thinking has impacted my business
- Inspiring creativity in the medical products space: presentation of design challenge (broad and engaging topic that represents real challenges we face in the medical device world)
- Empathy in design
- Brainstorming: the rules and the rhythm

Part II Quickly Moving from Ideas to Implementation

- Rolling up our sleeves: an introduction to rapid iteration
- Experimenting and asking the right questions
- Getting tangible: special guest to provide feedback on participant designs
- Conclusion: how will you apply this process?
- Q&A

Session: 203

New Materials Processing Technologies for Medical Devices

Moderators: *Mark Bonifacio, Bonifacio Consulting Services and Norris Tollefson, CIBA Vision*

Advances in Injection Molding of Biocompatible Fluoropolymers: *Ken Kelly, General Manager, Performance Plastics Ltd.*

Role of Mechanical Properties in Design Control and Validation: *Siddharth Desai VP R&D, I Flow Division, Kimberly Clark Corporation*

The Challenges of Choosing the Right Polymeric Material for Today's Medical Devices: *Len Czuba, President, Czuba Enterprises, Inc.*


Qualification of Components for Use in Medical Devices: *Scott Young, Senior Director, West*

Qualification of Liquid-filled Packaging for Class 3 Medical Devices: *Norris Tollefson, Materials Engineer R&D, CIBA Vision*

New Developments in Medical Packaging Materials: *Dhuanne Dodrill, President, Rollprint Packaging Products*

New Developments in Medical Micromolding: *Mark Bonifacio, Principal, Bonifacio Consulting Services*

Hardware Developments for Machine and Robotic Transfer Systems: *Stu Kaplan, President, Makuta Technics, Inc.*

In Association With: 

Session: 204

Morning: Revelations of Former FDA and Department of Justice Officials

Moderator: Nancy Singer, President, Compliance-Alliance, LLC

Faculty: Ron Johnson, former Regional Director, FDA's Pacific Region, Elaine Messa, former District Director, FDA's LA District, Nancy Singer, former DOJ prosecutor specializing in FDA matters

- How FDA Prepares and Plans for Inspections
- Investigative Principles and Techniques
- 483s, Warning Letters, and EIRs

Afternoon: Gearing Up For Complying with FDA Requirements

Moderator: Nancy Singer

- Electronic MDRS: Mike Santalucia, VP Regulatory Affairs, Bausch and Lomb
- Recalls: Larry Spears, Former Deputy Director for Regulatory Affairs at CDRH, currently Deloitte

Dealing with Contract Manufacturers: John Somers, President and CEO, Harmac Medical Products

Session: 300

Applying Product Design Tools

Chair: W. Heath Rushing, Principal Consultant, Adsurgo LLC

Morning: Overview of DfX with an emphasis on Design for Manufacturing (DFM) Tools: Brian Callahan, Executive VP of Clinical, Regulatory, and Quality Affairs, Histogenics, Inc.

- Overview of design regulations and guidance documents: FDA, GHTF, and ISO
- Tools for transferring from R&D and development to full scale manufacturing
- Change control systems to ensure success
- Outsourcing your design to a CMO partner
- Transferring pilot design to in-house manufacturing
- Q&A

Elements and Methods for Medical Product Design: Jose Wong, Director of Product Engineering, Farm Cleveland Clinic

The Right Prototype Tool at the Right Time: Joe Gordon, Director, Technical Innovation, Ximedica

Understanding Direct Metal Laser Sintering: Design for the Process and Unleash the Potential: Chuck Hansford, Vice President, Medical, Morris Technologies

Session: 301

Beyond Basic Risk Management: How Much is Enough?

Supplier Controls: How Much is Enough? Using Risk Management to prioritize your resources: Andrew Snow, President, Momentum Solutions, LLC

Post Production Controls, Emerging Endemic Problems and Recalls: How do I use Risk Management to steer decision making?: Jonathan Morris, Ph.D., VP Quality - Endovascular and Peripheral, Medtronic Cardiac and Vascular Group

Risk Management and the Regulatory Risk of Non-Compliance: Michael Barile, Founder and Managing Partner, Barile & Associates, Inc.

Design Risk Assessment - How much is enough: Walt Murray, Director Quality and Compliance Services, Mastercontrol and Harvey Rudolph, formerly FDA's Risk Management application SME for ORA

Risk Management in Design Transfer: Delores Morrison, Sr. Director of Engineering, HVT, Edwards Lifesciences

Session: 302

Product Development and FDA Approval Process for Medical Devices

Chairs: H. Semih Oktay, PhD, CardioMed Device Consultants, LLC and Nitin Salunke, PhD, Director of R&D, Cordis Corporation, a Johnson and Johnson Company

Product Development Process: Carolyn Rice, R&D Manager, Cordis Corporation, a Johnson & Johnson company

Intellectual Property Considerations During Product Development: Andrew I. Kimmel, Partner, Knobbe Martens

Panel Discussion

FDA Approval Process for Medical Devices: H. Semih Oktay, Ph.D.

Regulatory and Clinical Considerations: Industry Perspective: Garrett Pilcher, Sr. Regulatory Affairs Manager, Medtronic Inc.

Panel Discussion and Wrap-up

Session: 303

Medical Devices with Batteries

Chair: Quinn Horn Ph.D., Senior Managing Engineer, Exponent, Inc.

FDA's Perspective on Battery Reliability and Safety for Medical Devices: Ken Skodacek, Interdisciplinary Scientist, FDA / CDRH (Center for Devices and Radiological Health) (via teleconference) invited

Roadmap for Implanted Power Sources: Gaurav Jain, Manager, Battery Research, Medtronic Inc.

Characterizing Performance and Determining Reliability for Cells for Medical Devices: Quinn Horn, Ph.D.


Reliability and Life Assessment of Li-ion Batteries for Long-life Applications: Ratnakumar Bugga, Ph.D., Principal Member Technical Staff, Electrochemical Technologies Group, Jet Propulsion Laboratory, California Institute of Technology

Battery Maintenance and Diagnostics: Isidor Buchmann, CEO and Founder, Cadex Electronics Inc.

Portable Power Considerations for Medical Device Design: Robin Tichy, Ph.D., Marketing Manager, Micro Power Electronics, Inc.

Lithium Ion Batteries and Safety - what can we learn?: Jan Swart, Principal, Exponent, Inc.

Panel Discussion

In Association With: 

Session: 304

Morning: Balancing Risk and Reward in Your Product Portfolio

Moderator: Jon Cammack, CEO, The Science Cooperative, LLC

Faculty: Mike Parkes, COO, RCA Inc., Sarah Dyson, Medmarc, Sidney Kanazawa, McGuire Woods, Kyle Adriance, VP of Product Development, Salter Labs, Christopher Fedel, VP Product Development, Zimmer, and Ann Ferriter, FDA/CDRH Office of Compliance

Review of recent medical product malfunctions despite best practices in traditional failure analysis

- Presentation of the CERT Prevention model, an "early warning system for product recalls"
- Validation of the CERT model tested with information from commercial product malfunctions
- Tips for the audience in implementing risk mitigation strategies for their product portfolios

Afternoon: Product Disasters and Multifunctional Response Strategies

Moderator: Mike Parkes

Faculty: Jon Cammack, Steve Johnson, Vice-President of Operations/QA/RA, Hycor Biomedical, Inc., Jeffrey Rogers, Partner, McGuireWoods LLP, Mark Hubbard, VP, Strategic Communications, McGuireWoods Consulting, and Ann Ferriter

- How to assemble the forensics team on-site
- How to scope the critical event, approve action plan that the team develops, and identify "stop" points
- Techniques to minimize impact on company resources
- Tips on accelerating the process
- Risk mitigation recommendations to avert future critical events

In Association With: 

Session: 400

Product Life Cycle Management

Chair: W. Heath Rushing, Principal Consultant, Adsurgo LLC

Systems Engineering and Requirements Management: Todd Hansell, Director, Systems Design Quality Assurance, Covidien

Design Controls with an emphasis on Design Verification and Validation: David Maltz, Director, Device Technology, Novartis Pharma - TRD San Carlos

Process Design for International Manufacturing Base/Outsourcing and Technology Management: Sam Onukuri, Fellow, Engineering, Johnson & Johnson

Process Transfer from Small Scale to Large Scale: presenter TBA

Session: 401

Creating a Global Quality Management System

Chair: Sue Jacobs, Principal Consultant, QMS Consulting, Past Chair of ASQ Biomedical Division

Global Compliance - A Case Study: Vice President of Quality Assurance, Fisher & Paykel Healthcare, LTD.


Global Complaints & MDRs: Michael Heyl, Partner, Hogan & Lovells US LLP

CAPA, A Global Approach: Sue Jacobs

Managing a Global Supplier Chain: Speaker TBA

Design Controls Sample Size: Steven Walfish, Statistician, GE Healthcare, former Chair of ASQ Biomedical Division

Managing a Multi-Generational Quality Organization: Rosemarie Christopher, President & CEO, Med Exec International

In Association With: 

Session: 402

Medical Device Reliability Testing

Instructor: Mike Silverman, Founder and Managing Partner, Ops a la Carte

This workshop will discuss the different aspects of medical reliability testing, from FDA regulations to industry best practices. This seminar will cover different types of reliability tests used within the medical industry along with many case studies.

Areas covered include:

Introduction to Reliability Programs within Medical Industry

Reliability Challenges in the Medical Industry

Best Reliability Test Methods for the Medical Industry: HALT and ALT

How to Design a Better Reliability Test Program

Case Studies

- Medical Implantable
- Medical Device
- Medical Bionics

Session: 403

The A,B,C's of Product Sterilization Selection

Chair: Karl Hemmerich, President, Ageless Processing Technologies

Issues in Sterilization Selection: Karl Hemmerich

A Look at Ethylene Oxide Sterilization: Clark Houghtling, Synergy Health

Radiation: Gamma, E-beam, and X-ray: Clark Houghtling and Karl Hemmerich

Working with VHP - Micro Gamma/Steris/ASP: John Kowalski, PhD, Sterigenics

Steam and Dry Heat: Robert Reich, LexaMed

Product Development Examples

- Human Tissue: Martell Winters, Nelson Laboratories
- Combination Products: Byron Lambert, Abbott Vascular

Panel Discussion: Faculty and industry representatives

Session: 404

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1 Day	\$599	—	\$719	—
2 Days	\$849	\$425 a day	\$1019	\$509 a day
3 Days	\$999	\$333 a day	\$1199	\$400 a day
4 Days	\$1099	\$275 a day	\$1319	\$330 a day

Conference registration includes:

- Electronic session materials of presentations for registered sessions
- Networking lunch on registered sessions
- Coffee and refreshments during the session breaks
- Complimentary admission to all co-located exhibitions

Sponsorship Opportunities

The MD&M West Conference offers sponsorship opportunities to a limited amount of sponsors who are interested in presenting themselves as thought leaders in an intimate environment of medical device technologists.

Why Sponsor:

- ◆ As a conference sponsor you will have the opportunity to enhance your presence at MD&M West and gain unrivalled access to an audience of medical device technologists
- ◆ The conference is a highly effective means of promoting your business to a targeted group of key decision makers with a specific interest in your products and services
- ◆ Whether your primary marketing objective is to maximize your brand, drive new business or demonstrate your expertise, this event offers you the perfect platform

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