



**Your Trusted Resource for Medical Device and
Biopharma Development and Manufacturing**

BIOMEDevice

An MDM Event

EXPOSITION & CONFERENCE **December 6–7, 2011**
San Jose McEnergy Convention Center | San Jose, CA

Conference Program

BIOMEDeviceSanJose.com

CONFERENCE AGENDA

TUESDAY, DECEMBER 6, 2011

Product Development and FDA Approval Process for Medical Devices

Chairs: H. Semih Oktay, Ph.D., CardioMed Device Consultants; and Nitin Salunke, Ph.D., Director, R&D Engineering, Cordis Corporation, a Johnson and Johnson Company

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

- Overview of product development process.
- How do you plan for a successful design process?
- User needs and risk analysis.

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

- What should every product development professional know about the patent system?
- How important is patent protection to a medical device company?
- How to avoid accidental loss of patent rights?
- How to efficiently integrate a patent strategy into a product development plan?
- Is it better to patent or keep inventions as trade secrets?
- Why is it important to include the IP team during the entire product design and development process?
- How can patent and FDA strategies overlap and affect each other?

Panel Discussion

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

- Overview of the FDA process for medical device approval
- Pre-market Notification (510 (k))
- Pre-market Approval (PMA)
- Humanitarian Device Exemption (HDE)
- Investigational Device Exemptions (IDE)
- How to deal with FDA
- Preparing for FDA meetings

Regulatory and Clinical Considerations: Industry Perspective: *Zachary J. Woodson, Sr. Regulatory Affairs Manager, Medtronic CardioVascular*

- Conducting clinical trials around the globe.
- Managing information across geographies and vendors.
- Regulations across geographies.
- Understanding total product life cycle.
- Challenges during the product development and regulatory approval process for the US and global markets.

Panel Discussion and Wrap-up

WEDNESDAY, DECEMBER 7, 2011

Design and Development of a Medical Device: From Concept to Production

Chair: Barrett C. Craner, RAC, CQE, CRE, Vice President QA/RA, Stellartech Research Corporation

Best Practices in Medical Device Design and Development Process: Using templates for need finding, due diligence and proof of concept:

Avi Roop, CEO, Miret Surgical

- How to evolve from making observations, to understanding problems to defining unmet clinical need.
- How the statement of unmet clinical need is key to raising money, reducing time to market and communicating with your customer.
- How the integration of front end performance criteria, highly iterative prototyping processes and repeated customer interaction drive failure to occur earlier in the development life cycle and not in the more costly later development phases.

Human Factors in Medical Device Design: *Eric Bergman, Ph.D., Director, Human Factors Engineering, LifeScan Inc.,*

a Johnson & Johnson company

- A high level introduction to human factors engineering
- An overview of changing regulatory expectations
- Discussion of human factors as a risk management activity vs. its broader role in enhancing usability
- Interactive discussion/Q & A

Supplier Controls – Partnerships in design through transfer into manufacturing: *John P. Haynes, Materials Manager, BioCardia*

- All types of materials
- All types of devices
- Short time-frame needs for the product development environment
- Long-term needs of ramp-up and steady manufacturing
- Small and large lot production
- Finding obsolete or hard-to-find materials
- Controlling and approving suppliers
- Considerations for 2nd tier suppliers (suppliers of those who supply you)

Polymeric Medical Device Design - Materials Selection and Characterization: *James P. Oberhauser, Ph.D., Manager,*

BVS Polymer R&D, Abbott Vascular

- Polymeric medical device design requirements influence materials and manufacturing process selection.
- Thermal and deformation history in polymer processing dictate microstructure and macroscopic material properties.
- Polymer processing principles transcend the boundaries of medical device manufacturing, and learning from other industries can be instructive.

Panel Discussion: Speed to Market for Medical Devices

Panelists: Mir Imran, Chairman & CEO, InCube Labs and Modulus; Joe A. Heanue, Ph.D., President, Triple Ring Technologies, Inc.; Stacey Chang, Healthcare Director, IDEO; Roger A. Stern, Ph.D., President and CEO, Stellartech Research Corporation

Developing Medical Devices for Manufacturability

- Acquiring and agreeing on stable and sufficient product requirements before embarking on development
- Ease of assembly
- Low cost assembly
- Using approved suppliers where possible
- Cost of procurement
- Using proven technologies in order to minimize surprises during transfer to manufacturing

Software Verification and Validation: Implementing Critical Updates to IEC 60601: *Anura S. Fernando, Research Engineer,*

Underwriters Laboratories

- Brief history of software safety and the role of Verification and Validation (V&V)
- The role of IEC 60601-1-4 with Programmable Electrical Medical Devices (PEMS)
- Changes to the structure of IEC 60601-1 Third Edition that reflect the growing importance of the V&V of software in medical devices.
- Introduction of IEC 62304
- Regulatory perspectives
- Technology trends in device networking and “systems of systems”

Choices – IEC 60601-1 3rd Edition and Component Selection: *Mark Leimbeck, P.E., Program Manager, Health Sciences, Underwriters Laboratories Inc.*

- Background on the standard – the source of the risk management requirement and the intent.
- Certification options in assessment and licensing of components.
- The roles and responsibilities of both component and end-product manufacturers in risk management.
- Conclusion

Panel Discussion and Wrap-up

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 SAN JOSE McENERY CONVENTION CENTER | SAN JOSE, CA

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1 General Information

Please print clearly.

Promo Code: MB

First Name: _____ Last Name: _____
 Job Title: _____
 Company: _____
 Address: _____
 City: _____ State: _____ Post/Zip Code: _____
 Country: _____ Tel: _____ Fax: _____
 E-mail: _____

2 Attendee Information

What is the primary description of your employer? (check one)

- A. Biotechnology Company
- B. Medical Device Manufacturing (including in-house and contract manufacturing, design, R&D, packaging, and sterilization)
- C. Pharmaceutical Manufacturer
- D. Manufacturer of In Vitro Diagnostics
- E. Manufacturer of Medical Electronic Equipment
- F. Financial/Investment Company
- G. Other

(please specify)

What is your primary job function? (check one)

- A. Business Development/Strategic Planning
- B. Consulting
- C. Design Engineering
- D. Engineering
- E. Facilities/Safety
- F. Facility Engineering
- G. Senior/General Corporate Management
- H. Information Technology
- I. Laboratory Q/A
- J. Manufacturing MIS/ERP
- K. Operations/Manufacturing
- L. Process Engineering
- M. Product Marketing
- N. Production/Manufacturing (Also includes packing & sterilization)
- O. Project Engineering
- P. Purchasing/Supply Chain
- Q. Quality Assurance/Quality Control
- R. Regulatory/Legal Affairs
- S. Research & Development
- T. Sales/Marketing
- U. Specifying/Procurement Buyer
- V. Validation
- W. Other

(please specify)

What is your primary area of interest at the show? (check one)

- A. Assembly and Automation
- B. Cleanroom and Sterilization
- C. CNC Machine Tools and Lasers
- D. Contract Manufacturing/Outsourcing
- E. Design Services
- F. Electronic Components, Subassemblies, and Services
- G. Manufacturing/Production Machinery
- H. Medical Grade Materials
- I. Motors, Pumps, & Motion Control
- J. Packaging/Labeling & Bar Coding
- K. Plastics/Disposables
- L. Precision Plastic and Metal Components
- M. Process Systems and Controls
- N. Software
- O. Testing, Inspection, QA/QC Products and Services
- P. Entire Show
- Q. Other

(please specify)

What is your company's primary end product? (check one)

- A. Anesthesiology and Pulmonary Medicine
- B. Cardiovascular
- C. Contract Manufacturing/Contract Packaging
- D. General Medical Devices and Equipment
- E. In Vitro Diagnostics
- F. Medical Devices/Diagnostics
- G. Neurology
- H. Nutraceuticals
- I. Obstetrics and Gynecology
- J. Ophthalmic
- K. Orthopedics
- L. Pharmaceuticals
- M. Physical Medicine
- N. Radiology
- O. Services
- P. Surgical Instruments
- Q. Other

(please specify)

Do you wish to receive/continue to receive **Medical Product Manufacturing News (MPMN)** for FREE? Yes No

Signature: _____

3 Conference Selections

- Session 100: Tuesday, Dec. 6
Product Development & FDA Approval...
- Session 200: Wednesday, Dec. 7
Design & Development of a Medical Device

For a complete listing of session titles, dates, and times, please visit www.BIOMEDeviceSanJose.com

4 Fees

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