

2011 Florida Medical Device Symposium – Schedule of Events

Day One – Monday, May 2, 2011

- 12:00 – 2:00** Attendee Registration
- 2:00 – 2:15** Welcome & Introductory Remarks
Geary Havran – FMMC Chair
- 2:15 – 3:00** FDA Quality Systems Regulation
Kimberly A. Trautman – FDA’s Medical Device Quality Systems Expert (live via teleconference)
- 3:00 – 3:45** 510(k): Past, Present, Future – A Perspective
Heather Rosecrans – VP of Regulatory Affairs, MDMA
- 3:45 – 4:00** Refreshment Break (Salon DEF)
- 4:00 – 4:45** Compliance Issues in the Medical Device Industry
Bob Dormer – Hyman, Phelps & McNamara, PC
- 4:45 – 5:30** Panel Discussion: Current FDA Issues
Heather Rosecrans – VP of Regulatory Affairs, MDMA
Bob Dormer – Hyman, Phelps & McNamara, PC
Neil Di Spirito – Rumberger, Kirk & Caldwell, PA
- 5:30 – 7:30** Networking Reception & Exhibit Hall Grand Opening (Salon DEF)

Day Two – Tuesday, May 3, 2011

- 8:00 – 9:00** Full Breakfast Buffet in Exhibit Hall
- 9:00 – 9:45** Opportunities and Pitfalls in Selling a Small Medical Device Company – Creating Value in a Company to Attract Investors and Buyers
Rick Ferreira – President, Stryker’s Sustainability Division, Ascent
- 9:45 – 10:30** Washington Review: Comprehensive Update on Issues Facing the Medical Device Industry in the 112th Congress.
Mark Leahey – President & CEO, MDMA
- 10:30 – 10:45** Refreshment Break (Salon DEF)

Day Two (continued)

- 11:00 – 12:00** Outsourcing Panel: Costs, Benefits and Risk Analysis of “Offshoring” vs. Domestic Contract Manufacturing in the Medical Device Industry
Moderator: *Chris Delporte – Group Editor, Medical Product Outsourcing (MPO) Magazine*
- Panelists:** *Matthew Otten – VP, Business Development & Operations, Interplex Medical*
David Slick, Sr. – President & CEO, Command Medical
Gaet C. Tyranski – Business Unit Director, Healthcare and Life Sciences, Jabil
Gary Haberland – President & CEO, GENICON
- 12:00 – 1:30** Keynote Luncheon (Salon DEF)
Former U.S. Senator George LeMieux
- 1:30 – 2:15** Implementing Lean Manufacturing and Continuous Improvement in a Medical Device Company
Bill Mazurek – Director of Continuous Improvement, ConMed Linvatec
- 2:15 – 3:00** Overview of the New Usability Standard HE75 - How to Meet FDA Expectations through a Rigorous QSR Human Factors Engineering Process
Sean Hägen – Principal, Director of Research & Synthesis, BlackHägen Design
- 3:00 – 3:15** Refreshment Break (Salon DEF)
- 3:15 – 4:00** Tallahassee Review: Comprehensive Update on Business and Regulatory Issues before the Florida Legislature
John Ray – President, John Ray Consulting, LLC
- 4:00 – 4:15** Closing Remarks & Adjourn
Geary Havran, FMMC Chair
- Thank you to the FMMC Symposium Committee: Jim Jones, FTSI; Geary Havran, NDH Medical; Allen Craig, Interplex Sunbelt; John Ray, John Ray Consulting LLC; Jim Steele, Ascent; Stephanie Mattson, UL; Suzanne Christman, PCED; and Jim Pintsak, LGGS Florida.*