

7:00 AM – 4:00 PM Registration and Exhibits

THE 22nd *BIOMEDICAL FOCUS* CONFERENCE & EXPOSITION
The Future of Biomedical
MARCH 17 & 18, 2008

8:00 AM to 9:15 AM Welcome and Keynote Address

Larry A. Kuusisto, Ph.D.
The Future of Biomedical Quality

9:15 – 9:45 Visit Exhibits

9:45 AM - 10:45 AM SESSION ONE

Sourcing & CAPA	FDA	World Standards and Auditing	Reduce Your Risk
Session 111 The Changing World of Medical Device Standards Chuck Sidebottom Medtronic	Session 121 Recalls-A Case Study Kristi Zuroski & Timothy Phillips FDA	Session 131 Auditing in a Regulated Environment: Process Validation & CAPA Dennis Arter Columbia Audit Resources	Session 141 Reduce Risk through the Design Inputs Phase David Rothkopf MEDIcept, Inc.

10:45 – 11:00 Room Switch

11:00 AM - NOON SESSION TWO

Session 112 ISO 13485 Certification: Coming of Age? Art Ward, Ph.D. AJW Technology Consultants	Session 122 FDA 101 Janis Armendariz & Timothy Phillips FDA	Session 132 Design Control Dr. Andre Routh BSI Consultants	Session 142 Enterprise Risk Management Angelo Scangas Quality Support Group, Inc.
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12:15 – 1:30 Conference Luncheon & Visit Exhibits

1:30 PM – 2:30 PM SESSION THREE

Session 113 CAPA Challenges Part ONE Gateway Qualification <i>OR</i> The Path of Least Resistance Art Ward AJW Technology Consultants	Session 123 FDA Panel Discussion Janis Armendariz, Timothy Phillips, & Kristi Zuroski FDA	Session 133 Auditing and the Discovery Process: How to Reduce your Risk Marilyn Pehl Consultant	Session 143 Risk Assessment for Medical Device Business Russ Ziebel Consultant
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2:30 – 3:00 Visit Exhibits

3:00 PM – 4:00 PM SESSION FOUR

Session 114 CAPA Challenges Part TWO Gateway Qualification <i>OR</i> The Path of Least Resistance Art Ward AJW Technology Consultants	Session 124 Lean and Experience Management in Healthcare Dave Harreld	Session 134 Understanding Capability Indices Louis Asher 3M	Session 144 Challenges in Manufacturing, Quality, and Regulatory Hurdles Mark Tondra Diagnostic Biosensors, LLC
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7:00 AM- NOON Registration

THE 22nd BIOMEDICAL FOCUS CONFERENCE
The Future of Biomedical

MARCH 18, 2008 WORKSHOPS

8:00 AM -11:30 AM

Mix and Match

FULL DAY WORKSHOPS

HALF DAY WORKSHOPS

WORKSHOP 1	WORKSHOP 2	WORKSHOP 3	WORKSHOP 4 8:00 AM -11:30 AM	WORKSHOP 5 8:00 AM -11:30 AM	WORKSHOP 6 8:00 AM -11:30 AM
Russ Ziebel Risk Assessment for Medical Device Business	Dennis Arter Integrated Auditing	Pat Whitcomb DOE Case Studies in the Biomedical Industry	Michael Morton Living in Interesting Times: The Global Regulatory Environment Today and Tomorrow	Ashweni Sahni CAPA	Dr. Andre Routh Preliminary Hazard Analysis

Conference Luncheon

12:30 PM – 4:00 PM

Mix and Match

FULL DAY WORKSHOPS

HALF DAY WORKSHOPS

WORKSHOP 1	WORKSHOP 2	WORKSHOP 3	WORKSHOP 7 12:30 PM – 4:00 PM	WORKSHOP 8 12:30 PM – 4:00 PM	
Risk Assessment <i>Continued</i>	Integrated Auditing <i>Continued</i>	Design of Experiments <i>Continued</i>	BiJay Jayaswal and Dr. Peter Patton DFTS, CMMI and FDA's Software Validation Requirements	Angelo Scangas FMEA - A Risk Management Tool	

4:00 PM Conference Concludes

FULL DAY WORKSHOPS are listed in white

HALF DAY WORKSHOPS are listed in blue

Half day workshops (in blue) and are "mix and match"

You may select any two ½ day workshops you wish. Or choose one full day workshop.