

THE FOURTH ANNUAL
**MEDICAL DEVICE
 REGULATORY,
 REIMBURSEMENT AND
 COMPLIANCE CONGRESS**

**A Hybrid
 Conference &
 Internet Event**
 See Website

*Benchmarking Your Firm's Domestic and International Practices in
 Quality Systems, Reimbursement, Fraud and Abuse and Promotion*

November 9 – 11, 2009 • Washington, DC JW Marriott Hotel



Co Chairs

Ted Acosta, Esq., Principal,
 Ernst & Young LLP



Link Bonforte, President, LB1 Consulting
 LLC; Former Vice President, Ethics &
 Compliance, ConvaTec Inc.



Sujata T. Dayal, Corporate Vice President
 and Chief Compliance Officer, Global
 Operations, Biomet, Inc.



Doug Mowen, Managing Director,
 Medical Device Industry Lead,
 PricewaterhouseCoopers



Kristine A. Rapp, Esq., Vice President,
 Global Ethics and Compliance,
 Hospira, Inc.

**Leading Government
 Regulators and Prosecutors**



Carolyn M. Clancy, MD, Director,
 Agency for Healthcare Research
 and Quality



Emilia DiSanto, Chief Investigative
 Counsel and Special Counsel for
 Senator Grassley (R-IA)



David Hart, Esq., Assistant Attorney
 in Charge, Financial Fraud/Consumer
 Protection, Oregon Department of Justice



Sanjay J. Koyani, MPH, Director,
 FDA Web Communications Office
 of Public Affairs



Jack Mitchell, Chief of Oversight and
 Investigations, Special Committee on
 Aging, US Senate; Former Director,
 Commissioner's Office of Special
 Investigations (OSI), FDA



Kirk Ogrosky, Esq., Deputy Chief,
 Fraud Section, Criminal Division,
 US Department of Justice



Gerald Sullivan, Esq., AUSA,
 US Attorney's Office, Eastern
 District of Pennsylvania



Casper E. Uldriks, JD, Mdiv,
 Associate Director, CDRH, FDA

Featuring Special Sessions:

- The Implications of National Health Reform for the Medical Device Industry
- Federal Initiatives in Comparative Effectiveness Research (CER)
- Federal Panel: Key Congressional Transparency Initiatives
- State Panel: State Disclosure Initiatives
- Operational Implications of State and Possible Federal Disclosure Requirements
- New Trends in Social Media and New Media
- Implementation of the AdvaMed Code
- After the Implementation: Maintaining an Effective Compliance Program
- A Primer for Certifying Compliance with the AdvaMed Code
- Federal State Enforcement and Prosecution Initiatives
- Fair Market Value (FMV) Analysis Across Various Healthcare Professional (HCP) Arrangements
- FDA/CDRH Regulatory and Compliance Update
- Medicare Coverage and Payment for Medical Device Update
- Coverage and Reimbursement for Medical Devices Abroad Update
- Compliance Process Excellence: Implementation of Better Compliance Practices
- Global Compliance Best Practices Roundtable
- Medical Device Compliance Professional and Legal Counsel Best Practice Roundtable



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OVERVIEW:

The Fourth Medical Device Regulatory, Reimbursement and Compliance Congress (Device Congress), www.DeviceCongress.com, will take place November 9 – 11, 2009 at the JW Marriott Hotel in Washington, DC. The Device Congress will be offered both onsite and online (live and archived for 6 months via the Internet). The Device Congress is sponsored by media partners *Harvard Health Policy Review* and *Health Affairs*.

The Device Congress has been based at Harvard University for the past three years. This year we are bringing the event to Washington DC in recognition of the importance of the new administration and ongoing major initiatives in national health reform.

The audience will include executives, lawyers, compliance officers, and regulatory personnel from medical device manufacturers, as well as outside counsel and consultants to these industries. The goal of the Congress is to promote legal and regulatory compliance efforts within the medical device industry, identify best compliance practices, and foster continued dialogue between the industry and government regulatory and enforcement personnel.

The Device Congress will immediately precede the Tenth Annual Pharmaceutical Regulatory and Compliance Congress, www.PharmaCongress.com, November 11 – 13, 2009, at the JW Marriott Hotel in Washington, DC. The Pharma Congress is sponsored by the Pharmaceutical Compliance Forum, www.PharmaComplianceForum.org, a coalition of senior compliance officials and legal counsel from more than 50 of the largest pharmaceutical manufacturers.

Featuring Preconferences:

- US Hot Button Issues and Recent Compliance Code Changes for 2009: Are You Ready?
- Dangerous Documents: Finding Land Mines in Your FDA Reports and Emails

Special Sessions:

- The Implications of Comprehensive National Health Reform for the Medical Device Industry
- Federal Initiatives in Comparative Effectiveness Research (CER)
- Key Congressional Transparency Initiatives
- State Disclosure Initiatives
- Operational Implications of State and Possible Federal Disclosure Requirements
- New Trends in Social Media and New Media
- Implementation of the AdvaMed Code
- After the Implementation: Maintaining an Effective Compliance Program
- A Primer for Certifying Compliance with the AdvaMed Code
- Federal State Enforcement and Prosecution Initiatives
- Fair Market Value (FMV) Analysis Across Various Healthcare Professional (HCP) Arrangements
- FDA/CDRH Regulatory and Compliance Update
- Medicare Coverage and Payment for Medical Device Update
- Coverage and Reimbursement for Medical Devices Abroad Update
- Compliance Process Excellence: Implementation of Better Compliance Practices
- Global Compliance Best Practices Roundtable
- Medical Device Compliance Professional and Legal Counsel Best Practice Roundtable

And a Postconference on:

- Making Compliance Training Fun: Training the Trainer

Who Should Attend:

FROM MEDICAL DEVICE FIRMS

- Presidents
- Quality and regulatory officials
- Quality engineers
- Marketing officials
- Financial officials
- Reimbursement officials
- Compliance officers
- Legal counsel

OTHERS

- Physicians
- Nurses
- Lawyers in private practice
- Government officials
- Consultants
- Press
- Managed care officials
- Provider groups
- Insurance firm officials

SAVE THE DATE—The Device Congress is followed by:

THE TENTH ANNUAL **Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum** TRANSFORMATIONAL LEARNING — EFFECTIVE KNOWLEDGE EXCHANGE

November 11 – 13, 2009 • JW Marriott Hotel, Washington, DC

www.PharmaCongress.com

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R COMPLIANCE REPORT

Monday, November 9, 2009

PRECONFERENCE SYMPOSIA

PRECONFERENCE I: US Hot Button Issues and Recent Compliance Code Changes for 2009: Are You Ready?

8:00 AM WELCOME AND INTRODUCTIONS

Paul J. Silver, *Managing Director and Practice Leader, Life Sciences Advisory Services, Huron Consulting Group, Atlanta, GA (Moderator)*

An interactive discussion regarding recent legislative and compliance code changes and their potential operational impacts. The discussion will cover key issues, including:

- New Massachusetts and Vermont Legislation – Is your company ready for the impact to aggregate spend and disclosure requirements?
- Clinical Affairs Activities: From ghostwriting to payments – What should you be tracking to demonstrate compliance under increased public scrutiny?
- HCP Needs Assessments – Lessons from the DPAs: Does your company really know what it needs?
- A New Focus on Royalty Payments: Procedure, documentation and carve-outs – Does your process need an update?
- Changes to AdvaMed and Eucomed for 2009 – Do your policies and operations need to change?

Faculty:

Tracy Palmer Berns, Esq., *Associate General Counsel Regulatory Affairs, Covidien, Mansfield, MA*

Mark N. Bonaguro, Esq. (Invited), *Chief Compliance Counsel, Covidien, Mansfield, MA*

David L. Cavanaugh, Esq. (Invited), *Partner and Co-Vice Chair, Intellectual Property Department, WilmerHale, Washington, DC*

Mark A. DeWyngaert, MBA, PhD, *Managing Director, Huron Consulting Group, New York, NY*

Debjit A. Ghosh, *Managing Director, Huron Consulting Group, New York, NY*

Jacqueline K. Huber, *Corporate Vice President and Chief Compliance Officer, Biomet, Inc., Warsaw, IN*

Reaz Rasul (Invited), *General Manager, Lean Product Development, Medical, Science and Technology, GE Healthcare, Milwaukee, WI*

Attendees will be provided with Huron's updated 2009 International Medical Device Compliance Code Compendium as a tool for compliance implementation. The new compendium includes the updated AdvaMed and Eucomed codes, as well as the addition of new country and regional codes.

NOON PRECONFERENCE ADJOURNMENT;
LUNCH ON YOUR OWN

PRECONFERENCE II: Dangerous Documents: Finding Land Mines in Your FDA Reports and Emails

8:00 AM WELCOME AND INTRODUCTION

Nancy Singer, JD, LLM, *President, Compliance-Alliance, LLC; Founder, AdvaMed Medical Technology Learning Institute;*

Former Special Counsel, AdvaMed; Former Executive Director, Food and Drug Law Institute; Former Attorney, United States Department of Justice, Arlington, VA

SESSION OVERVIEW:

Guidant, Bayer, Merck, Eli Lilly, and American Home Products were sued. During discovery, they were forced to produce their employees' emails and other documents that they thought were confidential. These documents contained inflammatory statements that embarrassed the companies and forced them to enter into expensive settlements. During this interactive session, attendees will learn how lawyers can take sentences from memos and emails out of context and have them imply inappropriate conduct.

Specifically this session will cover:

- Who can be held criminally liable under the law
- What FDA investigators look for when reviewing documents
- The risks of leaving blanks and using white-out in required records
- How to write informative documents that don't make you a target
- How to distinguish between fact and opinion
- The dangers in not monitoring employees emails
- Types of information never to include in documents
- Words that will attract the attention of prosecutors or plaintiff's lawyers
- Why it is crucial to follow a document retention program
- How to build a program to avoid dangerous documents

NOON PRECONFERENCE ADJOURNMENT;
LUNCH ON YOUR OWN

Monday, November 9, 2009

DEVICE CONGRESS AGENDA:
DAY I – OPENING PLENARY SESSION

1:00 PM WELCOME AND INTRODUCTIONS

Doug Mowen, *Managing Director, Medical Device Industry Lead, PricewaterhouseCoopers, Florham Park, NJ (Co chair)*

HEALTH REFORM

1:15 PM THE IMPLICATIONS OF COMPREHENSIVE NATIONAL HEALTH REFORM FOR THE MEDICAL DEVICE INDUSTRY

David I. Johnson (Invited), *President, ConvaTec Inc., Skillman, NJ*

1:45 PM FEDERAL INITIATIVES IN COMPARATIVE EFFECTIVENESS RESEARCH (CER)

Carolyn M. Clancy, MD, *Director, Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services, Washington, DC*

2:15 PM THE IMPLICATION OF COMPARATIVE EFFECTIVENESS RESEARCH FOR THE MEDICAL DEVICE INDUSTRY

William Sarraille, Esq., *Partner, Sidley Austin, Washington, DC*

TRANSPARENCY AND DISCLOSURE

2:45 PM FEDERAL PANEL: KEY CONGRESSIONAL TRANSPARENCY INITIATIVES

Emilia DiSanto, *Chief Investigative Counsel and Special Counsel for Senator Grassley (R-IA), Washington, DC*

Jack Mitchell, *Chief of Oversight and Investigations, Special Committee on Aging, United States Senate; Former Director, Commissioner's Office of Special Investigations (OSI), FDA, Washington, DC*

Daniel F Donovan, III, Esq., *Partner, King & Spalding; Former Senior Investigative Counsel to Senator Charles E. Grassley (R-IA), Washington, DC (Moderator)*

3:30 PM BREAK

4:00 PM STATE PANEL: STATE DISCLOSURE INITIATIVES

David A. Catania, Esq. (Invited), *Member and Chair, Committee on Health, City Council, Washington, DC*

Allan Coukell, *Director, Pew Prescription Project, The Pew Charitable Trusts, Pew Health Group, Boston, MA*

Melissa J. Lopes, Esq. (Invited), *Deputy General Counsel, Massachusetts Department of Public Health, Boston, MA*

Benjamin S. Martin, Esq., *Associate, Health Care and Life Sciences Practice, Epstein Becker & Green, Washington, DC (Co moderator)*

Jeffrey L. Handwerker, Esq., *Partner, Arnold & Porter, Washington, DC (Co moderator)*

4:45 PM PANEL: OPERATIONAL IMPLICATIONS OF STATE AND POSSIBLE FEDERAL DISCLOSURE REQUIREMENTS

Angela Fifelsk, Esq. (Invited), *Director of Compliance Americas, Zimmer Holdings, Inc., Warsaw, IN*

Jacqueline K. Huber, *Corporate Vice President and Chief Compliance Officer, Biomet, Inc., Warsaw, IN*

Eric M. Baim, Esq., *Associate, Hogan & Hartson, Washington, DC (Moderator)*

ADVERTISING AND SOCIAL MEDIA: THE NEW FRONTIER

5:30 PM NEW TRENDS IN SOCIAL MEDIA AND NEW MEDIA

David Bloch, Esq. (Invited), *Principal Legal Counsel, Medtronic, Washington, DC*

Sanjay J. Koyani, MPH, *Director, FDA Web Communications, Office of Public Affairs, Food and Drug Administration, Rockville, MD*

Daniel A. Kracov, Esq., *Partner and Chair, FDA and Healthcare Practice, Arnold & Porter, Washington, DC*

Robin Strongin, *President and Chief Executive Officer, Amplify Public Affairs, Washington DC (Moderator)*

6:15 PM ADJOURNMENT AND OPENING NETWORKING RECEPTION

Tuesday, November 10, 2009

DEVICE CONGRESS AGENDA: DAY II

7:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

ADVAMED CODE COMPLIANCE

8:00 AM WELCOME AND OVERVIEW OF IMPLEMENTATION OF THE ADVAMED CODE OF ETHICS

Link Bonforte, *President, LBI Consulting LLC; Former Vice President, Ethics & Compliance, ConvaTec Inc., Belle Mead, NJ (Co chair)*

Kristine A. Rapp, Esq., *Vice President, Global Ethics and Compliance, Hospira, Inc., Lake Forest, IL (Co chair)*

John Bentivoglio, Esq., *Partner, Skadden Arps LLP; Former Special Counsel for Health Care Fraud and Chief Privacy Officer, United States Department of Justice, Washington, DC (Moderator)*

8:45 AM AFTER THE IMPLEMENTATION: MAINTAINING AN EFFECTIVE COMPLIANCE PROGRAM

Doug Mowen, *Managing Director, Medical Device Industry Lead, PricewaterhouseCoopers, Florham Park, NJ*

Jean Sands, *Manager, Pharmaceuticals and LifeSciences, PricewaterhouseCoopers, Chicago, IL*

9:15 AM ADVAMED CODE OF ETHICS CERTIFICATION: A PRIMER FOR CERTIFYING COMPLIANCE WITH THE CODE

Paul J. Silver, *Managing Director and Practice Leader, Life Sciences Advisory Services, Huron Consulting Group, Atlanta, GA*

Rosemary Weghorst, MHA, *Manager, Life Sciences Advisory Services, Huron Consulting Group, Chicago, IL*

FRAUD AND ABUSE

9:45 AM FEDERAL CRIMINAL ENFORCEMENT AND PROSECUTION INITIATIVES WITH REGARD TO MEDICAL DEVICE MANUFACTURERS

Kirk Ogrosky, Esq., *Deputy Chief, Fraud Section, Criminal Division, US Department of Justice, Adjunct Professor of Law, Georgetown Law School, Washington, DC*

10:15 AM FEDERAL CIVIL ENFORCEMENT AND PROSECUTION INITIATIVES WITH REGARD TO MEDICAL DEVICE MANUFACTURERS

Gerald Sullivan, Esq., *Assistant United States Attorney, US Attorney's Office, Eastern District of Pennsylvania, Philadelphia, PA*

10:45 AM BREAK

11:15 AM STATE ENFORCEMENT AND PROSECUTION INITIATIVES WITH REGARD TO MEDICAL DEVICE MANUFACTURERS

David Hart, Esq., *Assistant Attorney in Charge, Financial Fraud/Consumer Protection, Oregon Department of Justice, Salem, OR*

11:45 AM FEDERAL AND STATE FACULTY Q&A

Kathleen Meriwether, Esq., *Principal, Fraud Investigation & Dispute Services, Ernst & Young; Former Assistant United States Attorney, Eastern District of Pennsylvania, US Department of Justice, Philadelphia, PA (Moderator)*

12:15 PM NETWORKING LUNCHEON

**1:15 PM INTRODUCTION TO AFTERNOON
PLENARY SESSION**

Sujata T. Dayal, *Corporate Vice President and Chief Compliance Officer, Global Operations, Biomet, Inc., Warsaw, IN (Co chair)*

**1:30 PM FAIR MARKET VALUE (FMV) ANALYSIS ACROSS
VARIOUS HEALTHCARE PROFESSIONAL (HCP)
ARRANGEMENTS AND THROUGHOUT THE
CONTRACTING PROCESS**

Jeffrey E. Cohen, *Director of Compliance, Globus Medical, Inc., Audubon, PA*

Bernard J. Ford, MBA, *Managing Director, Health Care Disputes, Compliance and Investigations, Navigant Consulting, Inc., Chicago, IL*

David M. Hyman, Esq., *Partner, Wolff & Samson, West Orange, NJ*

**2:00 PM MEDICAL DEVICE FRAUD AND ABUSE
HYPOTHETICAL CASE STUDIES**

Kristine A. Rapp, Esq., *Vice President, Global Ethics and Compliance, Hospira, Inc., Lake Forest, IL*

Eve M. Brunts, JD, LL.M., *Partner, Ropes & Gray, Boston, MA (Co moderator)*

Kathleen Meriwether, Esq., *Principal, Fraud Investigation & Dispute Services, Ernst & Young; Former Assistant United States Attorney, Eastern District of Pennsylvania, US Department of Justice, Philadelphia, PA (Co moderator)*

FDA REGULATION

**2:45 PM FDA/CDRH REGULATORY AND
COMPLIANCE UPDATE**

Casper E. Uldriks, JD, Mdiv, *Associate Director for Regulatory Guidance and Government Affairs, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, Silver Spring, MD*

Gregory H. Levine, Esq., *Partner, Ropes & Gray, Washington, DC (Moderator)*

3:30 PM BREAK

**4:00 PM ROUNDTABLE ON THE TOP 10 DEVICE
MANUFACTURER-FDA REGULATORY ISSUES**

Dorothy J. Clarke, Esq., *Vice President, Regulatory Affairs, Office of Compliance, Medical Devices and Diagnostics, Comprehensive Care and Surgical Care, Johnson & Johnson, New Brunswick, NJ*

Danelle Miller, Esq., *Director and Regulatory Counsel, Roche Diagnostics Corporation, Indianapolis, IN*

Lauren R. Silvis, Esq., *Associate, Sidley Austin, Washington, DC (Co moderator)*

Gregory H. Levine, Esq., *Partner, Ropes & Gray, Washington, DC (Co moderator)*

REIMBURSEMENT

**4:45 PM UPDATE ON MEDICARE COVERAGE
AND PAYMENT FOR MEDICAL DEVICES**

Stuart M. Langbein, Esq., *Partner, Hogan & Hartson; Former Counsel, Office of the General Counsel, CMS Division, US Department of Health and Human Services, Washington, DC*

**5:15 PM UPDATE ON COVERAGE AND REIMBURSEMENT
FOR MEDICAL DEVICES DOMESTICALLY,
INCLUDING HYPOTHETICAL CASE STUDIES**

Marcia Nusgart, R.Ph., *President, Nusgart Consulting LLC, Bethesda, MD (Co moderator)*

Lynn Shapiro Snyder, Esq., *Senior Member, Health Care, Life Sciences and Litigation Practices, Epstein Becker & Green, Washington, DC (Co moderator)*

6:00 PM ADJOURNMENT

Wednesday, November 11, 2009

**DEVICE CONGRESS AGENDA:
DAY III – CLOSING PLENARY SESSION**

7:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:00 AM WELCOME AND INTRODUCTIONS

Ted Acosta, Esq., *Principal, Ernst & Young LLP; Former Senior Counsel, Office of Inspector General, US Department of Health and Human Services, New York, NY, USA and Paris, France (Co chair)*

GLOBAL COMPLIANCE

**8:15 AM GLOBAL COMPLIANCE BEST PRACTICES
ROUNDTABLE, INCLUDING HYPOTHETICAL
CASE STUDIES**

Larry Montes, MBA, *Vice President Health Care Compliance and Privacy, Cordis Corporation, a Johnson & Johnson company, Bridgewater, NJ*

Kristine A. Rapp, Esq., *Vice President, Global Ethics and Compliance, Hospira, Inc., Lake Forest, IL*

Eileen Erdos, *Principal, Fraud Investigation & Dispute Services, Ernst & Young LLP, Chicago, IL (Co moderator)*

Keith M. Korenchuk, JD, MPH, *Partner, Arnold & Porter, Washington, DC (Co moderator)*

COMPLIANCE BEST PRACTICES

**9:30 AM COMPLIANCE PROCESS EXCELLENCE:
IMPLEMENTATION OF BETTER COMPLIANCE
PRACTICES**

Mark N. Bonaguro, Esq., *Chief Compliance Counsel, Covidien, Mansfield, MA*

David Wysocky, *Director, Pharmaceuticals and LifeSciences, PricewaterhouseCoopers, Boston, MA*

10:15 AM BREAK

**10:30 AM KEYNOTE PANEL: MEDICAL DEVICE
COMPLIANCE PROFESSIONAL AND LEGAL
COUNSEL BEST PRACTICE ROUNDTABLE**

Mark N. Bonaguro, Esq., *Chief Compliance Counsel, Covidien, Mansfield, MA*

Sujata T. Dayal, *Corporate Vice President and Chief Compliance Officer, Global Operations, Biomet, Inc., Warsaw, IN*

Daniel J. Garen, Esq., *Chief Compliance Officer and Senior Counsel, Siemens Healthcare Sector, USA, Malvern, PA*

Gregg H. Vicinanza, Esq., *Associate General Counsel, Becton Dickinson and Company, Franklin Lakes, NJ*

Link Bonforte, *President, LB1 Consulting LLC; Former Vice President, Ethics & Compliance, ConvaTec Inc., Belle Mead, NJ (Moderator)*

NOON ADJOURNMENT

POST CONFERENCE SYMPOSIUM
*Making Compliance Training Fun:
Training the Trainer*

(Optional; Requires separate registration)

1:30 PM POST CONFERENCE SESSION COMMENCES

John Avellanet, *Managing Director, Cerulean Associates LLC; Former Chief Information Officer, Chrysalis Technologies, Williamsburg, VA*

Nancy Singer, JD, LLM, *President, Compliance-Alliance, LLC, Arlington, VA*

SESSION OVERVIEW:

Device firms need to train their staff in FDA's advertising and promotion regulations, the fraud and abuse laws, and more. If you find yourself in this role and don't relish the idea of giving training that people will forget, don't panic! There are some easily implemented techniques you can use to engage your audience, turn a tedious, boring training session into a memorable and engaging experience that will ensure your staff all retain this vital content and leave you looking like a star.

HOTEL INFORMATION: A special conference rate of \$289.00 single/double per night (plus tax) has been arranged. Please make reservations directly with JW Marriott Reservations by calling 202-393-2000 or 800-393-2503 and mention the conference code "Med Device 2009" to receive the reduced rate.

Reservations may also be made online at: www.jwmarriottdc.com and enter the conference code **hchcca**

Reservations at the conference rate will be accepted until Tuesday, October 20, 2009. After this cut-off date, reservations will be accepted on a space-available basis at the prevailing rate.

JW Marriott Hotel:

1331 Pennsylvania Avenue, NW • Washington, DC 20004

Reservations: 202-393-2000 or 800-393-2503

What You'll Learn:

- The 3 items to include in the invitation that will ensure people will sign up
- How to create a sense of anticipation before the session begins
- How to demonstrate that your information is credible
- How to immediately involve all the participants
- Techniques for generating discussion
- Ways to ensure people pay attention throughout the presentation
- What NOT to do when creating slides and graphs
- How to effectively use graphs to make your point
- Tips for handling difficult attendees
- How to create a simple training matrix that is easy to maintain
- How to encourage attendees to use the material they learned

4:30 PM ADJOURNMENT

THE FOLLOWING REGISTRATION TERMS AND CONDITIONS APPLY

REGARDING INTERNET REGISTRATIONS

1. Individuals or groups may register for Internet access. Organizations may register for group access without presenting specific registrant names. In such instances the registering organization will be presented a series of user names and passwords to distribute to participants.
2. Each registrant will receive a user name and password for access.
3. Internet registrants will enjoy six (6) months access from date of issuance of user name and password.
4. Only one user (per user name and password) may access archived conference. It is not permissible to share user name and password with third parties. Should Internet registrants choose to access post conference content via alternative media (Video iPod™, CD-ROM and Flash Drive), this individual use limitation applies. It is not permissible to share alternative media with third parties.
5. User name and password use will be monitored to assure compliance.
6. Each Internet registration is subject to a "bandwidth" or capacity use cap of 5 gb per user per month. When this capacity use cap is hit, the registration lapses. Said registration will be again made available at start of next month so long as registration period has not lapsed and subject to same capacity cap.

REGARDING ONSITE REGISTRATION, CANCELLATIONS AND SUBSTITUTIONS

1. For onsite group registrations, full registration and credit card information required for each registrant. List all members of groups registering concurrently on fax or scanned cover sheet.
2. No refunds will be given for "no-shows" or for cancellations. You may send a substitute or transfer your onsite registration to an online registration. For more information, please call the Conference Office at 800-503-7406.

METHOD OF PAYMENT FOR TUITION

Make payment to Health Care Conference Administrators LLC by check, MasterCard, Visa or American Express. Credit card charges will be listed on your statement as payment to Health Care Conference Administrators LLC. Checks or money orders should be made payable to Health Care Conference Administrators LLC. A \$20 fee will be charged on any returned checks.

PAYMENT OPTIONS

Registration may be made online or via mail, fax or scan.

You may register online at www.DeviceCongress.com.

Alternatively, you may use our printed registration form, enclose payment and return it to the Congress registrar at 3291 West Wilson Road, Pahrump, NV 89048, or fax the completed form to 760-418-8084 or scan the completed form to registration@hccconferences.com. Checks or money orders should be made payable to Health Care Conference Administrators LLC.

The following credit cards are accepted: American Express, Visa or MasterCard. Credit card charges will be listed on your statement as payment to Health Care Conference Administrators LLC.

For registrants awaiting company check or money order, a credit card number must be given to hold registration. If payment is not received by seven days prior to the Congress, credit card payment will be processed.

TAX DEDUCTIBILITY

Expenses of training including tuition, travel, lodging and meals, incurred to maintain or improve skills in your profession may be tax deductible. Consult your tax advisor. Federal Tax ID: 91-1892021.

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THE MEDICAL DEVICE CONGRESS

REGISTRATION FORM

HOW TO REGISTER: Fully complete the following (one form per registrant, photocopies acceptable). Payment must accompany each registration (U.S. funds, payable to Health Care Conference Administrators, LLC).

ONLINE: Secure online registration at www.DeviceCongress.com.

FAX: 760-418-8084 (include credit card information with registration)

MAIL: Conference Office, 3291 West Wilson Road, Pahrump, NV 89048

FOR REGISTRATION QUESTIONS:

TOLL-FREE: 800-503-7406 (Continental U.S., Alaska, Hawaii and Canada only)

PHONE: 775-537-2311

E-MAIL: registration@hcconferences.com

(Registration is not available by phone or e-mail.)

COMPLETE THE FOLLOWING. PLEASE PRINT CLEARLY:

NAME _____
SIGNATURE OF REGISTRANT - REQUIRED _____
JOB TITLE _____
ORGANIZATION _____
DEPARTMENT _____
ADDRESS _____
CITY/STATE/ZIP _____
TELEPHONE _____
FAX - Please include fax number if you wish to receive a confirmation letter. _____
E-MAIL _____
 Special Needs (Dietary or Physical)

ONSITE CONFERENCE ATTENDANCE

PRECONFERENCE REGISTRATION:

- PRECONFERENCE I: US Hot Button Issues and Recent Compliance Code Changes for 2009: Are you Ready? \$ 495
 PRECONFERENCE II: Dangerous Documents: Finding Land Mines in Your FDA Reports and Emails \$ 495

CONFERENCE REGISTRATION:

(November 9 – 11, 2009; does not include Preconference or Postconference):

- Through Friday, October 2, 2009 \$1,795
 After Friday, October 2 \$1,995

POSTCONFERENCE REGISTRATION:

- Making Compliance Training Fun: Training the Trainer \$ 495

GROUP REGISTRATION DISCOUNT:

Three or more registrations submitted at the same time receive the following discounted rates for conference registration only. To qualify, all registrations must be submitted simultaneously:

Conference:

- Through Friday, October 2, 2009 \$1,595
 After Friday, October 2, 2009 \$1,795

ONLINE CONFERENCE ATTENDANCE

All online registrants are automatically registered for both the preconference and the conference.

Online conference registration includes the live Internet feed from the Congress, plus six months of continued archived Internet access, available 24/7.

INDIVIDUAL REGISTRATION:

Includes preconference and conference:

- Through Friday, October 2, 2009 \$1,195
 After Friday, October 2, 2009 \$1,295

GROUP REGISTRATION:

Group registration offers the substantial volume discounts set forth below.

All group registrants are enrolled in the preconference and conference.

Group registration permits the organizational knowledge coordinator either to share conference access with colleagues or to assign and track conference participation to employees.

Conference Access: 5 or more \$595 each 20 or more \$395 each
 10 or more \$495 each 40 or more \$295 each

To register groups, please complete a form for each registrant marking the appropriate group discount. All forms must be submitted together to qualify for the group discount. Submit form via fax or mail.

See INTELLECTUAL PROPERTY POLICY policy below.

Terms and Conditions, continued

CONTINUING EDUCATION UNITS (CEUS)

The Congress does not offer CEUs; however, on-site attendees may request a Certificate of Attendance which they can present to their specific continuing education provider.

INTELLECTUAL PROPERTY POLICY

Unauthorized sharing of Congress content via Internet access through the sharing of user names and passwords or via alternative media (30GB Video iPod™, CD-ROM and Flash Drive) through the sharing of said media is restricted by law and may subject the copyright infringer to substantial civil damages. The Congress aggressively pursues copyright infringers.

If a registrant needs the ability to share Congress content within his or her organization, multiple Congress registrations are available at discounted rates.

The Congress will pay a reward for information regarding unauthorized sharing of Congress content. The reward will be one half of any recovery resulting from a copyright infringement (less legal fees and other expenses related to the recovery) up to a maximum reward payment of \$25,000. The payment will be made to the individual or individuals who in the opinion of our legal counsel first provided the factual information, which was necessary for the recovery.

If you have knowledge regarding the unauthorized Congress content sharing, contact the Congress registration office.

GENERAL TERMS AND CONDITIONS

The Congress program is subject to change. An executed registration form constitutes binding agreement between the parties.

FOR FURTHER INFORMATION

Call 800-503-7406, send e-mail to registration@hcconferences.com, or visit our website at www.DeviceCongress.com.

PAYMENT

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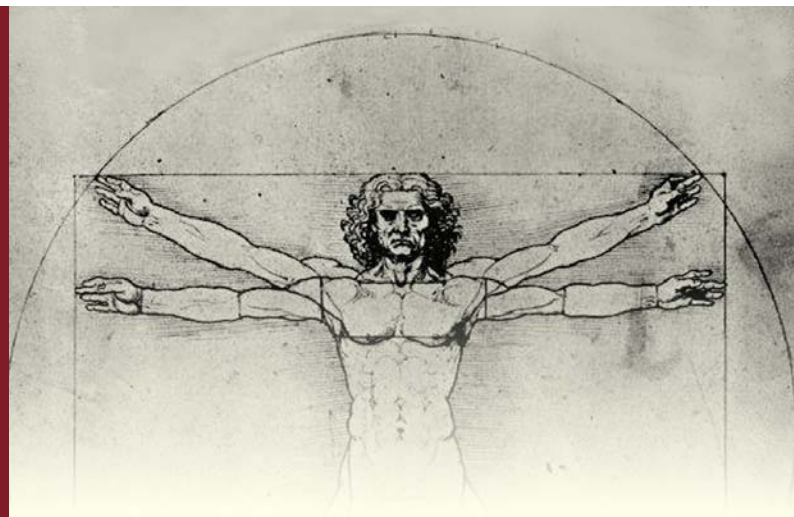
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