Updated 05/04/2015

2015 ARCHIVED WEBINARS

Reducing Drug and Device Batch Release Times
Speaker: Jerry Dalfors, Principal, JD Technologies
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Gender Distribution in Device Clinical Trials
Speakers: Rita F. Redberg MD MSc, Professor of Medicine and Director of Women's Cardiovascular Services at UC-San Francisco and Chief Editor of JAMA Internal Medicine; Sanket Dhruva MD, Cardiology Fellow, UC-Davis Medical Center
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

CAPA: How Good is Your Containment Program?
Speaker: James (Rusty) Lusk, Principal, Quality Systems International
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Risk-Based Monitoring of Clinical Trials
Speaker: Darshan Kulkarni, Kulkarni Law Firm, PC
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Aging Aseptic and Biological Manufacturing Facilities
Speaker: Herman Bozenhardt, Bozenhardt Consulting Services, LLC
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Top 7 Keys to eMDR Success
Speaker: Deborah Kacera, Regulatory and Industry Strategist, Pilgrim Quality Solutions
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Is Your Company Recall Ready? 10 Lessons from the Field
Speakers: Willie R. Bryant, Expert Consultant, Stericycle ExpertSOLUTIONS and Chris Harvey, Recall Strategist, Stericycle ExpertSOLUTIONS
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Conducting Effective Internal Quality Audits
Speaker: Susan Reilly, Reilly Associates, LLC
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Understanding China's New Medical Device Regulations
Speaker: John Balzano, Covington and Burling, LLP
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

How to Make Your Quality Control Unit Produce Quality Work
Speaker: Crystal Mersh, Co-founder and President, Quality Executive Partners, Inc.
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

FDA's New Inspection Approach
Speaker: Rich Yeaton, President, Atlantic Technical and Validation Services
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Secrets of Smart Risk-Based Device Packaging
Speaker: Abhishek (Abhi) Gautam, Manager of Packaging Engineering, ConMed
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Five Steps to Proven Device Purchasing Control Management
Speaker: Mike Heyl, Partner, Hogan Lovells
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Is Your Device a Secret Safety Risk?
Speaker: Rita King, CEO, MethodSense
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Device FDA Inspections: An Expert Tells All
Speaker: Jodi Scott, Partner, Hogan Lovells
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

How FDA's Tissue Guidances Will Impact Manufacturers and Users
Speaker: Stacie Ropka, Counsel, for Axinn, Veltrop & Harkrider, LLP
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

General Wellness Products: How to Make the FDA's New Rules Work For You
Speaker: Frederick Stearns, Partner, Keller and Heckman
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

FDA's New Inspectorate Re-Org to Put Pressure on SMEs
Speaker: Joanne Cochran, President, JWC Training Associates
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Reporting Failed Clinical Trial Data
Speaker: Scott Cunningham, Partner, Covington and Burling, LLP
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Spreadsheet Validation 2015
Speaker: David Harrison, Principal Consultant, CSV Compliance Limited
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Raw Materials Risk Management in GMP Facilities
Speaker: Mukesh Kumar, Regulatory Affairs and Quality Assurance, Amarex
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

2014 ARCHIVED WEBINARS

Selecting and Managing Device Suppliers
Speaker: Jeff Kasoff, Director of Quality, Medivators
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Delaying, Denying, Limiting, Refusing Inspections: What’s in the FDA Investigator’s New Handbook
Speaker: Lynn C. Tyler, Partner, Barnes and Thornburg, Food, Drug and Device Law Practice Group
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Digging for 483 Gold: How to Mine the FDA's Inspection Reports
Speaker: Michael Swit, Special Counsel, Duane Morris LLP

Internal cGMP Audits: Using Innovative Risk-Based Techniques to Revitalize Your Program
Speaker: John E. Lincoln, Principal, J.E. Lincoln and Associates, LLC
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Device De Novo Reclassification: FDA's New Direct De Novo Petitions in Action
Speakers: Jonathan Kahan, Partner and Co-director, Food, Drug, Medical Device and Agriculture Group, Hogan Lovells; Kristin Zielinski, Director of Regulatory Sciences, Hogan Lovells; and Kelliann Payne, Counsel, Hogan Lovells
This webinar has been pre-approved by RAPS as eligible for up to 1.5 credits towards a participant's RAC recertification.

Preparing for an FDA Inspection
Speaker: John Avellanet, Founder, Cerulean Associates LLC

Understanding the New FDA Purple Book on Biosimilars
Speakers: Lee Rosebush, counsel, and Nita Garg, associate, Baker & Hostetler LLP

Drug Promotion Enforcement Letters
Speaker: Julie Tibbetts, Partner in the Food, Drug & Device/FDA Group at Alston & Bird LLP

FCPA Compliance Roadmap for Drug and Device Companies
Speakers: Michael Burke, Corporate Practice Partner, Arnall Golden Gregory LLP; Ed Cadigan, Associate in the Litigation and Employment Practice Groups of Arnall Golden Gregory

FDA Device Advisory Panel Review Process
Speakers: Chris Sloan, Principal Consultant, Quintiles Consulting; Michael Morton, Vice President Global Regulatory Affairs, Medtronic, Inc.

Impact of GDUFA Performance Metrics on ANDA Approval Times
Speaker: Joan Janulis, Vice President and Regulatory Affairs Practice Head, Lachman Consultants

Life Science Customer Complaints
Speaker: Carol Kozlowski, Manager of Crisis Management for Insurance Services, RQA, Inc.

FCPA Compliance Roadmap for Drug and Device Companies
Speakers: Michael Burke, Corporate Practice Partner, and Ed Cadagin, Litigation and Employment Practice Associate, Arnall Golden Gregory LLP

Accelerating Growth with Modern Quality and Compliance Solutions
Speaker: Matthew Littlefield, President, LNS Research

What to Do Now for UDI
Speakers: Dan O'Leary, President, Ombu Enterprises, LLC; Don Guthner, Founder and Principle of Orgenix, LLC

Managing Risk for Clinical Trials
Speakers: Sherri Hubby, U.S. Director of Quality Assurance, Premier Research; Brian Nugent, Associate Director of Clinical Operations, Gilead Sciences

Improving Your FDA Import Success Rate
Speaker: Ben England, CEO, FDAImports.com

How to Implement USP 1058 for Lab Equipment Qualification
Speaker: Ludwig Huber, Ph.D., Director, Labcompliance

Complying with the New EMA Pharmacovigilance Rules
Speaker: Elisabethann Wright, Partner, Hogan Lovells, Brussels, Belgium

FDA's Clinical Biosimilarity Guidance
Speakers: Kevin Nelson, Partner, and Patrick Gallagher, Associate, Intellectual Property Practice Group, Duane Morris LLP

Choosing the Right Drug Name
Speakers: Susan Proulx, PharmD, President, Med-ERRS, Inc.

Product Liability Dangers of Off-Label Promotion
Speaker: Sara Dyson, Assistant Vice President of Loss Control, Medmarc Insurance Group

Expedite Your FDA Generic Drug Approval
Speaker: Andy Papas, Vice President of Regulatory Affairs at NSF Health Sciences Pharma Biotech

How to Achieve 510(k) Application Success for Device Software
Speaker: Cheryl Wagoner, Principal Consultant/Owner of Wagoner Consulting LLC

Preparing for Global Track & Trace Regulations
Speaker: William Fletcher, Managing Partner, Pharma Logic Solutions, LLC

Inspectional Readiness: Are Your SMEs Prepared for a Successful FDA Visit?
Speakers: Julie Larsen, Director of Inspection Readiness, BioTeknica; Arnold Solomon, President, FDA Strategic Compliances, LLC

Registering "Applicable Trial" Data on Clinicaltrials.gov
Speaker: Scott Cunningham, Partner, Covington and Burling LLP

Medical Device Recall or Product Enhancement?: Understanding When To Submit A Part 806
Speakers: Neil O'Flaherty, Principal Attorney, and Casper Uldriks, Counsel of Attorneys, OFLW Law

Recall Process Lifecycle
Speaker: Joe Falvo, Senior Manager: Post Market Risk Management, Ortho Clinical Diagnostics

How to Recover the Costs of a Recall
Speakers: Marialuisa Gallozzi, Partner, Covington & Burling, and Suzan Charlton, Special Counsel, Covington & Burling

Building Effective Internal Recall Committees
Speaker: Todd Halpern, Assistant General Counsel, Regulatory Law, Pfizer

Are you Ready to Handle a Global Recall?
Speaker: Mary Swift, Senior Manager, Regulatory Affairs, Terumo Cardiovascular Systems

Develop a Process Validation Roadmap
Speaker: Rich Yeaton, Validation Manager, Mangan Biopharm

FDA's New Device Reclassification Process
Speakers: Beth Bierman, Partner, Phoebe Mounts, Partner, and Michele Buenafe, Associate, Morgan Lewis FDA Practice.

Secrets of Smart Labeling Self-Audits
Speaker: Joseph McMillian, President, Heartland Consulting

Traditional Approaches for Cooperating with Outsourced Manufacturers and Suppliers are Failing
Speaker: Matthew Littlefield, president and principal analyst, LNS Research

Sample Size Considerations for Verification and Validation
Speaker: Steven Walfish, President, Statistical Outsourcing Services

Conducting Audits at Medical Conventions and Meetings
Speaker: Joseph McMillian, President, Heartland Consulting

Reduce Human Error on the Drug and Device Manufacturing Floor
Speaker: Ginette Collazo, Ginette M. Collazo, Inc.

The FDA's New Device Pre-Submission Program
Speaker: Albert Ghignone, CEO, AAG Incorporated

Device Supplier Controls: An FDA Perspective
Speaker: M. Isabel Tejero, Acting Lead, Quality Systems Working Group, Division of Manufacturing and Quality, Office of Compliance, CDRH, FDA

FDA Supplier Control Inspection and Enforcement Trends
Speaker: John Avellanet, Principal Consultant, Cerulean Associates

Lessons from a Veteran Supplier Manager: Understanding How to Manage Suppliers Whether You're a Big or Small Company
Speaker: David Parkin, Supplier Development Manager, Boston Scientific

Legal and Regulatory Issues Related to Quality Agreements
Speaker: Alan Minsk, Partner and Leader, Food and Drug Practice Team, Arnall Golden Gregory LLP

Assessment Tool for Choosing the Right Subcontractor or Supplier
Speaker: Jackie Torfin, Vice President of Quality, Heraeus Medical Components

Understanding the Role of Prevention-Oriented CAPA Strategies
Speaker: Jason Spiegler, Director, Strategic Market Development, Camstar Systems; Chair, ASQ Charlotte, NC Section

Inside the Mind of an FDA Investigator
Speaker: Ken Miles, Principal, Alpha Quality Assurance

Data Analysis Techniques for Devicemakers
Speaker: Dan O'Leary, President, Ombu Enterprises

CAPA Systems, Failure Investigations and Trending
Speaker: Greg Meyer RAC, CQA, President and Principal Consultant and Trainer at Compliance Media Inc.

Cut Drug Approval Time: Is a 505(b)(2) the Right Way to Go?
Speaker: Kurt Karst, Director, Hyman, Phelps & McNamara

HIPAA/HITECH Compliance Strategies for Medical Device Manufacturers
Speaker: Seth Mailhot, Partner and Lead, FDA Regulatory Practice, Michael Best and Friedrich LLP

Top Nine UDI Compliance Challenges
Speaker: Jay Crowley, Vice President of the UDI practice at USDM Life Sciences

Create an Inspection Readiness Gap Analysis
Speaker: Dr. David Lim, President and CEO, RegulatoryDoctor.com

The FDA Is Watching: What Twitter, Tradeshows and TV Have in Common
Speakers: Timothy Ayers, Principal, Life Sciences Compliance, Commercialization and Regulatory Counseling Department, Porzio, Bromberg and Newman; Michelle Axelrod, Principal, Porzio, Bromberg and Newman

CDRH's Office of Compliance Reorganization
Speakers: Steven Niedelman, Lead Quality Systems and Compliance Consultant to the FDA & Life Sciences Practice Team, King & Spalding, and Steve Silverman, Director, Office of Compliance, CDRH

Best Practices for Managing Clinical Trial Materials
Speaker: Hedley Rees, Managing Consultant, Pharma Flow

Device Software Validation and Verification
Speaker: John Lincoln, Principal, J.E. Lincoln and Associates, LLC.

2013 ARCHIVED WEBINARS

Medical Device Inspections
Speaker: Jodi Scott, Partner, Hogan Lovells

REMS 2014
Speaker: Howard Dorfman, Vice President and General Counsel, Ferring Pharmaceuticals, Inc.

Spreadsheet Validation 2014
Speaker: David Harrison, Principal Consultant, ABB Engineering Services

FDA's Proposed Generic Drug Safety Labeling Rule
Speakers: Daniel Kracov, head of the FDA and healthcare practice at Arnold & Porter LLP, and Dan Pariser, partner and specialist in healthcare product liability, Arnold & Porter LLP

Defending Your Brand from Attack by Drug Counterfeiters and Illegal Diverters
Speakers: Robert Reznick, Partner and Life Sciences Practice Co-Chair, Orrick, Herrington & Sutcliffe, and Elizabeth Howard, Partner and Intellectual Property Litigator, Orrick, Herrington & Sutcliffe

Ensuring Market Success Via Environmental Compliance
Speakers: George Valaitis, RoHS Program Manager with Global responsibilities, AB SCIEX and Jean Colombel, Vice President of the Life Sciences Industry, Dassault Systèmes

Perfecting Your Company Core Data Sheets
Speaker: Graeme Ladds, CEO, PharSafer Associates Ltd.

Metal Impurities in Finished Drug Products
Speaker: Nancy Lewen, Principal Scientist, Bristol-Myers Squibb

Device Off-Label Promotion
Speakers: Anne Walsh, Director, Hyman Phelps and Allyson Mullen, Associate, Hyman Phelps

Complaint Handling and Medical Device Reporting
Speaker: Mike Heyl, Attorney, Hogan Lovell

Cybersecurity Threats to Medical Devices
Speaker: Axel Wirth, National Healthcare Solutions Analyst, Symantec

Nonconforming Product Problems in Medical Devices
Speaker: Dan O'Leary, President, Ombu Enterprises LLC

EU Pharmacovigilance
Speaker: Elisabethann Wright, Partner, Hogan Lovells International

Preparing for Expanded Clinical Trial Data Transparency
Speaker: Scott Cunningham, Esq., Partner, Covington & Burling LLP

ADE? Or ADR?
Speaker: Dr. Hoss Dowlat, Ph.D, VP-Regulatory Affairs, PharmBio Consulting

Remote Monitoring of Clinical Trial Sites
Speaker: Ken Schiff, President and Owner, Quality Risk Management Associates, LLC

Is It a Cosmetic, a Drug, or Both?
Speaker: Kim Egan, Principal, Saltbox Consulting

New OTC Labeling Guidances
Speaker: Kari Sutherland, Attorney, Butler, Snow, O'Mara, Stevens & Cannada, PLLC

Avoiding Problems with FDA in Manufacturing Parenteral Products
Speaker: Barbara Immel, President, Immel Resources LLC

Building a CMC Scorecard for Drug Development Risk Assessment
Speaker: Bryan Knox, Senior Director of Pharmaceutics, Pharmatek

Physician Payment Disclosure to CMS
Speaker: Tim Robinson, Esq., Executive Vice President and General Counsel, MMIS, Inc. and Seth Lundy, Esq., Partner, King & Spalding

Device History Records
Speaker: Dan O'Leary, President, Ombu Enterprises LLC

Auditing Virtual Suppliers
Speaker: John Avellanet, Managing Director, Cerulean Associates LLC

Building Quality Into Clinical Trials With Effective Protocol Design
Speaker: Ken Schiff, President, Quality Risk Management Associates, LLC

Sec. 820.80: Acceptance Activities
Speaker: Dan O'Leary, CBA, CQA, CQE, CRE, CSSBB, CIRM Partner, Ombu Enterprises

Risk-Based Verification and Validation to Meet FDA 820.75 and ISO 13485 Requirements
Speaker: John Lincoln, Partner, J. E. Lincoln and Associates LLC

GLP and GMP Auditing for High-Potency Compounds
Speaker: Dean Calhoun, President, Affygility Solutions

Newly Proposed EU Medical Device Regs
Speakers: Peter Bogaert, Managing Partner, Brussels Office of Covington & Burling and François-Régis Babinet, Associate, Brussels Office of Covington & Burling

Tips and Tactics to Assure Compliance with FDA Financial Disclosure Requirements for Clinical Investigators
Speaker: Afia Asamoah, Attorney, Covington & Burling

Combination Products cGMP Final Rule
Speaker: Suzanne O'Shea, J.D., Counsel, Faegre Baker Daniels

Medical Device Excise Tax
Speaker: Dan Lynn, CPA, MBA, Tax Partner, Beene Garter

Final 510(k) Refuse-to-Accept, Premarket Reviews and eCopy Guidances
Speakers: Laurie Clarke, Partner, King & Spalding's FDA & Life Sciences Practice Group and Lynette Zentgraft, Senior Regulatory Consultant, King & Spalding's FDA & Life Sciences Practice Group

Reimbursement for Subject Injuries in Clinical Trials
Speakers: David A. Charapp, Partner, Duane Morris LLP and Erin M. Duffy, Associate, Duane Morris LLP

eCTD Requirements
Speaker: Antoinette Azevedo, Principal, e-SubmissionsSolutions.com

Equipment Maintenance, Calibration and Cleaning Programs
Speaker: Kenneth Christie, COO, Consulting Services at VTS Consultants Inc.

QSR's 820.20 — Management Responsibility
Speaker: Dan O'Leary, President, Ombu Enterprises LLC

Foreign Corrupt Practices Act
Speakers: Keith Korenchuk, Partner, Arnold & Porter, LLP and Samuel Witten, Counsel, Arnold & Porter, LLP

2012 ARCHIVED WEBINARS

Clinical Trial Disclosure Compliance Strategies
Speaker: Barbara Godlew, RN, BA, President, The FAIRE Company, LLC

Spreadsheet Validation
Speaker: David Harrison, Principal Consultant, ABB Engineering Services

International Drug and Device Recalls
Speaker: James M. Wood, Attorney, Reed Smith

Responding to Clinical Trial Inspectional Observations and FDA 483s
Speaker: Dr. Darshan Kulkarni, Principal Attorney, Kulkarni Law Firm

How Not to Ruin a Perfectly Good Product With a Flawed Study Design
Speaker: Dr. Debbie Wilkerson, Clinical Research Director, Medtronic Spinal

Creating, Staffing and Managing an Inspection War Room
Speaker: Dr. Darshan Kulkarni, Principal Attorney, Kulkarni Law Firm

FDA-adopted Columbia-Suicide Severity Rating Scale (C-SSRS) Categories for Prospective Assessment
Speakers: Dr. Kelly Posner, Founder, Center for Suicide Risk Assessment at Columbia University/New York State Psychiatric Institute; Dr. John Greist, CEO, Healthcare Technology Systems and Mike Federico, Vice President, ePRO solutions, ERT Inc.

Going "E" With Informed Consent for Clinical Trials
Speakers: Dr. Susan Brink, President and CEO, Consent Solutions Inc. and Sherri Bracy, Founder and Director, Bracy Consulting LLC.

Medical Device Software Recalls on the Rise
Speaker: Dr. David Vogel, Founder, Intertech Engineering Associates

Off-the-Shelf Versus Custom-Built Quality Systems
Speaker: Brian Dense, President, CiNQ Systems

Your Clinical SOPs Are Too Long!
Speakers: Steven Steinbrueck, President, Stonebridge GCP Consulting and Elizabeth Bodi, Clinical Research Senior Consultant, Halloran Consulting Group

Managing EMA Drug Process Validation
Speaker: Thomas Peither, President, Maas & Peither America Inc.

MDUFA 2012
Speakers: Steven Niedelman, Lead Quality Systems and Compliance Consultant to the FDA & Life Sciences practice team, King & Spalding and Pamela Furman Forrest, Partner, King & Spalding

Insider Insight on PDUFA V
Speakers: Peter Barton Hutt, Senior Counsel, Covington & Burling; Erika Lietzan, Partner, Covington & Burling; Scott Cunningham, Partner, Covington & Burling and Stefanie Doebler, Special Counsel, Covington & Burling

Complying with FDA's Unique Device Identification Rule
Speakers: Siobhan O'Bara, Healthcare Vice President, GS1 US and John Roberts, Director of Healthcare, GS1 US

Medical Device Reimbursement De-Mystified
Speaker: Ed Dougherty, Senior Healthcare Advisor, Arent Fox

Device Off-Label Promotion
Speakers: James Ravitz, Partner, Arent Fox LLP and Stephanie Trunk, Associate in the Health Law Group, Arent Fox LLP

Understanding the U.S. Biosimilar Pathway in 2012
Speakers: Erika Lietzen, Partner, Covington & Burling and Laura Sim, Associate in Food & Drug practice group, Covington & Burling

Process Validation for Medical Devices
Speaker: Dan O'Leary, President, Ombu Enterprises

Inspectional Readiness
Speakers: Julie Larsen, Director Inspection Readiness Services, BioTeknica Inc. and Arnold Solomon, President, FDA Strategic Compliances LLC

Physician Payment Sunshine Act
Speakers: Michaeline Daboul, President and CEO, MMIS Inc. and Tim Robinson Esq., Executive Vice President and General Counsel, MMIS Inc.

510(k) Process Changes Survival Guide
Speakers: Neil O'Flaherty, Principal, Olsson Frank Weeda Terman Matz PC (OFW Law); Evan Phelps, Principal, OFW Law and Nancy Mathewson, Associate, OFW Law

Part 806 Device Recalls
Speaker: Gordon B. Richman, Vice President, Strategic Compliance Consulting and General Counsel, EduQuest

Dietary Supplement GMP Inspections and Violations
Speakers: Dean Cirotta, Vice President, EAS Consulting Group and William Ment, Contract Consultant, EAS Consulting Group

Medical Device Complaint Management
Speaker: Susan Reilly, Owner and Principal Consultant, Reilly & Associates LLC

Legal and Regulatory Guide to EU's New Pharmacovigilance Regulations
Speaker: Elisabethann Wright BL, Partner, Hogan Lovells International

Develop a Process Validation Roadmap
Speaker: Rich Yeaton, President, East Coast Validation Services LLC

Requirements for Effective Environmental Monitoring Plans
Speaker: Kenneth Christie, COO, Consulting Services at VTS Consultants Inc.

Pharma/Device Social Media: What You Can and Can't Do Today
Speakers: Michelle Sherman, Editor and Contributing Author to the *Social Media Law Update* blog, Sheppard Mullin Law Firm and Seth Mailhot, Special Counsel, Sheppard Mullin Law Firm

Managing Data Integrity and Part 11 Compliance for Device Suppliers
Speaker: John Avellanet, Managing Director, Cerulean Associates LLC

Controlling Cross-Contamination in Outsourced Manufacturing
Speakers: Kevin Rosenthal, Director of Manufacturing, Pharmatek Laboratories Inc. and Stephanie Wilkins, PE, Lean Six Sigma Green Belt

Registering "Applicable Trial" Data on ClinicalTrials.gov
Speaker: Scott Cunningham Esq., Partner, Covington & Burling LLP

2011 ARCHIVED WEBINARS

eCTD Requirements Under PDUFA V
Speaker: Antoinette Azevedo, Principal, e-SubmissionsSolutions.com

Adaptive Clinical Trial Design and Model-Based Drug Development
Speakers: Olga Marchenko, Vice President, Quintiles Inc. and Seth Berry, Director of Clinical PK-PD Modeling and Simulation, Quintiles Inc.

Marketed Unapproved Drugs
Speaker: Kurt Karst, Director and Attorney, Hyman, Phelps & McNamara P.C.

Spreadsheet Validation
Speaker: David Harrison, Principal Consultant, ABB Engineering Services

Reduce Human Error on the Drug and Device Manufacturing Floor
Speaker: Ginette Collazo Ph.D.

A Snapshot of Social Media in Pharma: The Why, What and How
Speaker: Casey Ferrell, Market Research Analyst, Cutting Edge Information

Surviving the FDA's New PREDICT Import Screening Program
Speaker: Benjamin L. England Esq., Founding Member, Benjamin L. England & Associates LLC

Form 483 and Warning Letter Responses
Speaker: Gordon B. Richman, Vice President, Strategic Compliance Consulting and General Counsel, EduQuest

QSR Data and Trending
Speaker: James Eric Miller, Core Quality Systems Senior Quality Analyst, Roche Diagnostics

Root Cause Analysis
Speaker: Michele Piepoli, Managing Director, MHP Consultants LLC

Clinical Trial Billing Under Medicare
Speakers: Kevin R. Eskew, Managing Director, SNR Denton Health Care Group and Lisa Murtha Esq., Member, Sonnenschein Health Care Group

U.S. and EU Individual Case Safety Reports
Speaker: Graeme Ladds, CEO, PharSafer Associates Ltd.

Drug-Induced Liver Injury
Speaker: Einar Bjornsson, Professor of Gastroenterology and Hepatology, Landspitali University Hospital

FDA's Electronic Source Documentation Guidance
Speaker: Dr. Jules Mitchel, President, Target Health Inc.

eMDR Conversion and Implementation
Speaker: Eugene Reilly, Public Health Analyst, FDA Center for Devices and Radiological Health Office of Surveillance and Biometrics

Standardizing REMS
Speaker: Edward Fotsch M.D., CEO, PDR Network LLC

Comparative Effectiveness Research
Speaker: Josh Feldstein, President, Joint Center for Applied Value Analysis and Principal, MarCom Group International

Off-Label Promotion — The Elephant in the Room
Speaker: Sara Dyson Esq., Assistant VP for Loss Control, Medmarc Insurance Group

How to Align the FDA Approval Process with Paragraph IV Strategy
Speaker: Chad Landmon Esq., Partner, Axinn Veltrop & Harkrider LLP

Preparing for an FDA Preapproval Inspection
Speakers: Frederick H. Branding RPh JD, Principal Attorney, Olsson, Frank, Weeda, Terman, Bode and Matz P.C. and Cathy L. Burgess, Partner, Olsson, Frank, Weeda, Terman, Bode and Matz P.C. Health Care Group

Reducing Gender Disparities in Device Clinical Trials
Speaker: Rita Redberg M.D., Professor of Medicine, Division of Cardiology, University of California-San Francisco School of Medicine

Risk Strategies in Clinical Trial Contracts
Speaker: Joan Antokol, Managing Partner, Park Legal LLC

Medical Device Complaint Systems
Speaker: Dan O'Leary, President, Ombu Enterprises LLC

A World Apart
Speakers: Steven Datlof MD JD, Partner, Hogan Lovells and Elisabethann Wright BL, Partner, Hogan Lovells International

GLP Compliance
Speaker: Anne Maczulak PhD RQAP-GLP, Principal Consultant, Acorn GLP Consulting

New EU Annex 11 Rules: Part 11's Get-Tough European Cousin
Speaker: Martin Browning, President and Co-Founder, EduQuest

Dissecting the Drug and Device Industries' Leading Legal Cases
Speaker: Alan Minsk, Partner and Chair of the Food & Drug Practice Team, Arnall Golden Gregory LLP

Practical Approaches to Lifecycle Signal Detection
Speaker: Elizabeth Garrard PharmD. R.Ph., Chief Safety Officer, Drug Safety Alliance Inc.

Spreadsheet Validation
Speaker: David Harrison, Principal consultant, ABB Engineering Services

Supplier Quality Management
Speaker: Steven Sharf, President, GMP Concepts

Social Media Strategies for Pharma
Speaker: Zoë Dunn, Independent Digital Marketing and Communications Consultant

Form 483 and Warning Letter Responses
Speaker: Gordon B. Richman, Vice President, Strategic Compliance Consulting and General Counsel, EduQuest

Perspectives on the FDA Guidance for Suicidality Monitoring in Clinical Trials
Speaker: Kelly Posner Ph.D., Founder, Center for Suicide Risk Assessment at Columbia University/New York State Psychiatric Institute

Medical Device Quality Audits
Speaker: John Gagliardi, President, MidWest Process Innovation LLC

Organizing Data & Doc Archives
Speakers: David Chesney, Quality and Compliance Management Services Vice President, PAREXEL Consulting and Peter D. Smith, Vice President for Pharmaceutical Compliance, PAREXEL

2010 ARCHIVED WEBINARS

Designing & Executing Observational Studies
Speaker: Peggy Schrammel, VP-Registries and Post Approval Development, United BioSource

Electronic Health Records and REMS
Speaker: Edward Fotsch M.D., CEO, PDR Network LLC

New Safety Reporting Requirements for Drugs and Biologics
Speakers: Joan Antokol, Managing Partner, Park Legal LLC and Dr. John (Jack) McLane, COO, Clinquest Inc.

Root Cause Analysis
Speaker: Michele Piepoli, Managing Director, MHP Consultants LLC

Purchasing Controls for Medical Device Manufacturers
Speaker: Dan O'Leary, President, Ombu Enterprises LLC

Reduce Supply Chain Risks
Speaker: Martin Browning, Founder and President, EduQuest

Clinical Trial Billing Under Medicare
Speakers: Holley Thames Lutz Esq., National Chair, Sonnenschein Health Care Group and Lisa Murtha Esq., Member, Sonnenschein Health Care Group

Supplier Quality Agreements for Warehouses & Shippers
Speaker: Jim Darnell, Managing Consultant, Tunnell Consulting

Bayesian Statistics in Medical Device Clinical Trials
Speaker: Dr. Robert Thiel, Founder and CEO, THIEL Statistical Consultants

Structured Product Labeling
Speaker: Antoinette Azevedo, Founder, e-SubmissionsSolutions.com

Reduce Human Error on the Manufacturing Floor
Speaker: Ginette Collazo Ph.D.

Medical Device Supplier Audits
Speaker: Steven Niedelman, Senior Consultant, Crowell & Moring LLP

Change Control Forms for Medical Devices
Speaker: Barbara Immel, President, Immel Resources LLC

A World Apart: Understanding Differences in EU and U.S. Medical Device Regulations
Speakers: Cristiana Spontoni, European Partner, Squire, Sanders & Dempsey LLP and Maureen Bennett, Partner, Squire, Sanders & Dempsey LLP

REMS Pitfalls and Challenges
Speaker: Edward Fotsch M.D., CEO, PDR Network LLC

Off-Label Promotion
Speaker: Alan Minsk, Chair of the Food and Drug Practice Team, Arnall Golden Gregory

Writing and Enforcing Effective SOPs
Speaker: Annalisa Pizzarello, Head of Global Compliance, Amgen

Analytical Method Validation Crash Course
Speaker: Melissa Smith, Co-chair, PDA Task Force for Method Development and Qualification

Clinical Trial Inspections
Speaker: David Rosen, Partner, Foley & Lardner

New 'Tag-Along' Part 11 Inspections
Speaker: Gordon Richman, Vice President, Strategic Compliance Consulting and General Counsel, EduQuest

Process Validation for Medical Devices
Speaker: Mike Long

Spreadsheet Validation
Speaker: David Harrison, Principal Consultant, ABB Engineering Services

Federal Pharma and Device Physician Gift Law
Speaker: John Patrick Oroho, Principal, Porzio, Bromberg & Newman P.C.

Direct-To-Consumer Broadcast Ads
Speakers: Dara Katcher Levy, Attorney, Hyman, Phelps & McNamara P.C. and Carrie Martin, Associate, Hyman, Phelps & McNamara P.C.

Emergency Planning Under the New FDA Guidance
Speaker: John C. “Jack” Garvey, Founder, Compliance Architects

Assuring GLP Compliance
Speaker: Chitra Edwin Ph.D RAC, Principal, Biotechnology Consulting Solutions

Medical Device Supplier Quality
Speaker: Dan O’Leary, President, Ombu Enterprises LLC

Falsified Data in Clinical Trials
Speakers: David Clissold, Director, Hyman, Phelps & McNamara and Nisha Shah, Associate, Hyman, Phelps & McNamara

How to Write and Maintain Bulletproof Company Core Data Sheets
Speaker: Alan Hassell, Independent Consultant

eCTD Regulatory Strategy and Product Lifecycle
Speaker: Gina Ross, Manager of the Regulatory Publishing Department, Beckloff Associates Inc.

cGMPs From An Auditor's Perspective
Speaker: Robert Schiff Ph.D., CEO, Schiff & Company

International Drug and Device Recalls
Speaker: James M. Wood, Attorney, Reed Smith

QSR Data and Trending
Speaker: James Eric Miller, Core Quality Systems Senior Quality Analyst, Roche Diagnostics

Cleaning Validation Risks
Speaker: Rich Yeaton, President, East Coast Validation Services LLC

Serious Adverse Event Reporting for OTCs and Dietary Supplements
Speaker: Ivan Wasserman, Partner, Manatt Phelps & Phillips LLP

Adverse Event Compliance in Drug and Biologic Clinical Trials
Speaker: Charles H. Pierce MD, PhD, FCP, CPI, Pierce One Consulting

GLP Compliance
Speaker: Chitra Edwin PhD RAC, Principal, Biotechnology Consulting Solutions Ltd.

Form 483 and Warning Letter Responses
Speaker: Dr. Marla Phillips, Director of Med-XU, Xavier University Leadership Center