

## PROGRAM ADDENDUM

# 2011 RAPS The Regulatory Convergence

22–26 October 2011 • Indianapolis • RAPS.org/2011



### SESSION UPDATES

#### Sunday, 23 October 2011

8:00 am–5:00 pm

Combination Product Regulation in the US Market

Unable to Attend:

**Patricia Y. Love, MD, MBA**, deputy director, Office of Combination Products, OC, US FDA

Added Faculty:

**Thinh Nguyen**, director, Office of Combination Products, OC, US FDA

**John (Barr) Weiner, JD**, associate director for policy and product classification officer, Office of Combination Products, OC, US FDA

8:30 am–5:00 pm

The Essentials: US Regulatory Affairs - Drugs and Biologics (Part 2)

**Virginia Perry, RAC, CQE, FRAPS**, president, Perry-D'Amico & Associates

#### Monday, 24 October 2011

10:30 am–12:00 pm

Software as a Medical Device and Home Use of Medical Devices

Unable to Participate:

**Jonathan Sackner-Bernstein, MD**, associate center director, technology & innovation, CDRH, US FDA

1:30–3:00 pm

Health Information Technology: What Impact Does It Have on Regulatory?

Updated Faculty Information:

**Robert Jarrin**, senior director, government affairs, Qualcomm Incorporated

Impact of Regulatory Milestones on Business Performance

Added Faculty:

**Christopher-Paul Milne, DVM, MPH, JD**, associate director, Tufts Center for Drug Development

**Michael C. Morton, RAC, FRAPS**, senior director, global regulatory affairs, Medtronic

Biomarker Qualification: A Journey from Inception to Application

Unable to Attend:

**Holly Soares, PhD**, director, clinical biomarkers neuroscience, Bristol Myers Squibb

Added Faculty:

**Leah Burns, MPH**, director, global health economics and outcomes research, neuroscience, Bristol-Myers Squibb

3:30–5:00 pm

Addressing Human Factors Combination Product Clinical Trials (*New Title*)

Unable to Attend:

**Patricia Y. Love, MD, MBA**, deputy director, Office of Combination Products, OC, US FDA

Added Faculty:

**Molly Follette Story, PhD**, human factors and accessible medical technology specialist, Office of Device Evaluation, CDRH, US FDA

## PROGRAM ADDENDUM

### Food Safety Regulation and Impact of Legislation

Unable to Attend:

**Leon H. Bruner, DVM, PhD**, senior vice president, science and regulatory affairs, chief science officer, Grocery Manufacturer's Association

Added Faculty:

**Shannon Cole, MS, PMP**, senior director, science program management, Grocery Manufacturer's Association

### Oversight of Lab Developed Tests (LDTs)

Unable to Attend:

**Kristin Baxter, PhD**, assistant director of translational research and policy, Genetic Alliance

Added Faculty:

**Liz Horn**, director, Genetic Alliance BioBank, Genetic Alliance

### The Role of Regulatory in Startup Small Venture Companies and Large Publically Traded Companies

Unable to Attend:

**Barry Sickels, PhD**, vice president, regulatory affairs, AstraZeneca

## Tuesday, 25 October 2011

8:30–10:00 am

### GMP: Auditing in Drugs and Biologics

Added Faculty:

**David Doleski**, team leader, NGDMT 3, DMPQ, CDER, US FDA

### Safety in Clinical Trials

Unable to Attend:

**Theresa M. Palabrica, MD**, senior director, clinical affairs, Thoratec Corporation

**Sally Van Doren, PharmD**, president & CEO, BioSoteria, Inc.

Added Faculty:

**Doug Worth**, director, regulatory affairs, PHP Program, Thoratec Corporation

### Update of China Medical Device Supervision, Regulation and Technical Evaluation

Unable to Attend:

**Wei Xu**, researcher, Center for Medical Device Evaluation, State Food and Drug Administration

### USP Strategies and Initiatives in Biologics and Biotechnology

Added Faculty:

**Barbara Rellahan, MS, PhD**, team leader, Division of Monoclonal Antibodies, CDER, US FDA

10:30 am–12:00 pm

### Case Studies (A–mAb and Vaccine) and the QbD Pilot Simultaneous Review

Unable to Attend:

**Sam Venugopal**

Added Faculty:

**Usha Srinivasan, MS, RAC**, manager, R&D operations, Marcadia Biotech Inc.

### Clinical Trial Data for Medical Devices and IVDs

Added Faculty:

**Christy Foreman**, acting director, Office of Device Evaluation, CDRH, US FDA

### Foods and Global Borderline Issues with Drugs, Cosmetics, Botanicals and Food Supplements

Added Faculty:

**Daniel Fabricant, PhD**, director, Division of Dietary Supplement Programs, Office of Nutrition, Labeling and Dietary Supplements, CFSAN, US FDA

**Sara O'Connor**, manager, Submission Management Division, Natural Health Products Directorate, Health Canada

### Global Markets–Focus on Device/IVD Regulation in Taiwan

Added Faculty:

**I-Ning Tang**, senior reviewer, Division of Medical Devices and Cosmetics, Taiwan FDA

## PROGRAM ADDENDUM

1:30–3:00 pm

The Future Regulation of Probiotics

Added Faculty:

**Sara O'Connor**, manager, Submission Management Division, Natural Health Products Directorate, Health Canada

510(k) Reform

Unable to Attend:

**Janet Trunzo, MS**, executive vice president, technology & regulatory affairs, Advanced Medical Technology Association (AdvaMed)

Added Faculty:

**April Veoukas**, director, regulatory affairs, Abbott Laboratories

3:30–5:00 pm

MDUFMA Reauthorization

Unable to Attend:

**Janet Trunzo, MS**, executive vice president, technology & regulatory affairs, Advanced Medical Technology Association (AdvaMed)

Added Faculty:

**April Veoukas**, director, regulatory affairs, Abbott Laboratories

Supply Chain Integrity and Counterfeiting

Added Faculty:

**Barry Conlon**, chief executive officer, FreightWatch International USA Inc.

### Wednesday, 26 October 2011

8:30–10:00 am

FDA Process Validation Guidance–The Lifecycle Approach to Validation

Added Faculty:

**David Doleski**, team leader, NGDMT 3, DMPQ, CDER, US FDA

Regulatory Affairs: Partnership and Interaction with Business Colleagues

Unable to Attend:

**Anthony Waclawski, PhD**, vice president of global regulatory strategy, Bristol-Myers Squibb Company

Added Faculty:

**Daniel Mannix, PhD**, group director, global regulatory strategy, Bristol-Myers Squibb Company

## PROGRAM ADDENDUM

### EXHIBITOR UPDATES

#### Exhibiting companies not listed in the Exhibitor Guide:

**Arbour Group, booth #: 504**

**[www.arbournroup.com](http://www.arbournroup.com)**

**1 Parkview Plaza, Suite 660**

**Oakbrook Terrace, IL 60181**

**United States**

**Email: [info@arbournroup.com](mailto:info@arbournroup.com)**

Arbour Group is a leading provider of regulatory software compliance products and services to pharmaceutical, medical device and biotechnology companies. We also offer pre-packaged enterprise validation solutions that significantly reduce costs and streamline the testing process. Our services include 21 CFR Part 11 compliance, software validation, risk governance & assessment, SaaS and data center compliance. We offer global enterprise software testing capabilities that include the expertise, processes, methodologies, resources and tools required for cost effectiveness.

**Eliassen Group - Life Sciences Consulting, booth #: 6**

**[www.eliassen.com](http://www.eliassen.com)**

**Contact: Jayne Gill**

**Email: [jgill@eliassen.com](mailto:jgill@eliassen.com)**

**FreightWatch International, booth #: 505**

**<http://freightwatchintl.com>**

**7501 N Capital of Texas Hwy A-120**

**Austin, TX 78731**

**United States**

**Contact: Ron Greene**

**Phone: + 1 512 225 6492**

**Email: [ron.greene@freightwatchintl.com](mailto:ron.greene@freightwatchintl.com)**

FreightWatch is the world leader in logistics security services, offering the only active monitoring solutions that provide organizations with complete cargo transparency and supply chain integrity from origin to destination. Using our layered solutions, organizations can actively monitor their cargo anywhere in the global supply chain, to mitigate the risks associated with theft, spoilage, counterfeiting and more.

**Imaging Office Systems, booth #: 333**

**[www.imagingoffice.com](http://www.imagingoffice.com)**

**5275 Emco Drive**

**Indianapolis, IN 46220**

**United States**

**Contact: Yves Graham**

**Phone: +1 219 864 1225**

**Email: [ygraham@imagingoffice.com](mailto:ygraham@imagingoffice.com)**

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## PROGRAM ADDENDUM

**Massachusetts College of Pharmacy & Health Sciences, booth #: 1**

<http://www.mcphs.edu>

179 Longwood Ave.

Boston, MA 02115

United States

Contact: Brian Barilone

Phone: +1 617 879 5032

Email: [brian.barilone@mcphs.edu](mailto:brian.barilone@mcphs.edu)

For nearly 200 years Massachusetts College of Pharmacy and Health Sciences (MCPHS) has been on the leading edge of health care education. Our tradition is to look ahead. And if you are thinking of advancing yourself here as a graduate student, you're looking toward your own future. At MCPHS, we're committed to helping you expand your knowledge, marketability and effectiveness as a health care professional. Come to MCPHS to take the next step toward success.

**MedXView, booth #: 103**

[www.medxview.com](http://www.medxview.com)

185 Alewife Brook Pkwy.

Cambridge, MA 02138

United States

Contact: Peter Rais

Phone: +1 617 491 0908

Email: [peterrais@medxview.com](mailto:peterrais@medxview.com)

As the leading provider of Regulatory Submission Publishing Software and Services, MedXview is dedicated to getting you to the market quickly and compliantly. Our Premier software solution, eCentral™, provides an all-inclusive and user-friendly environment for document management, data standardization and collaborative eSubmission Publishing.

**New England Ovis, booth #: 506**

225 Rollins Road

Rollinsford, NH 03869

United States

Contact: Julie Hurley

Phone: +1 603 750 5087

Email: [hurley.julie@comcast.net](mailto:hurley.julie@comcast.net)

New England Ovis (NEO) is a caesarian-derived sheep farm located in the northeast United States. Biosecurity and ongoing surveillance has maintained this SPF flock free of over 30 pathogens including all zoonoses and respiratory pathogens. NEO has all ages and sexes of sheep available for research year-round. Daily, gentle human interaction with NEO SPF sheep on the farm results in easy to handle animals and streamlines the transition into the research setting.

**Perrigo Company, booth #: 432**

[www.perrigo.com](http://www.perrigo.com)

515 Eastern Avenue

Allegan, MI 49010

United States

Contact: Denise Curtis

Phone: +1 269 673 1331

Email: [dcurtis@perrigo.com](mailto:dcurtis@perrigo.com)

More than 7,000 Perrigo employees around the world commit themselves each day to the important mission of making health care affordable. As our company grows, we are reaching out to people around the world who can join our team and become part of this important mission. Perrigo's locations are in the United States, Israel, Mexico, the United Kingdom, India, China and Australia.

## PROGRAM ADDENDUM

### **Roche Diagnostics, booth #: 405**

**www. Roche.com**

**9115 Hague Rd.**

**Indianapolis, IN 46250**

**United States**

**Contact: Kathy Sanders**

**Email: [kathy.sanders@roche.com](mailto:kathy.sanders@roche.com)**

At Roche, 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. Our success is built on innovation, curiosity and diversity, and on seeing each other's differences as an advantage. To innovate healthcare, Roche has ambitious plans to keep learning and growing – and is seeking people who have the same goals for themselves.

### **Whitney Consulting Ltd., booth #: 519**

**www.whitneyconsulting.net**

**25 Robinson Road**

**Littleton, MA 01460**

**United States**

**Contact: Chang-Hong Whitney**

**Phone: 978-633-3313**

**Email: [changhong@whitneyconsulting.net](mailto:changhong@whitneyconsulting.net)**

14 years of China RA consulting and product registration experience in medical device, implantable and disposable products, IVD equipment and reagents, radiology systems, medical software and other medical products. Through offices in Beijing and Boston, we offer clients timely responses and solutions to their most challenging China regulatory issues.

### **W. L. Gore & Associates, Inc., booth #: 301**

**<http://www.gore.com/change-life>**

**P. O. Box 2400**

**Flagstaff, AZ 86003**

**United States**

Gore is a technology-driven global company built on entrepreneurial innovation, integrity, and teamwork. Through our product leadership, we've been changing lives and changing industries including fabrics, medical devices, electronics, and manufacturing for more than 50 years. What can you change by joining Gore?

### **Additional Exhibitor Updates**

- Clinivation (booth # 504 in the Exhibitor Guide) is no longer exhibiting at 2011 RAPS
- Pearl Pathways (booth # 432 in the Exhibitor Guide) is now located in booth # 325
- Contact person for TUV Rheinland of North America, booth # 303, has changed to:  
**Contact: Katherine Russian**  
**Email: [krussian@us.tuv.com](mailto:krussian@us.tuv.com)**
- The address for Reglera, booth # 318, has changed. The new address is:  
**11925 W. I-70 Frontage Rd. North Suite 900**  
**Wheat Ridge, CO 80033**  
**United States**
- The address for Worldwide Translations Inc., booth # 224, has changed. The new address is:  
**2994 Marble Cliff Court**  
**Henderson, NV 89052**  
**United States**