

2010 RAPS
annual **conference**
& **exhibition**

24–27 October 2010
San Jose, CA
San Jose McEnery Convention Center

RAPS.org/ac2010



REGULATORY AFFAIRS
PROFESSIONALS SOCIETY

Making better healthcare products possible™

You're Invited!

Succeed
in the
global
regulatory landscape



It's All About You!

For more than three decades, the RAPS Annual Conference has brought together regulatory constituents from across the globe, representing every facet within the regulatory community to connect, analyze, strategize *and celebrate*.

2010 RAPS Annual Conference & Exhibition will be the best yet, bringing you four comprehensive days of:

- **More than 70 education sessions** covering the *most relevant and timely regulatory topics* you face today—defined within seven core education tracks and five full-day workshops for your convenience
- **More than 2,000 fellow regulatory colleagues** of every ilk—some you know and *some you need to know*—will converge to amplify their professional reach
- **More than 200 leading industry experts** sharing best practices and new strategies for success—further bolstering your knowledge base and growing your professional network
- **More than 100 exhibitors** supporting the regulatory profession through innovative technologies, products and services
- **Ways to engage now, during and after** the conference to *live the experience all year long*

Take part in this exclusive convergence of the regulatory community and position your company and yourself for success in the global regulatory landscape. Register today at **RAPS.org/ac2010**!

Connect with colleagues, speakers and exhibitors on RAPS' Annual Conference & Exhibition LinkedIn network to get real-time insight on special events and activities related to the 2010 conference!

Visit **RAPS.org/ac2010** for a complete list of ways to engage now, during and after the conference and register today!

2010 RAPS Annual Conference & Exhibition will bring you invaluable opportunities to grow as a professional.

RAPS Annual Celebration

RAPS' largest social gathering of regulatory professionals for 2010 will be on Tuesday, 26 October, from 6:00–8:00 pm. Join us for an evening of fun, networking and celebration. The evening includes complimentary hors d'oeuvres and cocktails.

Exhibitors' Reception

Connect with companies at the cutting edge of regulatory affairs while enjoying light refreshments and cocktails in a relaxed atmosphere. The reception will take place on Monday, 25 October, from 5:00–6:00 pm in the exhibit hall.

2010 Fellows Induction and RAPS Awards Presentation

Recognize the dedication, leadership and accomplishments of two stellar groups of your colleagues, honored during the keynote address on Monday, 25 October, from 8:30–10:00 am, for their leadership and outstanding contributions to the regulatory profession.

RAPS Fellows Situation Rooms

Engage RAPS Fellows in thought-provoking discussions in Situation Rooms on key issues, and take advantage of important networking opportunities within these mini-education sessions.

Dine-Arounds

San Jose has a restaurant to fit your taste and budget. Join your colleagues for spirited conversation and networking over great food and drink on Monday evening, 25 October, after the Exhibitor's Reception to get a taste. Sign up for Dine-Arounds in the registration area for the restaurant of your choice by 1:30 pm on Monday. Spaces are limited.

RAPS Foundation 5K Fun Run

Donate only \$40 to the RAPS Foundation and receive a t-shirt and an opportunity to participate in the annual RAPS Foundation 5K Fun Run held on Tuesday, 26 October from 6:15–7:00 am. Walkers are welcome! Sign up at the registration desk by 5:00 pm on Monday, 25 October to ensure your spot in this fun event!

RAPS Bookstore

Explore the extensive collection of essential regulatory publications in the RAPS Bookstore, including recently updated editions from the *Fundamentals of Regulatory Affairs* series and a number of brand new RAPS-published products. Browse, ask questions and take advantage of special offers!

Advance with the RAPS Career Center

Access a wealth of career opportunities and professional development resources. Also featured will be an up-to-date list of job openings and access to the autumn **2010 RAPS Virtual Career Fair**. Be sure to bring your resume and get it into the hands of the right people in the right organizations.

Learning Lab: Test-drive RAPS On-demand Education Products

Back by popular demand, RAPS' onsite conference Learning Lab provides exclusive access to all RAPS Online University courses and certificate programs as well as select on-demand Webcasts.

Exclusive Networking: Expand Your Professional Reach

The RAPS Annual Conference is unmatched for regulatory professionals to exclusively connect with each other as well as with industry thought-leaders and service providers as a unified, singular community. **2010 RAPS Annual Conference & Exhibition** will offer you more than 25 hours of networking opportunities to grow your professional network with **connections that last a lifetime!**

KEYNOTE ADDRESS



Vijay Govindarajan
Strategy and Innovation Expert
 25 October, 8:30–10:00 am

Vijay Govindarajan is an internationally renowned authority on strategy execution, strategic innovation, industry transformation, and global strategy and organization. He is the Earl C. Daum 1924 professor of international business at the Tuck School of Business at Dartmouth College and founding director of Tuck's Center for Global Leadership. He has worked with 25% of the Fortune 500 corporations to challenge and escalate thinking about strategy including: Boeing, Coca-Cola, Colgate, Deere, FedEx, Hewlett-Packard, IBM, J.P. Morgan Chase, Johnson & Johnson, The New York Times Co., Procter & Gamble, Sony and Wal-Mart.

Vijay Govindarajan will challenge and escalate our thinking about strategy, innovation and new business models as they relate to regulatory as keynote speaker at **2010 RAPS Annual Conference & Exhibition!**

Get the latest updates from Vijay by following his blog at www.vijaygovindarajan.com.

GE Healthcare

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SPECIAL SESSION

Stories from the Front Lines
New models for health and success
 27 October, 10:30 am–12:00 pm

Esteemed panelists from the leading edge of business, science and regulatory will give first-hand accounts of how they are guiding their organizations through today's opportunities and challenges. Join us for a dynamic discussion that will examine the impact of entrepreneurs and innovators on industry, individuals and communities around the world.

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RAPS Thanks Our Dedicated Annual Conference Planning Committee Members for
Their Commitment to Excellence in the **2010 RAPS Annual Conference** Program Development!

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Susan James, GlaxoSmithKline (RAPS President)

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Reed Tarwater, PhD, The Anson Group
Chang-Hong Whitney, MBA, Whitney Consulting Ltd.

RAPS 2010 EXHIBITORS *as of 12 May 2010*

- | | | | |
|---|--|---|---|
| Aerotek Scientific LLC | FOI Services Inc. | Medtronic Inc. | Scantron Corporation |
| AKOS Ltd. | Fortress Medical Systems LLC | Michor Consulting e.U. | Society of Quality Assurance |
| Applied Clinical Trials | GE Healthcare | National Standards Authority of Ireland
(NSAI) | Sparta Systems Inc. |
| Aris Global | Hurley Consulting Associates | NextDocs Corporation | STATKING Consulting Inc. |
| Assurx Inc. | Idem Translations Inc. | Northeastern University | Stearns International Inc. |
| Beckloff Associates | Johnson & Johnson Family of
Companies | OmniLingua Worldwide LLC | Stericycle |
| Biologics Consulting Group | KEMA Quality | Opus Regulatory | Tarius |
| BSI | Kendle | Pacific Bridge Medical | The Cambridge Group |
| CanReg Inc. | KJ International | Pilgrim Software | The Clinical Trial Company Ltd. |
| CCA Inc. | Klien Hersh International | Pleasetech LTD | The University of Iowa
Pharmaceuticals |
| Center for Professional Innovation &
Education | LanguageWorks Inc. | Premier Research | Thomson Reuters |
| Clinivation Inc. | LORENZ Life Sciences Group | Prolifiq Software | Title21 Software Inc. |
| Corporate Translations | MakroCare | PSC Biotech | TJP Healthcare Communications |
| Design Space Inpharmatics | MasterControl Inc. | Quadrite | TransPerfect Translations International
Inc. |
| DoubleBridge Technologies Inc. | McCarthy Consultant Services Inc. | QUMAS | TÜV SÜD America Inc. |
| ECLINSO | Medcert GmbH | Reed Technology | Underwriters Laboratories |
| Emergo Group | MEDFOCUS LLC | Regulatory & Clinical Research
Institute Inc. (RCRI) | USC Regulatory Science Program |
| Excel Translations Inc. | Medical Device Safety Service GmbH
(MDSS) | Regulatory Presentation Management | VGM Pharmatech Translations |
| EZ Risk Management LLC | MedTrials | RegXia Inc. | Virtify |
| FDAnews | | | |



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SCHEDULE AT A GLANCE

Program subject to change.

SATURDAY, 23 OCTOBER 2010

4:00–7:00 pm Registration Open

SUNDAY, 24 OCTOBER 2010

7:00 am–6:00 pm Registration, RAPS Information Station and Bookstore Open

8:30 am–5:00 pm Preconference Workshops

MONDAY, 25 OCTOBER 2010

7:00 am–5:00 pm Registration, RAPS Information Station, Bookstore, Learning Lab and Career Center Open

8:30–10:00 am Keynote Address

10:00 am–6:00 pm Exhibit Hall Open

10:30 am–12:00 pm Educational Sessions

12:15–1:15 pm Situation Rooms

1:30–3:00 pm Educational Sessions

3:30–5:00 pm Educational Sessions

5:00–6:00 pm Exhibitors' Reception

6:30 pm Dine-Arounds

TUESDAY, 26 OCTOBER 2010

6:15–7:00 am RAPS Foundation 5K Fun-Run

7:30 am–5:00 pm Registration, RAPS Information Station, Bookstore, Learning Lab and Career Center Open

8:30–10:00 am Educational Sessions

10:00 am–3:30 pm Exhibition Hall Open

10:30 am–12:00 pm Educational Sessions

12:15–1:15 pm Situation Rooms

1:30–3:00 pm Educational Sessions

3:30–5:00 pm Educational Sessions

6:00–8:00 pm RAPS Annual Celebration Reception

WEDNESDAY, 27 OCTOBER 2010

7:30–10:30 am Registration, RAPS Information Station, Bookstore and Learning Lab Open

8:30–10:00 am Educational Sessions

10:30 am–12:00 pm Special Session

PRECONFERENCE WORKSHOPS

24 October, 8:30 am–5:00 pm • 6 ACPE Points • 6 RAC Points

- **NEW!** Combination Products: Overview and Current Status
- **NEW!** Regulatory Considerations for Asia Pacific (Pharmaceuticals)
Session will begin at 8:00 am
- **NEW!** Regulatory Managers Boot Camp
- The Essentials: EU Regulatory Affairs
- The Essentials: US Regulatory Affairs

Limited space—register early!

View the complete schedule at RAPS.org/ac2010 and register today!

SEVEN CORE EDUCATION TRACKS

Visit RAPS.org/ac2010 for full track descriptions and register today!

- Biologics/Biotechnology
- Clinical
- Compliance and Audits
- **NEW!** Foods and Dietary Supplements
- Medical Devices and In Vitro Diagnostics (IVDs)
- Pharmaceuticals
- Regulatory Business

SELECT MUST-SEE SESSIONS BY TRACK

Visit RAPS.org/ac2010 for complete information on more hot-topic sessions and register today!

BIOLOGICS AND BIOTECHNOLOGY

Regenerative Medicine–Regulatory Pathway in US, EU and Japan

25 October, 10:30 am–12:00 pm

The overlap and differences in regional approaches to the current regulatory framework for regenerative medicine products will be thoroughly discussed.

Session Leader

Darin J. Weber, PhD, senior consultant, Biologics Consulting Group Inc.

Biosimilars

25 October, 3:30–5:00 pm

In the light of healthcare reform in the US, current thinking on non-clinical and clinical requirements for biosimilars as well as the current status of regulations in the EU and US will be framed and discussed. The current thinking on biosimilars for more complex biologics such as monoclonal antibodies will also be explored.

Session Leader

Blair Fraser, senior consultant, Biologics Consulting Group LTD

CBER Executive Staff Briefing

26 October, 3:30–5:00 pm

Global regulatory affairs expert Douglas Hunt will lead FDA's Center for Biologic Evaluation and Research (CBER) staff in a discussion about the Center's recent activities and trends, as well as upcoming initiatives and current developments.

Session Leader

Douglas Hunt, senior director, regulatory affairs, Baxter Healthcare Biosciences Division

CLINICAL

Safety Review in Clinical Trials, Including Vigilance Reporting

25 October, 1:30–3:00 pm

Because IDE regulations don't specifically define AE/SAE requirements, strategies for interpreting the requirements for reporting that are not UADE and discussion of the overlapping and contrasting requirements for the US and EU will be addressed in this session.

Session Leader

Robin Newman, MSN, CPNP, CCRA, RAC, senior clinical and regulatory affairs manager, Siemens Healthcare

CLINICAL (continued)

Ethical Issues in Clinical Trials

25 October, 3:30–5:00 pm

Guidance on European and FDA positions on ethical conduct of clinical trials within and outside these geographical territories as well as the requirements for informed consent and clinical trial approval for trials run in PMS phase and marketing trials will be discussed by expert faculty leading this session.

Session Leader

Joy Frestedt, PhD, RAC, CCTI, president and CEO, Frestedt Inc.

Update from FDA's GCP Team and Revised MEDDEV resulting from 2007/47/EC Revision

26 October, 10:30 am–12:00 pm

Gain a clear understanding of the current FDA GCP requirements for pre- and postmarket approval products (devices) through a comprehensive discussion on the new regulatory guidance from Europe on clinical trials including the areas of overlap and conflict between the European and US regulatory requirements.

Session Leader

Ibim Tariah, technical director, BSI Healthcare

COMPLIANCE AND AUDITS

Achieving Compliance during Equipment and Computer System Validation: A Risk-Based Approach

25 October, 10:30 am–12:00 pm

Take in hands-on examples and methods to avoid pitfalls that can result in costly computerized validation mistakes, warning letters, 483s, delays in project schedules and global compliance problems. In this session, you will hear firsthand how to set up successful IQ OQ PQ projects as well as how to perform audits of your company equipment/process validation programs, their suppliers or sister company sites using a risk-based approach.

Session Leader

Michael J. Gregor, president, Compliance Gurus Inc.

Rules for Good Clinical Practice/GCP Audits

26 October, 10:30 am–12:00 pm

Steps that sponsors, monitors, and auditors can take to decrease anxiety, enhance communication, and convey audit findings to restore a clinical study to compliance will be identified in this session, including an explanation of ICH GCP standards useful to address issues of implementing GCP on a global scale, ensuring investigator compliance, dealing with research misconduct issues, and implementing safety monitoring programs.

Session Leader

Mukesh Kumar, PhD, RAC, senior director, regulatory affairs and quality assurance, Amarex Clinical Research

COMPLIANCE AND AUDITS (continued)

Establishing a Regulatory Intelligence Program: Challenges and Lessons Learned

26 October, 1:30–3:00 pm

The geographical region in which we reside no longer dictates how we work. Cutting-edge strategies and technologies such as weblogs and wikis that can be used to promote collaboration and knowledge sharing between geographically and culturally separated teams will be discussed.

Session Leader

Mary K. Overland, PhD, RAC, director, regulatory intelligence and external affairs, GE Healthcare

FOOD AND DIETARY SUPPLEMENTS

Strategies for Implementing the “New” GMPs for Dietary Supplements and Reporting of Serious Adverse Events

25 October, 1:30–3:00 pm

Essential elements of the final rule on GMPs for dietary supplements will be discussed. Speakers will delve into the critical issues related to compliance and outline strategies for mitigating concerns.

Session Leader

Robert Schiff, PhD, RAC, president and CEO, Schiff & Company Inc.

Global Regulatory Environment

26 October, 10:30 am–12:00 pm

The full spectrum of food legislation and global requirements for product registration and maintenance (for selected geographies) as well as strategies for meeting regulatory compliance requirements will be addressed in this impactful session.

Session Leader

Sara O'Connor, unit head, product submission coordination, Natural Health Products Directorate, Health Canada

Enforcement and Compliance: Regulatory Compliance for Food, Dietary Supplement and Medical Food Companies

26 October, 3:30–5:00 pm

The Obama Administration is making major changes to the Bush-era enforcement resources and attitudes. This panel will examine food and dietary supplement enforcement actions. Panelists will offer their perspectives and predictions for the vigor and direction of food-related enforcement cases.

Session Chair

James O'Reilly, professor of law, University of Cincinnati

MEDICAL DEVICES AND IVDS

BiMO Inspections

25 October, 10:30 am–12:00 pm

FDA conducts over a thousand inspections per year of research with biologics, drugs and medical devices under the bioresearch monitoring program, frequently causing anxiety for clinical sites and regulatory professionals. Learn what to expect during these inspections and what records and staff should be available so you can be better prepared.

Session Leader

Matthew J. Tarosky, PharmD, EJD, CCRP, deputy director, division of bioresearch monitoring, CDRH, US FDA

Japan Regulation for Devices

25 October, 1:30–3:00 pm

In this session led by Japanese regulatory expert Kyochi Tadano, PhD, you will hear directly from senior officials of Japan's Pharmaceuticals and Medical Devices Agency, providing the latest on the agency's major initiatives in this impactful session, including future agency direction, PMDA's current activities and challenges for timely medical device review, and more effective lifecycle management.

Session Leader

Kyoichi Tadano, PhD, director, international affairs division, PMDA

CDRH Executive Staff Briefing

26 October, 8:30–10:00 am

In this session led by policy expert Mark Gordon, MS, RAC, you will hear a detailed review of the past year at FDA's Center for Devices and Radiological Health (CDRH), as well as an overview of initiatives, milestones and current trends for the next year. A high-level overview of the changes to the 510(k) review process will be provided, as well as an update on staffing structure.

Session Leader

Mark Gordon, MS, RAC, FRAPS, vice president, global regulatory advocacy and policy, Boston Scientific Corporation

PHARMACEUTICALS

FDA Advisory Committee Meeting Preparation

26 October, 3:30–5:00 pm

Based upon the White Paper, The Seven Mistakes Teams Make When Preparing for an FDA Advisory Committee Presentation, this session will provide case studies and examples of avoidable pitfalls that can result in a less-than-optimal performance at an FDA advisory committee meeting as well as present best practices for planning, preparation, rehearsal, and delivery of your scientific data to an FDA advisory committee.

Session Leaders

John Dalpe, Jr., vice president, marketing, Interactive Holdings LLC
Pete Taft, president and managing partner, Taft and Partners

Diagnostics/Theranostics-Regulation of Cross-Over Products

27 October, 8:30–10:00 am

The pairing of a diagnostic test to a therapeutic, the essential element of theranostics or companion diagnostics, is in some cases already a reality and theranostics are considered the pathway to personalized medicine. This session will review the regulatory challenges and hurdles facing this emerging area of companion diagnostics.

Session Leader

Prem K. Narang, PhD, FCP, vice president, global regulatory affairs, GE Healthcare-MDX

PHARMACEUTICALS (continued)

REMS

27 October, 8:30–10:00 am

Since its 2007 initiation, FDAAA and other global changes in regulatory requirements have significantly altered risk management approaches within the pharmaceutical industry. Hear from experts in pharmacovigilance, epidemiology, and risk management who will present tactics to lead an organization or a project team in Risk Evaluation and Mitigation Strategy (REMS) design utilizing a decision-tree approach, as well as address important considerations for risk assessment studies.

Session Leader

Edward Tabor, MD, vice president, Quintiles

RAC



Full conference attendees who hold an RAC credential earn **12 RAC recertification points** for attending the conference and may also earn six points for attending a preconference workshop.

ACPE Accreditation



Extension Services in Pharmacy at the University of Wisconsin-Madison School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Selected portions of this Annual Meeting are approved for pharmacy CE credit.

Specific hours of credit for approved presentations and the Universal Program numbers assigned to those presentations are found elsewhere in program materials. Credit is based on documented program attendance, completion/return of a signed copy of the Program Evaluation/Post-test and completion/return of the CE Request form.

REGULATORY BUSINESS

Regulatory Business 201

26 October, 8:30–10:00 am

In order to be a true “business partner” and to gain an understanding of the business process and how regulatory fits in, it is critical to build a regulatory strategy that aligns with your organization’s business model. Advising a company of regulatory filing implications, setting expectations and understanding the importance of outcomes are key components of career progression.

Session Leader

O. Reed Tarwater, PhD, RAC, FRAPS, director, pharmaceutical consulting services, Anson Group

Starting Your Own Consulting Company

26 October, 10:30 am–12:00 pm

Learn practical strategies and key steps to develop a plan for starting your consulting company including business planning, operational aspects, key marketing elements, and collaboration.

Session Leader

Anne M. Tomalin, RAC, president, CanReg Inc.

Why Regulatory is Key Throughout the Due Diligence Process

26 October, 3:30–5:00 pm

Transactions involving FDA-regulated firms or products present unique challenges for regulatory professionals, many of whom frequently have little experience with the demands of a commercial transaction. This session will explore how to prepare and execute due diligence efforts, including how to identify the essential elements in conducting such reviews, often with limited resources and subject to tight time lines.

Session Leader

Raymond Huml, MS, DVM, RAC, executive director, global due diligence, Quintiles Corporate Development

The smart investment is **you.**

Take advantage of the exclusive benefits RAPS membership provides you for 12 months! Access current, clear and concise information on markets and regulations within and across geographic lines; a global private network of more than 12,000 colleagues, industry thought leaders and regulators within a neutral forum; and great savings on essential educational programs and professional development resources. Get started at RAPS.org!

Not a RAPS member? Register for **2010 RAPS Annual Conference & Exhibition** and membership to RAPS is included! The smart investment is you. The right choice is RAPS!

Driven Globally, Adapted Locally

Network with your local colleagues and RAPS chapter leaders, sharing the ideas, approaches and activities occurring in your region at the Chapter Roundtables during lunch on 25 and 26 October.

