

RAPS EXECUTIVE DEVELOPMENT PROGRAM

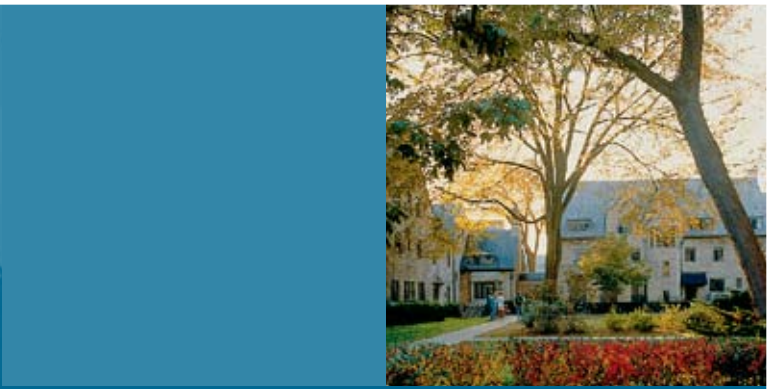
Kellogg School of Management at Northwestern University • James L. Allen Conference Center • 14–17 June 2010 • Evanston, IL • RAPS.org/exec/june2010

Progress
in your
career.

Strengthen
your
leadership
skills.

Face
tomorrow's
business
realities.





In its 10th year, the RAPS EXECUTIVE DEVELOPMENT PROGRAM receives high praise from those who have completed it—about 20% vice presidents and senior executives, 50% directors and 30% managers. Participants have come from a wide range of organizations—from pharmaceutical and medical device multinationals to biotech start-ups and consultancies.



- Abbott
- Acceleron Pharma Inc.
- Acumed LLC
- Advanced Medical Optics
- Advanced Sterilization Products
- AFB International
- AGA Medical Corporation
- Akros Pharma Inc.
- Alberto Culver USA Inc.
- Align Technology Inc.
- Allergan Inc.
- AMAG Pharmaceuticals Inc.
- American Medical Systems
- Amgen
- Amylin Pharmaceuticals Inc.
- Andrx Pharmaceuticals
- ANS Inc.
- Aspect Medical Systems
- Astellas Pharma Global
- AstraZeneca R&D
- Auxilium Pharmaceuticals Inc.
- Barco
- Barr Laboratories Inc.
- Bausch + Lomb
- Baxter Healthcare
- Beckloff Associates Inc.
- Becton Dickinson
- Biogen Inc.
- Biolex Inc.
- Biolipox AB
- BioMarin Pharmaceutical Inc.
- Bioness Inc.
- Bio-Rad Laboratories
- Boston Scientific
- Bristol-Myers Squibb Co
- Broncus Technologies Inc.
- CanReg Inc.
- CaridianBCT Biotechnologies
- Carl Zeiss Microimaging AIS Inc.
- CBMS-JPMO
- Cephalon Inc.
- CIBA Vision
- Clarkston Consulting Co Ltd.
- Cochlear Americas
- Cochlear Ltd.
- Codman
- Cook Pharmica
- CooperVision Inc.
- Cordis Corporation
- Covidien
- CSL Bioplasma
- Cytochroma Inc.
- DADE Behring Inc.
- Davol Inc.
- Depomed Inc.
- Development Inc.
- Disetronic Medical Systems Inc.
- Draeger Medical Systems Inc.
- Dyax Corporation
- EKR Therapeutics Inc.
- Elekta Inc.
- EMD Serono Inc.
- Endo Pharmaceuticals Inc.
- Endo-Therapeutics Inc.
- ETEX Corporation
- Ethicon Endo Surgery Inc.
- Ethicon Inc.
- Excel Tech Ltd.
- FAST Diagnostics
- Favrille Inc.
- Flexmedical
- Forest Laboratories Inc.
- Fred Hutchinson Cancer Research Center
- GE Healthcare
- Genomic Health
- Gen-Probe Incorporated
- Genzyme Corporation
- GlobImmune Inc.
- Greater China Becton Dickinson
- Grunenthal GmbH
- Health Hero Network Inc.
- Heraeus Kulzer Inc.
- Hitachi Chemical Diagnostics
- Hoffmann-LaRoche Inc.
- Hollister Incorporated
- IKARIA/INO-T
- ImClone Systems Incorporated
- Immucor Inc.
- Instrumentation Laboratory
- Integra LifeSciences Corporation
- Intel, Digital Health Group
- Intendis, Inc.
- Intervet Inc.
- J & J Cordis
- JM Consulting Services LLC
- Johnson & Johnson
- KCI USA Inc.
- Kensley Nash Corporation
- Kimberly-Clark Corporation
- Kyphon Inc.
- LifeCell Corporation
- LifeNet
- Lifescan Scotland Ltd.
- MacroGenics Inc.
- Marlys Chellew
- McNeil Consumer Healthcare
- Medela Inc.
- Medical Device Consultants Inc.
- MedImmune Inc.
- Medtronic Inc.
- Merck & Co Inc.
- Molnlycke Health Care
- Nektar Therapeutics
- Neovista Inc.
- New England Research Institutes Inc.
- Nitinol Devices and Components
- Novartis
- Noven Pharmaceuticals Inc.
- Novo Nordisk Inc.
- Palomares Consulting Inc.
- Paragon MedSystems
- Patton Boggs LLP
- PDL BioPharma Inc.
- Philips Healthcare
- Poniard Pharmaceuticals
- Procter & Gamble
- Reata Pharmaceuticals
- Replidyne Inc.
- Robert Bosch Company
- Roche Diagnostics
- Roxane Laboratories Inc.
- Sage Products Inc.
- Sanmina-Sci Corporation
- Sanofi-Aventis Pharmaceuticals
- Shionogi USA Inc.
- Shire
- Siemens
- Smith & Nephew Inc.
- Solvay Pharmaceuticals Inc.
- St. Jude Medical
- Starpharma Pty Ltd.
- Steris Corporation
- Straumann USA
- Stryker Spine
- SurgRx
- Takeda Global Research & Development Center
- Terumo Cardiovascular Systems
- Terumo Heart Inc.
- The Weinberg Group Inc.
- Theragenics Corporation
- Thomson Reuters
- Tibotec Inc.
- Tikvah Therapeutics Inc.
- Trans1 Inc.
- Transport Pharmaceuticals Inc.
- Tri-State Centurion
- Tyco Healthcare Valleylab
- UCB Pharma SA
- Upsher-Smith Laboratories Inc.
- Ventana Medical Systems Inc.
- Viropharma Inc.
- Vistakon
- W.L. Gore Associates Inc.
- Wright Medical Technology Inc.
- Zimmer Inc.

Face tomorrow's business realities.

Succeeding at the executive level in the regulatory profession requires more than scientific and technical knowledge. As you progress in your career, you must continually strengthen your leadership and business skills to better face the high-level challenges of senior management and contribute meaningful solutions that drive your organization's success.

The Regulatory Affairs Professionals Society (RAPS), the premier organization for regulatory professionals, together with the esteemed faculty at the Northwestern University's Kellogg School of Management, has created a unique opportunity to prepare high-potential executives to confidently take on broader business and leadership responsibilities. The RAPS Executive Development Program in Evanston, IL, 14–17 June 2010, offers an essential opportunity to strengthen your business and problem-solving skills while exploring the healthcare product industry's most defining issues. Hear directly from some of the world's best business professors in an intimate learning environment that specifically caters to regulatory professionals like you. You will develop the powerful leadership skills you need to tackle formidable management challenges and strategically position your organization to succeed globally.

Educational sessions will cover these key business areas:

- Change Management
- Crisis Management
- Decision Making
- Negotiation
- New Product Development
- Operations Management
- Strategy

KELLOGG SCHOOL OF MANAGEMENT

Located in the Chicago suburb of Evanston, IL, the Kellogg School of Management at Northwestern University has been making strong leaders stronger since 1908. The school's professors are preeminent scholars and passionate educators dedicated to providing the knowledge and information to outsmart the competition, excel in the fast-paced global economy, solve problems creatively and build consensus across diverse groups.

In 2009, the Kellogg School of Management was named the top school for business marketing and executive MBA programs, as well as one of the top three schools for business management by *US News & World Report*.

“This was one of the best programs I have ever attended. The caliber of the professors was outstanding. It certainly made me want to learn more in the area and apply this to my work environment.”

—Former RAPS Executive Development Program participant

AGENDA

MONDAY, 14 JUNE 2010

8:30–8:45 am

Welcome, Program Introduction and Participant Introductions

Edward F. X. Hughes, MD, MPH, academic director, Executive Leadership Program and professor of management, strategy and health industry management, Kellogg School of Management

8:45 am–12:00 pm

Leadership: What it's all About and why it Matters: Some Critical Principles

This module introduces the topic of leadership and shows what research is revealing as the essential elements of the topic. This session covers what leaders do and how they do it and discusses the challenges in persuading others to act on the strategy that has been developed. It also emphasizes that opportunities for leadership exist at all levels within your organization and the environment outside your immediate work plan at all stages of your career.

Edward F. X. Hughes, MD, MPH, academic director, Executive Leadership Program and professor of management, strategy and health industry management, Kellogg School of Management

1:00–2:30 pm

Making Better Decisions I: Using the Research to Improve Your Skills

This session reviews the latest research findings related to decision making. Research findings identify the major difference between effective and ineffective decision making is the ability to collect, process and act upon information in an unbiased fashion. This session challenges us—via brainstorming under pressure, unearthing multiple agendas and optimizing use of cross-functional skills—to be better decision makers.

Brian Uzzi, PhD, Richard L. Thomas Professor of Leadership and Organizational Change, professor of management and organizations and of sociology, Kellogg School of Management

2:45–4:15 pm

Making Better Decisions II: Understanding Decision Dynamics

This session focuses on how decisions get made, who is or should be involved in making decisions, how and what levers are pulled to get decisions made, and on developing strategies to effectively communicate your decisions to others in your organization.

Brian Uzzi, PhD, Richard L. Thomas Professor of Leadership and Organizational Change, professor of management and organizations and of sociology, Kellogg School of Management

4:30–6:00 pm

Strategic Challenges for the Regulatory Affairs Professional

This two-part session has been a centerpiece of the Executive Development Program since its inception. Session participants will identify, in a highly interactive fashion, the critical managerial and strategic challenges facing both you as a regulatory professional in your firm and within the profession as a whole.

Edward F. X. Hughes, MD, MPH, academic director, Executive Leadership Program and professor of management, strategy and health industry management, Kellogg School of Management

6:00–6:30 pm

Networking Reception

TUESDAY, 15 JUNE 2010

8:30–11:45 am

Dispute and Conflict Management

This session looks at disputes and organizational (or interpersonal) conflicts and how active engagement can be used to resolve these disputes. Mediation also is discussed. Through exercises, participants experience techniques that can lead the disputing parties to successful resolution of the issues causing the conflict.

Lynn Cohn, JD, director, Program on Negotiations and Mediation, Northwestern Law School

1:00–4:15 pm

Responding to Crisis: Converting Challenges into Opportunities

In today's business world, organizations and individuals increasingly find themselves the targets of aggressive legal actions, unanticipated media coverage and social pressure. The speed with which information spreads can turn what originally were challenges into crisis situations. Managing such situations demands swift and decisive action. Organizations and their leaders must be prepared to anticipate, recognize and manage rapidly changing strategic environments. This session challenges the prevailing view of crises as mere public relations or communications issues. Case studies and crisis simulation exercises balance the theoretical and conceptual frameworks and help you improve your strategic thinking as well as your team management and communication skills in high-stress situations.

Daniel Diermeier, PhD, IBM Professor of Regulation and Competitive Practice and professor of managerial economics and decision sciences, Kellogg School of Management



4:30–6:00 pm

Strategic Challenges for the Regulatory Affairs Professional II

This session will identify, again in a highly interactive manner, appropriate responses to surmount the managerial and strategic challenges facing you as a regulatory professional and the profession as a whole to enable the true skill-set to be realized and leadership opportunities seized.

Edward F. X. Hughes, MD, MPH, academic director, Executive Leadership Program and professor of management, strategy and health industry management, Kellogg School of Management

6:00–6:30 pm

Networking Reception

WEDNESDAY, 16 JUNE 2010

8:30–11:45 am

Developing new Products for Your Organization's Brand Portfolio

New products are a critical growth lever; few things can drive as much top- and bottom-line growth as a strong new product's introduction. However, new products are also expensive, time-consuming and usually unsuccessful. Developing a new product strategy, which includes a clear understanding of the regulatory challenges raised by the product, is one of the most important ways you can improve your odds of success. This session reviews the seven keys to a strong new product strategy and evaluates the strategic options for launching new products into established and emerging categories. After discussing the concepts, participants will break into teams to apply the concepts to a case.

Timothy Calkins, MBA, clinical professor of marketing and health enterprise management, Kellogg School of Management

1:00–6:00 pm

Negotiating Productive Agreements

Update your skills based on current research regarding the art and science of negotiation and conflict resolution. Using an experiential exercise, this session draws on class participation, faculty analysis and discussion of the results to demonstrate effective mediation techniques.

Leigh Thompson, PhD, J. Jay Gerber Distinguished Professor of Dispute Resolution and Organizations, director of Teams and Group Research Center, Kellogg School of Management

6:00–6:30 pm

Networking Reception

THURSDAY, 17 JUNE 2010

8:00 am–12:30 pm

Implementing Change: Innovation Adoption and People Management Challenges

Have you seen your innovative ideas for change go nowhere while antiquated designs persist? Often what makes or breaks a hit innovation is powerfully subtle. What is now understood is that ideas, consumption patterns, messages, buzz and innovations often spread like outbreaks of infectious diseases and the insight into managing this process lies in knowing how to capture the power of social epidemics. This session uses a unique computer simulation to illustrate how social epidemics work. Your role is to sell a firm on implementing a new idea using the tools of viral leadership. Walk away with the skills and confidence to champion new ideas and lead change efforts. This session provides you with the tools to successfully promote the adoption and launch of new ideas, products or services.

Brian Uzzi, PhD, Richard L. Thomas Professor of Leadership and Organizational Change, professor of management and organizations and of sociology, Kellogg School of Management

12:30–12:45 pm

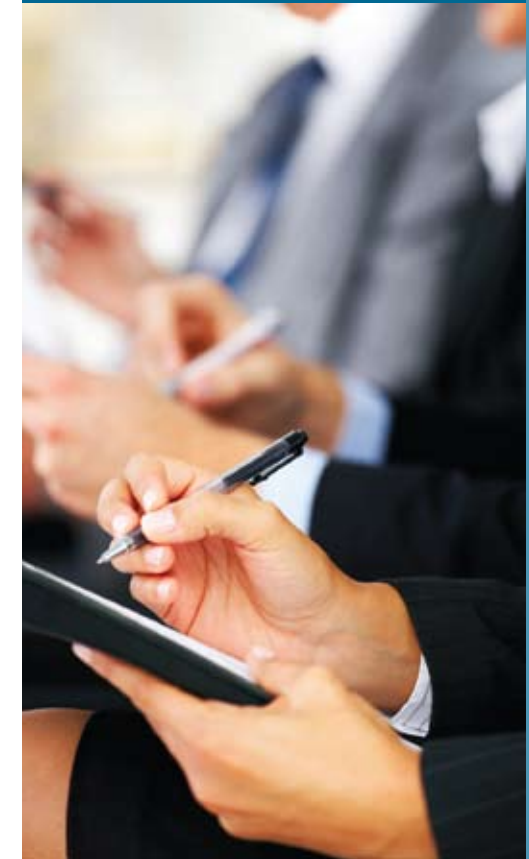
Concluding Remarks

James Drury, MHA, co-academic director, Executive Development Program and assistant director, Health Industry Management Program, Kellogg School of Business

Edward F. X. Hughes, MD, MPH, academic director, Executive Leadership Program and professor of management, strategy and health industry management, Kellogg School of Management

1:45 pm

Program Adjournment



FACULTY

Timothy Calkins, MBA, is a clinical professor of marketing and health enterprise management. He teaches marketing strategy and biomedical marketing courses for MBA students and seminars for Kellogg's Executive Programs. Prior to joining Kellogg in 1998, Calkins was a marketing executive with Kraft Foods for nearly 11 years. He has received numerous awards including a gold EFFIE and the Hill Holiday Against all Odds Award for championing excellent advertising. He co-edited *Kellogg on Branding* and recently published *Breakthrough Marketing Plans*. Calkins received his MBA from the Harvard Business School.

Lynn Cohn, JD, is the director of the Program on Negotiations and Mediation at Northwestern Law School. She has trained lawyers, real estate professionals, management and union representatives, government employees, community groups and corporate employees in effective negotiation, mediation, conflict management and arbitration techniques. Her clients include the National Association of Realtors, Smith Barney, the Illinois Commerce Commission, American Airlines, Kirkland & Ellis, Sidley Austin Brown & Wood and Mayer Brown Rowe & Maw. Cohn received her JD from Northwestern University School of Law.

Daniel Diermeier, PhD, is the IBM Distinguished Professor of Regulation and Competitive Practice and a professor of managerial economics and decision sciences at the Kellogg School of Management and of political science at the Weinberg College of Arts and Sciences (by courtesy). He serves as the director of Kellogg's Social Enterprise Program and is the founding director of the Center for Business, Government and Society at Kellogg. His teaching focuses on the interaction of business and politics, crisis management, the anticipation and management of political risk and strategic aspects of corporate social responsibility. Diermeier is a leading scholar in the study of both economics and politics, having lectured and consulted globally on media and issue management, activities and consumer boycotts, political strategy and regulatory management. He served three years as an assistant professor of political economy at Stanford University's Graduate School of Business. He has been the recipient of various teaching awards, most recently the 2000 Best Teacher Award for the Kellogg-WHU International Executive MBA Program and the L.G. Lavengood Professor of the Year Award (June 2001).

James D. Drury, MHA, is co-academic director for the Executive Development Program at Kellogg and assistant director of Kellogg's Health Industry Management Program. He is a former director of education for the American College of Healthcare Executives. He received his MHA from the University of Missouri.

Edward F. X. Hughes, MD, MPH, is co-academic director for the Executive Development Program and a professor of management, strategy and health industry management in the Kellogg School of Management. He is also the professor of preventive medicine in The Medical School, Northwestern University. He first came to Northwestern in 1977 as the founding director of the university's Center for Health Services and Policy Research, now the Institute for Health Services Research and Policy Studies, and served as its director for 18 years. His research interests center on health policy, managed care, the pharmaceutical, biotechnology and medical device industries, and the efficient utilization of scarce resources in the health industry. He is one of the five co-founders of the Association for Health Services Research, a charter member of its board of directors and served as its first vice president. In October 1999, Hughes was awarded The Latiolais Honor Medical. Hughes received his MD from Harvard Medical School, his MPH from Columbia University School of Public Health, and originally trained in surgery at Columbia Presbyterian Medical Center in the City of New York.

Leigh Thompson, PhD, is the J. Jay Gerber Distinguished Professor of Dispute Resolution and Organizations in the Kellogg School of Management at Northwestern University. Her research focuses on negotiation, team creativity and learning. In 1991, Thompson received the multi-year Presidential Young Investigator Award from the National Science Foundation (NSF) for her research on negotiation and conflict resolution and has been funded continuously by NSF. In 1994-95, Thompson was a fellow at the Center for Advanced Study in the Behavioral Sciences in Stanford, California. She has published more than 70 research articles and chapters. She has authored several books including *The Mind and Heart of the Negotiator (Third Edition)*, *Shared Knowledge in Organizations* (with David Messick and John Levine) and *Making the Team*.

Brian Uzzi, PhD, is the Richard L. Thomas Professor of Leadership and Organizational Change, professor of management and organizations and of sociology. His research focuses on networking, the social structure of markets and organizational decline. Uzzi received his MBA from Carnegie Mellon and his PhD is from SUNY at Stony Brook.



REGISTRATION FORM

PARTICIPANT LISTING INFORMATION (Please print the following information)

Your business address will be used for the conference participant listing.

If you would like to provide RAPS with an address update, please visit RAPS.org.

RAPS Member ID#: _____

Mr Ms Dr First Name _____ MI ____ Last Name _____

Advanced Degree: JD PhD PharmD MD DDS DMD SCD DVM RAC

Title _____

Company _____

Address _____

City State/Province _____

Mail Stop _____ Postal Code _____ Country _____

Phone (with area/country code) _____

Fax (with area/country code) _____

Business E-mail Address (required for confirmation) _____

Please list special dietary requirements (please submit by 7 June 2010) _____

Please list special accessibility requirements (please submit by 7 June 2010) _____

Please provide name and number of individual to contact in case of an emergency:

Name _____ Phone Number _____

REGISTRATION FEES (All fees in US dollars)

	Register by 24 May	Register after 24 May
RAPS Member	<input type="checkbox"/> \$5,750*	<input type="checkbox"/> \$5,850*
Nonmember**	<input type="checkbox"/> \$5,935*	<input type="checkbox"/> \$6,035*

* Registration fees include all onsite meals on 14–17 June 2010 and lodging on the nights of 13–16 June 2010 at the James L. Allen Center. RAPS will coordinate directly with the program manager at the Kellogg School of Management to arrange a room reservation for each participant. RAPS will forward a housing confirmation to each participant by 1 June 2010. For more information about the James L. Allen Center, visit www.kellogg.northwestern.edu/execed/allen_center/index.htm.

** **CHECK HERE** The above nonmember fees include RAPS membership for 12 months for qualified applicants. I have reviewed and understand the membership qualifications and accept membership with the Regulatory Affairs Professionals Society.

Total Conference Registration Fee \$ _____

METHOD OF PAYMENT

International Wire Transfer: Fax a completed form and copy of bank wire confirmation to confirm your registration to: RAPS account #702267562; ABA #061000104 Swift Code SNTRUS3A; SunTrust Bank, Richmond, VA. Must reference name of registrant. All bank charges are the responsibility of the payer.

Check #: _____ American Express MasterCard Visa

Account#: _____ Exp. Date: _____ Billing Postal Code: _____

Name as it appears on the card: _____

Signature: _____

HOW TO REGISTER



ONLINE:
RAPS.org/execed/june2010
(credit card only)



BY MAIL:
RAPS c/o SunTrust Lockbox Dept
PO Box 79546
Baltimore, MD 21279-0546



BY FAX:
+1 301 770 2924 (credit card or wire)

Full payment must accompany this form.

Questions? Please call RAPS Solutions Center at +1 301 770 2920, ext. 200.

REGISTRATION POLICIES AND PROCEDURES

Please visit RAPS.org for full conference registration policies.

RAPS membership is individual and must be paid in full to qualify for conference member fees. Please visit the RAPS website at RAPS.org for complete membership qualifications.

Confirmed Registration: Registrations received without payment will not be processed or returned. Email raps@raps.org or call the RAPS Solutions Center at +1 301 770 2920, ext. 200, if you have not received confirmation within five (5) business days from submittal of registration.

Deadlines: Early registration is encouraged. All registrations must be received by RAPS no later than 7 June 2010. After 7 June 2010, please contact RAPS Solutions Center at +1 301 770 2920, ext. 200, to inquire about registration options and availability.

Cancellations and Refunds: Written cancellations received by 5:00 pm ET on 24 May 2010 will be refunded after the conference in full minus a \$100 administrative fee. Refunds will not be granted for failure to attend, late arrivals, early departures, changes to the agenda or speaker roster or balance due registrations received after the registration deadline. **RAPS DOES NOT ACCEPT PHONE CANCELLATIONS.**

Substitutions: Substitutions are accepted with written notification from the original registrant in advance of the meeting. In event of substitution, membership acquired through conference registration remains with the original registrant; nonmember substitutes will be required to pay applicable nonmember fees.

Meeting Cancellation: RAPS reserves the right to cancel any conference at its sole discretion, whereupon all registration fees will be refunded. RAPS is not responsible for any costs incurred due to a cancellation.

Agenda/Speakers: Subject to change without notice.



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RAPS.org/exec/june2010



5635 Fishers Lane
Suite 550
Rockville, MD 20852
USA

■ WASHINGTON, DC ■ BRUSSELS ■ TOKYO



“Excellent program,
I would recommend
it to anyone.”

—Former RAPS Executive
Development Program
participant



“This was an extremely
useful program that I
will recommend to all
of my colleagues.”

—Former RAPS Executive
Development Program
participant

