



RAPS Executive Development Program

- Kellogg School of Management
- Northwestern University
- 6-9 June 2011
- RAPS.org/exec/june2011

THE **POWER** OF REGULATORY LEADERSHIP



The highly acclaimed **RAPS Executive Development Program** at the Kellogg School of Management consistently receives exceptional feedback 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 Laboratories Inc.
- Abmis Pharmaceutical Products
- Acceleron Pharma Inc.
- Acumed LLC
- Advanced Medical Optics
- Advanced Sterilization Products
- AFB International
- Allergan Inc.
- AMAG Pharmaceuticals Inc.
- American Medical Systems
- Amgen
- Amylin Pharmaceuticals Inc.
- Andrx Pharmaceuticals
- Aspect Medical Systems
- Astellas Pharma Global Development Inc.
- AstraZeneca R&D
- Auris AG
- Auxilium Pharmaceuticals Inc.
- Barco
- Barr Laboratories Inc.
- Baxter Healthcare Corporation
- Bayer Healthcare LLC
- BD
- Beckloff Associates Inc.
- BioBridges LLC
- Biogen Idec Inc.
- BioMarin Pharmaceutical Inc.
- Bioness Inc.
- Bio-Rad Laboratories
- Biovail Technologies Ltd.
- Boston Scientific Corporation
- Bowman FDA Regulatory Consulting Group
- Broncus Technologies Inc.
- Cadence Pharmaceuticals
- CanReg Inc.
- CardianBCT Biotechnologies
- Catalent Pharma Solutions
- CBMS-JPMO
- Celera
- Celgene Corporation
- Centurion Medical Products Corporation
- Cephalon Inc.
- Chimerix Inc.
- Chiron Corporation
- Cochlear Ltd.
- Codman & Shurtleff Inc.
- Conmed Linvatec Corporation
- Cook Pharmica
- CooperVision Inc.
- Cordis Corporation
- Covidien
- CSL Behring LLC
- Cytochroma Inc.
- Dade Behring
- Daiichi Medical Research Inc.
- Davol Inc.
- Dendreon Corporation
- Depomed Inc.
- DePuy Mitek
- Domecus Consulting Services
- Elekta Inc.
- Energizer Personal Care
- ETEX Corporation
- Ethicon Endo Surgery Inc.
- EV3 (Covidien)
- FAST Diagnostics
- Forest Laboratories Inc.
- ForHealth Technologies Inc.
- GE Healthcare
- Genomic Health
- Gen-Probe Inc.
- Genzyme Corporation
- GlobelImmune Inc.
- Grifols Biologicals Inc.
- Grunenthal GmbH
- Heraeus Kulzer Inc.
- Heyer Regulatory Solutions LLC
- Hill-Rom Inc.
- Hollister Incorporated
- IKARIA
- Immucor Inc.
- Instrumentation Laboratory
- Integra LifeSciences Corp
- Intel, Digital Health Group
- JM Consulting Services LLC
- Johnson & Johnson Inc.
- Kensey Nash Corporation
- Kimberly-Clark Corporation
- Kyphon Inc.
- Leo Pharmaceutical Products
- Lifecell Corporation, A KCI Company
- Lifescan Scotland Ltd
- Lohmann & Rauscher GmbH & Co. KG
- MacroGenics Inc.
- MAP Pharmaceuticals Inc.
- McNeil Consumer Healthcare
- Medical Device Consultants Inc.
- MedImmune Inc.
- Medtronic Inc.
- Merck & Co Inc.
- MFL Pharma Quality Compliance
- Micro Typing Systems Inc.
- Midmark Corporation
- Molecular Biometrics Inc.
- Nektar Therapeutics
- New England Research Institutes Inc.
- Noramco
- Novartis
- Orthofix Inc.
- Palomares Consulting Inc.
- Paragon MedSystems
- PDL BioPharma Inc.
- Philips Healthcare
- Praxair Healthcare Services
- Pro Saludis AB
- Procter & Gamble
- ProEd Communications Inc.
- Promega Corporation
- Regeneron Pharmaceuticals Inc.
- Resolute Regulatory Affairs Consulting Service Inc.
- Robert Bosch Healthcare Inc.
- Roche Diagnostics
- Roxane Laboratories Inc.
- Sage Products Inc.
- Sanofi-Aventis
- Schering-Plough Canada Inc.
- Schwarz Biosciences Inc.
- Shire
- Shire Human Genetic Therapies Inc.
- Siemens Medical Solutions
- SkinMedica
- Smith & Nephew Inc.
- Solvay Pharmaceuticals Inc.
- Spectranetics
- St. Jude Medical Inc.
- Starpharma Pty Ltd.
- STERIS Corporation
- Stryker Corporation
- Takeda Pharmaceutical Company Limited
- Talecris Biotherapeutics
- Terumo Heart Inc.
- Teva Pharmaceutical Industries Ltd.
- Theragenics Corporation
- Topcon Medical Laser Systems Inc.
- Trans1 Inc.
- Trevena Inc.
- UCB Pharma SA
- Upsher-Smith Laboratories Inc.
- Vertex Pharmaceuticals Inc.
- Virbac Inc.
- Viropharma Incorporated
- Volcano
- W.L. Gore Associates Inc.
- Wright Medical Technology Inc.
- Zimmer Inc.



Whether you are a seasoned executive or a fast-rising manager, the path to regulatory leadership requires more than scientific and functional expertise. You need well-honed management skills and a strong grasp of business fundamentals—high-level thinking, problem-solving ability and strategic foresight to confidently lead your organization through increasingly critical challenges.

In fact, regulatory professionals spend nearly 30% of their time on business and strategy—with engagement directly related to job level.* The higher you rise, the higher the stakes.

For the 11th consecutive year, RAPS is collaborating with the Kellogg School of Management to bring you the top-rated RAPS Executive Development Program, an intense four-day program featuring action-based learning designed specifically for the experienced regulatory professional.

Educational sessions will address the following essential business areas:

- Executive Leadership
- Strategic Challenges
- New Product Strategy
- Change Management
- Crisis Management
- Conflict Management
- Negotiation
- Decision Making

Return charged and ready to turn your regulatory leadership into organizational success.

KELLOGG SCHOOL OF MANAGEMENT

Located just outside Chicago, in Evanston, IL, the Kellogg School of Management at Northwestern University has been molding strong leaders since 1908, with an approach that fosters collaboration and inspires you to put your ideas into action.

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.

The Kellogg School of Management is consistently named among the world's top business schools for MBA and executive education programs.

*2010 RAPS Scope of Practice & Compensation Report for the Regulatory Profession



 **Kellogg**
School of Management

day **1**

Monday, 6 June

8:30 am

Welcome and Program Introduction

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

8:45–11:45 am

Managing Change: Innovation Adoption and People Management Challenges

Edward Zajac, PhD, James F. Bere Distinguished Professor of Management and Organizations, professor of health industry management, Kellogg School of Management

Participants learn about the role of leaders in the formulation of a competitive organizational strategy through discussion of a case dealing with a specific organization. Following a group case discussion, definitions of strategy are reviewed and approaches to strategy development are explored. Particular attention is paid to how organizations define themselves, what their corporate culture is like, and how they should develop their strategy so that it can be successful throughout all aspects and branches of the organization.

1:00–6:00 pm

Negotiating Productive Agreements

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

Participants will update their skills based on current research regarding the art and science of negotiations 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.

6:00–6:30 pm

Reception

6:30–7:30 pm

Dinner at the Allen Center

“What a valuable program. The professors were outstanding and the real-world application to regulatory was inspiring.”

– Former RAPS Executive Development Program participant

day **2**

Tuesday, 7 June

8:30–11:45 am

Thinking Strategically About New Products

Timothy Calkins, MBA, clinical professor of marketing, Kellogg School of Management

New products are a critical growth lever; few things can drive as much top-line and bottom-line growth as a strong new product introduction. However, new products are also expensive, time-consuming and usually unsuccessful. Developing a clear new product strategy, which includes a clear understanding of the regulatory challenges raised by the product, is one of the most important ways to improve the odds of success. This session will review the seven keys to a strong new product strategy and evaluate 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.

1:00–4:15 pm

Responding to Crisis: Converting Challenges Into Opportunities

Daniel Diermeier, PhD, IBM Professor of Regulation and Competitive Practice, Kellogg School of Management

In today's business world, organizations and individuals increasingly find themselves as 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. During this session, a faculty member will challenge 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 participants improve their strategic thinking as well as their team management and communication skills in high-stress situations.

4:30–6:00 pm

Strategic Challenges for the Regulatory Professional I

Edward F.X. Hughes, MD, MPH

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

6:00–6:30 pm

Reception

6:30–7:30 pm

Dinner at the Allen Center

Agenda

Agenda

day 3 Wednesday, 8 June

8:30–11:45 am

Dispute and Conflict Management

Lynn Cohn, JD, director of the program on negotiations and mediation, Northwestern Law School

This session looks at disputes and organizational (or interpersonal) conflicts and how they can negatively impact an organization. It also reviews how active engagement can be used to resolve these disputes. Further, mediation is discussed and exercises are used to have participants experience techniques that can lead the disputing parties to successful resolution of the issues causing the conflict.

1:00–4:15 pm

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

Leigh Thompson, PhD

Update your skills based on current research regarding the art and science of negotiations 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.

4:30–6:00 pm

Strategic Challenges for the Regulatory Professional II

Edward F.X. Hughes, MD, MPH

Building on discussions from the day prior (Part I), this session will seek to identify, again in a highly interactive manner, appropriate responses to surmount the managerial and strategic challenges facing regulatory professionals and the profession as a whole to enable the true skill-set of a regulatory professional to be realized and leadership opportunities seized.



6:00–6:30 pm

Reception

6:30–7:30 pm

Dinner at the Allen Center

How to Register



ONLINE:

RAPS.org/execed/june2011
(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)

REGISTRATION FEES (All fees in US dollars)

All registration fees include accommodations at the James L. Allen Center and meals for the duration of the program.

	Register by 16 May	Register after 16 May
RAPS Member	☐ \$6,150	☐ \$6,250
Nonmember	☐ \$6,335*	☐ \$6,435*

*Includes RAPS membership for 12 months for qualified applicants.

For complete program information and to register, visit RAPS.org/execed/june2011

day 4 Thursday, 9 June

8:30–11:45 am

Leadership: What it is All About and Why it Matters

Edward F.X. Hughes, MD, MPH

This session introduces the topic of leadership and shows what the research is unearthing to be the essential elements of the topic. It covers what leaders do and how they do it and discusses the challenges confronted in persuading others to act on the strategy that has been developed. The session also emphasizes the existence of opportunities for leadership at all levels within one's organization and within organizations and the environment outside of one's immediate work plan at all stages of one's career.

11:45–11:55 am

Concluding Remarks

James Drury, MHA
Edward F. X. Hughes, MD, MPH

1:00 pm

Program Adjournment

Transit to Airports (Cabs, Limos, etc.)

Faculty

Timothy Calkins, MBA, is a clinical professor of marketing of health enterprise management, and teaches marketing strategy biomedical marketing courses for MBA students, as well as seminars for Kellogg's Executive Programs. Prior to joining Kellogg in 1998, Calkins was a marketing executive with Kraft Foods for almost 11 years. He has received numerous awards including a gold EFFIE and the Hill Holiday Against All Odds Award for championing excellent advertising. He has been a speaker at numerous industry conferences. Calkins holds an MBA from the Harvard Business School. He co-edited *Kellogg on Branding* and is the author of *Breakthrough Marketing Plans: How to Stop Wasting Time and Start Driving Growth* (2008).

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. Clients include the National Association of Realtors, Smith Barney, the Illinois Commerce Commission, American Airlines, Kirkland & Ellis, Sidley Austin Brown & Wood, Mayer Brown Rowe & Maw, among others. Cohn holds a 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. He has lectured and consulted globally on media and issue management, activities and consumer boycotts, political strategy and regulatory management. Diermeier is a leading scholar in the study of both economics and politics. Previously, he spent three years as an assistant professor of political economy at Stanford University's Graduate School of Business. At Kellogg, Diermeier has been the recipient of various teaching awards, including the Best Teacher Award for the Kellogg-WHU International Executive MBA Program and the coveted L.G. Lavengood Professor of the Year Award.

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

Edward F.X. Hughes, MD, MPH, is co-academic director of the RAPS Executive Development program, a professor of management and strategy and of health industry management in the Kellogg School and a professor of preventive medicine in The Medical School, Northwestern University. He holds an MD from Harvard Medical School and MPH from Columbia University School of Public Health and originally trained in surgery at Columbia Presbyterian Medical Center in New York. He first came to Northwestern 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. Previously, Hughes was associated with the National Bureau of Economic Research and the Mt. Sinai School of Medicine. His research interests center on health policy, managed care, on the pharmaceutical, biotechnology and medical device industries and on the efficient utilization of scarce resources in the health industry. Hughes consults with, and speaks before, many national and international healthcare organizations, healthcare providers, managed care organizations, pharmaceutical, biotechnology and medical device firms. He is one of five cofounders of the Association for Health Services Research, a charter member of its Board of Directors and served as its first vice president. He was chosen by Faulkner and Gray's Health Information Center as a charter member of *The Health Care 500*, now *The Health Care 1500*, a directory of the most influential Americans in the field of health policy and is a member of *Who's Who in America*. In October 1999, Hughes was awarded "The Latiolais Honor Medical," the highest honor in Managed Healthcare by the Pharmaceutical Care Management Association. He also teaches leadership and is a member of the Leadership Council of the School.



Leigh Thompson, PhD, is the J. Jay Gerber Distinguished Professor of Dispute Resolution & Organizations at 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*.

Edward Zajac, PhD, holds the James F. Bere Chair in Management and Organizations and is also a professor of health industry management. His research, teaching and consulting focuses on strategic management issues. His research on strategic alliances, strategy formulation, and implementation and on organizational governance has been published widely in major academic journals. Zajac's PhD, MA and MBA in organization and strategy are from the Wharton School, University of Pennsylvania. He has chaired the International Strategic Management Society Conference and is currently the chairman of the Business Policy and Strategy Division of the Academy of Management. In 1996, he received the Sidney J. Levy Teaching Award for excellence as a classroom instructor. Zajac is founder and director of Kellogg's Center for Research on Strategic Alliances.

5635 Fishers Lane
Suite 550
Rockville, MD 20852
USA

■ WASHINGTON, DC ■ BRUSSELS ■ TOKYO

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6–9 June 2011

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“

Time well spent. I can't begin to tell you how much I took away from this program.

”

– Former RAPS Executive Development Program participant

“

I'd recommend [the program] to anyone looking to take that next step in their regulatory career.

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– Former RAPS Executive Development Program participant