



RAPS Executive Development Program

Kellogg School of Management
Northwestern University
11–14 June 2012
RAPS.org/Kellogg



Turn regulatory leadership into organizational success.

Since 1908, the Kellogg School of Management has made strong leaders stronger. *Business Week* ranks the school third out of all US business schools while *The Wall Street Journal* puts it fifth on their list of best business schools in the country.

The **RAPS Executive Development Program** at the Kellogg School of Management is the only program of its kind that exclusively caters to senior regulatory professionals. Participants in this acclaimed program come from a broad range of organizations—from pharmaceutical and medical device multinationals to biotech start-ups and consultancies.

For the 12th consecutive year, RAPS is collaborating with the Kellogg School of Management to bring you the RAPS Executive Development program. The intensive four-day program presents a unique opportunity to develop your business management skills through dynamic discussions with some of the world's best business professors from the Kellogg School of Management, in an intimate learning environment.

The program covers the following essential business areas:

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

Take away powerful business and leadership lessons—along with the inspiration to turn them into action.

RAPS Executive Development Program

alumni are among the world's top performing regulatory professionals.



Regulatory professionals are increasingly taking on higher-level roles within their organizations. On average they spend 30% of their time on business and strategy, with increased engagement in these areas as they move up in job level.* Critical factors such as the globalization of the healthcare products sector and the need for new models for product development, lifecycle management and regulation pose immense challenges to regulatory leaders.

Stepping up to face these challenges requires more than regulatory knowledge. To excel, you need well-honed management skills and a competent mastery of business fundamentals—high-level thinking, problem-solving and strategic foresight.

You will learn strategies and techniques to help prepare you to outsmart the competition, excel in the fast-paced global economy, solve problems creatively and build consensus across diverse groups.

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

Alumni represent the following organizations:

Abbott Laboratories Inc.
 Abmis Pharmaceutical Products
 Acceleron Pharma Inc.
 Acumed LLC
 Advanced Medical Optics
 Advanced Sterilization Products
 AFB International
 Alcon
 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.
 BioMerieux Inc.
 Bioness Inc.
 Bio-Rad Laboratories
 Biovail Technologies Ltd.
 Boston Scientific Corporation
 Bowman FDA Regulatory Consulting Group
 Broncus Technologies Inc.
 Cadence Pharmaceuticals
 CaridianBCT Biotechnologies
 Catalent Pharma Solutions
 CATO Research
 CBMS-JPMO
 Celera
 Celgene Corporation
 Centurion Medical Products
 Cephalon Inc.
 Chimerix Inc.
 Chiron Corporation
 Cochlear Ltd.
 Codman & Shurtleff Inc.
 Conmed Linvatec Corporation
 Cook Pharmica
 CooperVision Inc.
 Cordis Corporation
 Covidien
 CryoLife Inc.
 CSL Behring LLC
 Cytochroma Inc.
 Cyberonics 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
 Getinge Sourcing LLC
 Globelimmune Inc.
 Grifols Biologicals Inc.
 Grunenthal GmbH
 Heraeus Kulzer Inc.
 Heyer Regulatory Solutions LLC
 Hill-Rom Inc.
 Hollister Incorporated
 Hospira Inc.

IKARIA
 Immucor Inc.
 Instrumentation Laboratory
 Integra LifeSciences Corp
 Intel, Digital Health Group
 JHP Pharmaceuticals Inc.
 JM Consulting Services LLC
 Johnson & Johnson Inc.
 Kensey Nash Corporation
 Kimberly-Clark Corporation
 Kyphon Inc.
 Kythera Biopharmaceuticals 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
 Optuminsight
 Orthofix Inc.
 Palomares Consulting Inc.
 Paragon MedSystems
 PDL BioPharma Inc.
 Philips Healthcare
 Praxair Healthcare Services
 Pro Saludis AB
 Procter & Gamble
 ProEd Communications Inc.
 Qserve Group BV
 Quest Diagnostics 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
 Sanofi-Pasteur Inc
 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
 Targen Inc.
 Terumo Heart Inc.
 Teva Pharmaceutical Industries Ltd.
 Theragenics Corporation
 Thoratec Corporation
 Topcon Medical Laser Systems Inc.
 Trans1 Inc.
 Transkaryotic Therapies 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.

agenda

It was wonderful to learn from such a diverse group of professionals with a wide range of specialties. It really gave me a broad perspective on how to tackle day-to-day challenges.

– Former RAPS Executive Development Program participant

DAY 1: MONDAY, 11 JUNE

8:30 am	<p>Welcome and Program Introduction</p> <p><i>Edward F. X. Hughes, MD, MPH</i>, academic director, Executive Leadership Program and professor of management and strategy and health industry management, Kellogg School of Management</p>
8:45–11:45 am	<p>Managing Change: Innovation Adoption and People Management Challenges</p> <p><i>Edward Zajac, PhD</i>, James F. Bere Distinguished Professor of Management and Organizations, professor of health industry management, Kellogg School of Management</p> <p>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.</p>
1:00–6:00 pm	<p>Negotiating Productive Agreements</p> <p><i>Leigh Thompson, PhD</i>, J. Jay Gerber Distinguished Professor of Management and Organizations, director of Teams and Group Research Center, Kellogg School of Management</p> <p>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.</p>
6:00–6:30 pm	Reception
6:30–7:30 pm	Dinner at the Allen Center

DAY 2: TUESDAY, 12 JUNE

8:30–11:45 am	<p>Thinking Strategically About New Products</p> <p><i>Timothy Calkins, MBA</i>, clinical professor of marketing, Kellogg School of Management</p> <p>New products are a critical growth lever; few things can drive as much top- 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.</p>
1:00–4:15 pm	<p>Responding to Crisis: Converting Challenges Into Opportunities</p> <p><i>Daniel Diermeier, PhD</i>, IBM Professor of Regulation and Competitive Practice, Kellogg School of Management</p> <p>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. 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.</p>
4:30–6:00 pm	<p>Strategic Challenges for the Regulatory Professional I</p> <p><i>Edward F.X. Hughes, MD, MPH</i></p> <p>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.</p>
6:00–6:30 pm	Reception
6:30–7:30 pm	Dinner at the Allen Center



DAY 3: WEDNESDAY, 13 JUNE	
	Dispute and Conflict Management
8:30–11:45 am	<i>Lynn Cohn, JD</i> , 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.
	Making Better Decisions: Using the Research to Improve Your Skills
1:00–4:15 pm	<i>Leigh Thompson, PhD</i> This module challenges us—via brainstorming under pressure, unearthing multiple agendas and optimizing use of cross-functional skills—to be better decision makers. Understand how decisions get made, who is or should be involved in making decisions, how and what levers are pulled to get decisions made, and how to develop strategies to effectively communicate your decisions to others—physicians, managers, nurses and others in your organization.
	Strategic Challenges for the Regulatory Professional II
4:30–6:00 pm	<i>Edward F.X. Hughes, MD, MPH</i> Building on discussions from the previous day (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
DAY 4: THURSDAY, 14 JUNE	
	Leadership: What it is All About and Why it Matters
8:30–11:45 am	<i>Edward F.X. Hughes, MD, MPH</i> This session introduces the topic of leadership and shows what research is unearthing as 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
	<i>Edward F. X. Hughes, MD, MPH</i>
1:00 pm	Program Adjournment

“Very stimulating experience. It gave me great exposure to new concepts and ideas. I found applying new theories to case situations during the program to be very beneficial. I could apply what I learned immediately to my role and continue to do so.”

– Former RAPS Executive Development Program participant



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 published *Breakthrough Marketing Plans* (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 Juris Doctor 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. Diermeier has been the recipient of various teaching awards, including the 2000 *Best Teacher Award* for the Kellogg-WHU International Executive MBA Program and the coveted *L.G. Lavengood Professor of the Year Award* (June 2001).

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, an MPH from Columbia University School of Public Health and originally trained in surgery at Columbia Presbyterian Medical Center in New York. He is one of the 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*.

Leigh Thompson, PhD, is the J. Jay Gerber Distinguished Professor of Dispute Resolution & Organizations at the Kellogg School of Management. 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 over 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 focus 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 he is currently the chairman of the Business Policy and Strategy Division of the Academy of Management. Zajac is founder and director of Kellogg's Center for Research on Strategic Alliances.

“Great diverse class, but not too large. We built up a great rapport and by the end we were very comfortable solving problems together.”
 – Former RAPS Executive Development Program participant

Classes take place at the James L. Allen Center, a state-of-the-art lakefront facility on Northwestern University's Kellogg School of Management campus.

Registration fees include meals and lodging at the Allen Center, which was designed to host Kellogg's executive programs. The facility also offers study areas, Internet connection, snack rooms, laundry service, an exercise room and 24-hour concierge service.

Registration Fees (US dollars)	Register by 11 May	Register after 11 May
RAPS Member	\$6,150*	\$6,350*
Nonmember*	\$6,375*	\$6,575*

*Includes RAPS membership for 12 months for qualified applicants.



Online
RAPS.org/Kellogg (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)

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

register

5635 Fishers Lane
Suite 550
Rockville, MD 20852
USA

■ WASHINGTON, DC ■ BRUSSELS ■ TOKYO

Such a rich learning environment.
I'd recommend [the program] to
anyone looking to take that next
step in their career.

– Former RAPS Executive Development
Program participant

RAPS Executive Development Program

Kellogg School of Management • Northwestern University • 11–14 June 2012 • RAPS.org/Kellogg

