

## Frances J.R. Richmond

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### Education/Nationality

1973 B.N.Sc., Queen's University, Kingston, Canada  
1974 M.Sc., Physiology, Queen's University, Kingston, Canada  
1976 Ph.D., Neurophysiology, Queen's University, Kingston, Canada  
1988 NDC, National Defense College, Canada  
\*born in Canada; currently hold US and Canadian citizenship

### Honours/Awards

1969 John Thorburn Scholarship; Ontario Scholarship; 100th Anniversary Scholarship  
1970 Susan Near Scholarship in Psychology  
1972 W.B. Saunders Book Prize  
1973 Queen's University Medal in Nursing  
Studentship - Medical Research Council of Canada  
1977-1978 Fellowship - Medical Research Council of Canada  
1979 Scholarship - Medical Research Council of Canada  
Research Associateship - Killam Foundation, (awarded but declined)  
1987 Basmajian Award for Excellence in Research  
2012 TOPRA Award for Excellence in Education

### Professional Experience/Academic Appointments

1973-1976 Demonstrator, Physiology 210, 312, 510, 474/874,  
Department of Physiology, Queen's University,  
Kingston, Ontario  
1976-1978 Lecturer, Department of Physiology, Queen's University,  
Kingston, Ontario  
MRC Postdoctoral Fellow, NIDR, National Institutes of Health,  
Bethesda, Maryland, U.S.A.  
MRC Postdoctoral Fellow, Departement de Physiologie,  
Université de Montréal, Montréal, P.Q.  
1979-1983 Assistant Professor and MRC Scholar, Department of Physiology,  
Queen's University, Kingston, Ontario  
1983-1984 Associate Professor and MRC Scholar

- 1984-1987 Associate Professor
- 1987-present Full Professor
- 1988-1990 Associate Dean, Life Sciences, Faculty of Medicine
- 1990-1995 Member, MRC Group in Sensory-Motor Physiology
- 1990-1996 Member, Networks of Centres of Excellence, Neural Regeneration and Functional Repair
- 1993-1994 Visiting Scholar seconded as Policy Analyst, Industry Canada
- 1994-1995 Clinical Research Scientist, Alfred E. Mann Foundation for Scientific Research, Sylmar, CA. (sabbatical appointment)
- 1995-2000 Director, MRC Group in Sensory-Motor Neuroscience;  
Preclinical and Clinical Trials Consultant, Advanced Bionics Corp., Sylmar, CA
- 2000-2008 Research Professor, School of Pharmacy;  
Director, Regulatory Science Master's Program, USC;  
Director, Regulatory and Clinical Science, Alfred E Mann Institute for Biomedical Engineering  
Cross-appointed as Professor, Cell and Neurobiology
- 2008-2017 Professor, of Clinical Pharmacy, Titus Family Department of Clinical Pharmacy and Pharmacoeconomics and Policy;  
Director, Regulatory Science Programs, USC School of Pharmacy
- 2010-2015 Director, Regulatory Knowledge and Support Group, LA Basin Clinical and Translational Science Institute
- 2011-2017 Director, International Center for Regulatory Science at USC  
Adjunct Professor of Health Economics and Policy, TJAB
- 2017-Present Professor and Chair, Department of Regulatory and Quality Sciences  
USC School of Pharmacy

## Teaching Activities at Queen's University

- Physiology 474/874 - Mammalian Neurophysiology; course supervisor/lecturer  
4th year honours life sciences and graduate students.
- Physiology 312/510 - Vertebrate Physiology  
3rd year honours life sciences and first year medical students.
- Phase I - Medicine - first year - 5 lectures and 3 lab demonstrations
- Physiology 210 - Mammalian Physiology –  
Primarily nursing, rehabilitation therapy and physical education students
- Physiology 320 - Mammalian Neuroscience - 3rd year life sciences students
- Human Pathophysiology - Special lecture series; 10 lectures to engineering and research  
staff of A.E. Mann Foundation and Advanced Bionics Corporation, 1994-1995.
- Physiology 434 - Advanced Physiology  
1990, 1992, 1995, 1996 - 1 project student
- Physiology 884 - Graduate Student lab course 1996, 1997
- Physiology 801 - Beyond Academia (graduate course)  
(enrollment: 25) 1996, 1997, 1998

## Teaching Activities at USC - Outside Regulatory Science Program

- Pharmacy 309 – Biological Sciences I- 4-6 hours either on sensorimotor neuroscience  
or embryology, 2000-2004
- Pharmacy 406 – Pharmaceutics IV- 2 hours on regulatory management of new drugs  
2000-2003
- Biomedical Engineering 416- Development and Regulation of Medical Products  
1999-2004 – co-supervisor  
2005-present, 3-4 afternoons
- Molecular Pharmacology and Toxicology 501- 2 hours, industrial toxicology  
2000-2002
- Molecular Pharmacology and Toxicology 603- Signal Transduction  
2000 course supervisor

BISC 406L- Biotechnology 2001 lecturer,  
2008 to present, 3 hours, FDA regulation

Pharmacy 670 Marketing and Development in the Pharmaceutical Industry  
2010 to 2015, coorganizer and speaker.

Pharmacy 508 Pharmacy Literature Analysis and Drug Information  
2010 to present, 2 hours X2

Pharmacy 510 Pharmacy Practice and Experience II  
2010 to present, 2 hours

CPTX 609 Preclinical Experimental Therapeutic Drug Development  
2011 to present, 2 hours

BME 201 Biomedical Engineering Practice  
2013 to present 3 hours

## Teaching Activities at USC -In Regulatory Science Program

All of these courses are part of Regulatory Science offerings and are team taught; participation and role varies with year and need but I typically was involved with design and initial development in the early years of each course and participate in at least a lecturing capacity in most for reasons of continuity and quality assurance. Courses managed as primary instructor in 2018 are underlined, a few are given 2 or three times each year.

RXRS 416 - Medical Products from Idea to Market

MPTX 511 - Introduction to Regulation

MPTX 512 - Regulation of Drugs and Biologics

MPTX 513 - Regulation of Medical Devices and Diagnostics

MPTX 514 - Regulation of Foods and Dietary Supplements

MPTX 515 - Quality Systems and Standards

MPTX 516 - Medical Products and the Law

MPTX 517 - Structure and Management of Clinical trials

MPTX 630 - Internship

MPTX 518 - Writing Regulatory Submissions

MPTX 519 - International Regulation

MPTX 521 - Seminar program

MPTX 522 - Clinical Trial Design

MPTX 602 - Science, Research and Ethics

RSCI 508 Quality systems for Drugs

RSCI 509 Quality Systems for Devices

RSCI 520 - Risk Management Theory

RSCI 527 - Medical Product Safety

RSCI 529 - Risk Management Tools

RSCI 531 - Industrial Approaches to Drug Discovery  
RSCI 532 - Drug Development  
RSCI 541 – Drug Development, Reimbursement and Marketing  
RSCI 601 - Biomedical Commerce  
RSCI 603 - Managing Complex Projects  
RSCI 604 - Regulation in Asia  
RSCI 605 - Managing Human Resources  
RSCI 606 – Emerging Technologies  
RSCI 608 - Regulation in Europe and the Americas  
RSCI 607 -Research Design

Diverse other commitments to courses in different departments including School of Business, Engineering and Pharmacy that total less than 4 hours per course may not be listed.

## Supervision or Cosupervision

***Master of Science Students (Queen's)***

1. G. Bakker (1980)
2. D. Bakker (1980)
3. J. Keane (1981)
4. J. Armstrong (1983)
5. C. Hammond (1987)
6. D. Gordon (1987)
7. D. Thomson (1991)
8. T. Liinamaa (1995)
9. K. Singh (1999)

***Ph.D. Students (Queen's)***

1. D. Bakker (1983)
2. D. Gordon (1990)
3. E. Smits (1993)
4. D. Thomson (1994)
5. A. Dupont (2001)
6. E. Melis (transferred, 1998)

***Post-doctoral Fellows (Queen's)***

1. S. Selbie (1990-1992)
2. J. Runciman (1994)
3. L. Kamibayashi (1994-1995)

***Master of Science (USC) (management of core program)***

- |                       |                |
|-----------------------|----------------|
| 16+ enrolled students | (2001)         |
| 50 enrolled students  | (2002)         |
| 45 enrolled students  | (2003)         |
| 60 enrolled students  | (2004)         |
| 75 enrolled students  | (2005)         |
| 75 enrolled students  | (2006)         |
| 80+enrolled students  | (2007)         |
| 80+enrolled students  | (2008)         |
| 90+ enrolled students | (2009-present) |

***Regulatory Science DRSc (USC)(management of core program)***

- |                  |        |
|------------------|--------|
| Martin Solberg   | (2011) |
| Michael Jamieson | (2011) |
| Susan Bain       | (2011) |
| Duane Mauzey     | (2012) |
| Tony Chan        | (2012) |
| Taranjit Singh   | (2012) |
| Ellen Whalen     | (2013) |
| Valerie Ramsey   | (2013) |

Haven McCall	(2013)
Neal Storm	(2013)
JoAnn Pfeiffer	(2013)
Chin-Wei Soo	(2014)
Neal Storm	(2014)
Patrick Dimapindan	(2014)
Kwabena Dankwah	(2015)
Bill Leitner	(2015)
Cesar Medina	(2015)
Nancy Smerkanich	(2015)
David Locke	(2015)
Caroline Mosessian	(2015)
Simone Turnbull	(2016)
Clare Elser	(2016)
Darin Oppenheimer	(2016)
Ali Rejaei	(2017)
Grant Griffin	(2017)
Terry Church	(2017)
Grant Dagliyan	(2018)
Jennifer Wiley	(2018)
Alicia Colarossi	(2018)
John Hartigan	(2019)

20+ students in progress

### ***Other programs***

1. Kathy Knodel Thesis committee, EDD (2009) USC
2. Josh Page Thesis supervisor, MS Regulatory Affairs and Health Policy(2015)  
MCPHS

## **University Committees: Queen's**

### ***1980-1989:***

Member; Advisory Committee for Selection of Dean, Arts and Science (1980)  
 Departmental Committee on Selection, Renewal and Tenure (1985)  
 Member; Advisory Committee, Queen's National Scholars Program (1985-1987)  
 Member and Scientific Officer; Graduate Research Committee, Faculty of Medicine (1985-1987)  
 Member; Steering Committee, Conference on Teaching and Learning (1986)  
 Member; Advisory Committee for Selection of Dean, Faculty of Medicine (1986-1987)

### ***1990-1999:***

Chairman; Queen's National Scholarship Program (1988-1991)  
 Member; Committee to Design the "First Year Experience" (1990-1991)  
 Member and Co-chair; Committee to Evaluate Policies Re. Teaching Assistants  
 Member; Faculty of Medicine Education Awards Committee (1990-1992)

Member; Search Committee for Headship in Urology (1992)  
Member; Search Committee for Headship in Pharmacology (1992)  
Member, Search Committee for Directorship of Animal Care (1996)  
Chair, Grievance Panel re: Authorship and Intellectual Property (1996)  
Member, Faculty of Medicine Promotions Committee (1996-1999)  
Member, Neuromuscular Search Committee (1997-1998)  
Member, Selection Committee for Headship of Department of Physiology (1997-1998)  
Member, Appointments Committee, Department of Physiology (1998-1999)

## **University Committees: USC**

Member, Advanced Technology Committee, 2002-2005  
Member, ad hoc Committee on Animal Facilities, 2001-2002  
Member, Financial Disclosure Committee, 2004- 2012  
Chair, HSC Conflict of Interest in Research Committee, 2012-present  
Member, University Advanced Technology Committee, 2006-2008  
Co-chair, Education Section. Clinical and Translational Research Steering Committee, 2006-2008  
Member, Human Subjects Steering Subcommittee, 2005-present  
Member, Continuing Education Faculty Advisory Committee, 2008-2012  
Chair, Technology-enhanced Learning and Distance Education Committee for Prizes and Grants, 2007  
Member, USC School of Pharmacy Committee on Distance Learning Initiatives, 2009 to 2011  
Member, USC School of Pharmacy Committee on Strategic Planning, 2009-present  
Member, Steering Committee, Center for Technology and Innovation in Pediatrics 2010-2014  
Member, Committee on Clinical Coordinator Training, 2011-present  
Member, COI Compliance Process Improvement Workgroup, 2011-present  
Member, University Corporate Research Group, 2011-present  
Chair, Conflicts of Interest in Research Committee at Health Sciences, 2012-present

## **Past/ Present Professional Memberships**

Canadian Physiological Society (Councillor, 1987-1989; Secretary, 1991-1994; President, 1997-1998)  
Canadian Federation of Biological Societies (Member, Board of Directors, 1991 – 1999)  
Canadian Association for Neuroscience  
Society for Neuroscience  
American Association of Anatomists  
American Association of Colleges of Pharmacy  
American Association of Pharmaceutical Scientists



Drug and Information Association  
Regulatory Affairs Professionals Society  
Orange County Regulatory Affairs Professionals Society  
American Society for Quality  
Society for Quality Assurance  
Association of Graduate Regulatory Educators  
National Academy of Inventors  
Registered as a Nurse in Ontario #73-4338 7 and California # 575628

## Scholarly and Professional Activities

- 1985 Symposium Organizer; Receptors in Skeletal Muscle: Changing Perspectives. Canadian Federation of Biological Societies, Toronto, Canada  
Co-chairman Organizing Committee; The Control of Head Movement Satellite Symposium of the International Congress of Biological Societies, Vancouver, July, 1986  
Member; Nominating Committee, Canadian Physiological Society
- 1986 Session Chairman, Winter Meeting, Canadian Physiological Society.  
Organizer; IUPS Satellite Symposium, "The Control of Head Movement"  
Co-editor of textbook: "The Control of Head Movement" published by Oxford University Press  
Councillor; Canadian Physiological Society  
Member; Grants Study Section, NIH, "Neurologic, Muscular, Perceptual and Cardiovascular Aspects of Falls and Gait Disorders in Elderly People"
- 1987 Member; Fellowships Committee (Ph.D.), Medical Research Council of Canada  
Session chairman and member of organizing committee; Engineering Foundation Conferences, "The Development and Roles of Models"  
Participant; National Defence College Course
- 1988 Associate Chairman, Fellowships Committees (Ph.D. and Health Sciences Professionals), Medical Research Council of Canada
- 1989-1993 Chairman; Fellowships Committee (Ph.D.) Medical Research Council of Canada
- 1990-1993 Member; Polanyi Prize Committee
- 1990-1992 Member; Canadian Federation of Biological Societies Committee on Equal Opportunities (1991-1994)
- 1991-1994 Secretary; Canadian Physiological Society
- 1991 Rapporteur - Workshop - Canada's Participation in the HFSP and Our Future Role in International Scientific Research

Scholarly and Professional Activities Continued:

- 1992-1993 Panel Member; Ontario Graduate Studentships
- 1992-1995 Member, Fellowships Committee - International Human Frontiers in Science Program
- 1993-1996 Member; Ontario Council of Graduate Studies Appraisals Panel
- 1993-1994 Policy Analyst; Industry Canada
- 1994-1995 Sabbatical experience as clinical research scientist, A.E. Mann Foundation for Scientific Research
- 1995 Symposium organizer and co-chair: Sensorimotor Transformations in the Nervous System, held at Queen's University, Kingston
- 1995 Workshop organizer and chair: Looking Ahead in Sensorimotor Control Big Questions for 2001, Workshop supported by Human Frontiers Science Program, held in Kingston, Canada
- 1996-1997 Invited Member, Biomedical Engineering Review Panel, Medical Research Council
- 1997-1998 Vice-President, Canadian Physiological Society
- 1998 Organizer and Chair - Conference for Research in Action and Perception, held in Kingston, Canada
- 1997-1998 President, Canadian Physiological Society
- 1998-2005 Member, Scientific Advisory Committee of the International Doctoral School in Biomedical Sciences and Engineering, Aalborg, Denmark
- 2000 Co-organizer, Mann Institute Symposium "Can We Make the Blind See?," Los Angeles California
- 2000 Co-organizer, Mann Institute Symposium "Putting the Brain in Command", Los Angeles, California
- 2000 Short-course Organizer and Program Chair, "Clearing Roadblocks in the New-Product Path" Irvine, CA , October 2000
- 2000 Short-course Organizer , "RA101", with Regulatory Affairs Professionals Society, Pasadena, CA, November 2000
- 2000 Short-course Organizer and Program Chair "The Regulation of Dietary Supplements and Functional Foods," Pasadena, CA, November 2000

- 2000-2003     Advisory board- UCLA Extension Program
- 2000-2010     Advisory Board- School of Policy Planning and Development
- 2007-2010     Southern California Biomedical Council Subcommittee on Education/Training
- 2008, 2011     Referee and Site Reviewer, Arizona Science Foundation
- 2008-2011     Editorial Board of Medical Product Outsourcing
- 2009-2012     Medical Management Systems Council, (unpaid, arms length board for ethics oversight at Underwriters Laboratory)
- 2011-2014     Board of Directors, Drug Information Association
- 2013-2017     CTSI Regulatory Science Workgroup
- 2013- 2017     Board of Directors, Association of Graduate Regulatory Educators.
- 2013-2015     USP Regulatory and Compendial Science Consortium
- 2014-2015     Chair, Audit Committee, Drug Information Association, Board of Directors
- 2015            Secretary, Board of Directors, Association of Graduate Regulatory Educators
- 2015-2017     President, Association of Graduate Regulatory Educators
- 2018            Cofounder, Committee for International Pharmaceutical Regulatory Science Education Promotion
- 2018-2021     Member, FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee
- 2018-present   Advisory Board member, West Coast Consortium for Technology and Innovation in Pediatrics

### **Past Referee/Consultant for Journals and Agencies:**

Journals:       Journal of Neurophysiology, Experimental Brain Research, Canadian Journal of Physiology and Pharmacology, Journal of Comparative Neurology, Journal of Morphology, Journal of Neuroscience, Journal of Biomechanics, Regulatory Focus; Medical Product Outsourcing (editorial board), Drug Information Journal, Therapeutic Innovation and Regulatory Science, Journal of Neural Engineering, Pharmaceutical Medicine, Frontiers in Regulatory Science

Agencies: Medical Research Council of Canada, National Institutes of Health, National Science Foundation, American Osteopathic Association, British Columbia Health Foundation, Glaxo Canada, Ontario Ministry of Health, ISC, Arizona Science Foundation; Society for Quality Assurance

**Invited Presentations and Lectures (1984 – Present, selection only):**

- |         |      |   |
|---------|------|---|
| April   | 1984 | Organization of Primary Afferent Projections from Neck Muscles. University of Washington, Seattle, U.S.A.                                   |
| October | 1984 | Unusual Forms of Mammalian Skeletal Muscle Architecture. Society for Neuroscience Satellite Conference, Tucson, U.S.A.                      |
| January | 1985 | Neck Muscle Architecture, Receptors and Movement. Neurosciences Institute, Rockefeller University, New York, U.S.A.                         |
| May     | 1985 | Discussion Leader: Tensorial Approaches to Neck Muscles. National Institutes of Health, Washington, U.S.A.                                  |
| June    | 1985 | Chairman: Receptors in Skeletal Muscle: Changing perspectives. Canadian Federation for Biological Sciences, Toronto, Canada                 |
| July    | 1985 | Structure and Function of Skeletal Muscle Receptors. Engineering Foundation Conference, Henniker, N.H., U.S.A.                              |
| October | 1985 | Biventer Cervicis: A Complex Muscle for a Complex Motor Task. Northwestern University, Chicago, U.S.A.                                      |
| January | 1986 | Biological and Career Pressures on Women in Science. Forum on Women's Issues, Ontario Advisory Council of Women's Issues, Kingston, Canada. |
| May     | 1986 | Achieving Excellence: Challenges for Faculty. Panel Presentation, Queen's University Council, Kingston, Canada.                             |
| May     | 1986 | Moving Muscles: Studies in Neurophysiology. Canadian Science Writers' Association, Kingston, Canada.  |
| July    | 1986 | Structure and Function of Neck Muscles. IUPS Satellite Symposium, "The Control of Head Movement", Whistler, B.C.                            |
| April   | 1987 | Basmajian Revisited: Muscle Physiology is Motor Physiology. Basmajian Award Lecture, Queen's University, Kingston.                          |
| May     | 1987 | Problems for Women in Science. Panel Presentation. Science Writer's Association, Toronto, Canada.   |
| July    | 1987 | Architectural Specializations in Skeletal Muscle. Engineering Foundation Conference, Henniker, N.H., U.S.A.                                 |

- August 1988 Do Excitatory Reflexes Exist in the Neck of the Alert Cat? ENA Symposium on Posture and Locomotion. Rheinfelden, Switzerland.
- August 1990 Organization of Natural Head and Neck Movements in the Cat. First World Congress of Biomechanics. San Diego, U.S.A.
- November 1990 Neurophysiology of Pain. Symposium on "Dealing with the Patient in Pain". Kingston, Canada.
- December 1990 Control of Head Movement: Is the Neck Another Limb? Dept. of Kinesiology, UCLA, Los Angeles, U.S.A.
- January 1991 Architectural and Functional Specializations Muscles: Complex Rules for Complex Muscles. Dept. of Zoology: Ohio State University, U.S.A.
- April 1991 Specializations of Fiber Architecture. Symposium on Functional Architecture of Skeletal Muscle; Forum in Cellular and Organ Biology, Chicago, U.S.A.
- September 1991 Sensory-Motor Organization of the Head Movement System. Symposium on "Muscle Afferents and the Spinal Control of Movement" to honour Y. Laporte, Paris, France.
- August 1993 Neuromuscular Control of the Two-Part Neck IUPS Symposium on Head Movement, Glasgow, U.K.
- April 1994 Muscles: Why Can't They be as Simple as the Textbooks Suggest? Southwestern University Medical School. Dallas, Texas.
- May 1994 The Anatomy of Muscle Architecture. Implications for Motor Control. 2nd International Symposium, The Medical Research Council Group in Sensory-Motor Physiology, Queen's University. Kingston, Ontario.
- July 1994 Mechanical Stability in Complex Muscles-Neural and Architectural Considerations. 2nd World Congress on Biomechanics Symposium on Muscle Mechanics. Amsterdam, Holland.
- July 1994 Skeletal Muscle: Structural Engineering Nightmare. Wright State University, Dayton, Ohio.
- December 1994 Postural Modifications of Neck-Muscle Synergies during Head Movement. Dept. of Kinesiology, UCLA, Los Angeles, U.S.A.

- July 1995 1995 Structural and Biomechanical Factors Underlying Head-Neck Motor Function. Third International Symposium on the Head/Neck System, Vail, Colorado.
- December 1996 Elements of Style in Muscle Architecture. Invited Lecture. Society for Comparative and Integrative Biology, Albuquerque, NM.
- March 1998 Multiarticular Motor Systems: Lessons from the Head and Neck. Invited Lecture. Department of Electrical Engineering, University of Arizona, Tempe, Arizona.
- November 1998 Animal Models of Motor Systems: Cautionary Tales from Studies of Head Movement. Invited Speaker. Peripheral and Spinal Mechanisms in the Neural Control of Movement, University of Arizona, Tucson, Arizona.
- March 1999 Head Movement from Many Different Angles, Institute of Movement, University College London.
- April 1999 Controlling the Multiarticulated Neck. Department of Biokinesiology and Physical Therapy, University of Southern California.
- January 2000 Regulation of Dietary Supplements  
Moving Forward with Complementary Therapeutics,  
Continuing Education Program, USC
- February 2000 Recruitment of Subjects: Similarities and Differences in Drug and Device Trials  
Foundations of Clinical research Trials, Advanced Series  
University of Southern California Short-course
- March 2000 The Evolving Regulatory Climate for Dietary Supplements in the US.  
Hong Kong Business Mission on Herbal Products and Dietary  
Supplements, Los Angeles
- November 2000 Health Claims on Supplements: Enforcement Actions of Federal  
Authorities. The Regulation of Dietary Supplements and Functional  
Foods, Pasadena CA
- January 2001 Managing Biocompatibility Projects: Practical Applications  
MD&M West 2001 Conference, Anaheim, CA
- December 2001 Ethics of Clinical Research: When does NIH and OHRP become  
involved? OCRA conference “Conducting Successful Clinical Trials  
under Good Clinical Practice Regulations to Facilitate the Product  
Approval Process”
- December 2001 Preclinical Testing and Clinical Trials of BION Injectable Stimulators to



		Treat Disuse Atrophy, ITRI, Taiwan
November	2002	Clinical Trials in 2002: Trends and Issues, Novartis, NW Regional Meeting, Jackson Hole, Wyoming
October	2003	The ...omics Revolution. AOAC/FDA Joint Meeting, Irvine CA.
March	2004	Bioethics Biomedical Education Symposium. USC Marshall School of Business
August	2005	Overview of Drug Development. Amgen, Thousand Oaks
January	2005	Ephedra: What It Tells Us about Regulatory Systems. QSAD Annual meeting, Ojai ,CA
March	2006	Beyond the Codes: Practical Ethical Principles and Considerations for the Regulatory Professional, RAPS Horizons Conference, San Diego, 2006
April	2006	US Regulation of Generic Drugs and Dietary Supplements. Tiansin
July	2006	Training Methods and Outcomes in Regulatory Science. World Congress of Pharmacology, Beijing, China
October	2006	Graduate Training in Regulatory Affairs, Regulatory Affairs Career Forum, Minneapolis, MN
March	2007	Advanced Training and Recruitment in Regulatory Affairs. Horizons RAPS meeting, San Francisco, CA
April	2007	Tools for Assessment in TEL and Distance Learning, TEL_DL Faculty Forum, University of Southern California
August	2007	Good Laboratory Practices, City of Hope invited presentation
September	2007	New Regulations for US Dietary Supplements. China Life Sciences Summit, Beijing
February	2008	Moderator and speaker: Filling the Life-Sciences Industry's Pipeline, Human resources Conference, SCBC, Los Angeles, CA
July	2008	Participant, webinar, "The European Medical Device Directive: Upcoming Changes" FOI Teleconferences
July	2008	Speaker, "Risk management" American Society for Quality, Northridge CA
September	2008	Speaker, "Analysis of New Policies of American FDA" Fourth Annual China International Life Science Summit, Hangzhou, China
November	2008	Speaker, "Clinical trials for Generic Pharmaceuticals" and "505b(20) Applications for Novel Drugs and Novel Formulations, Xpo Pharm, Seoul, Korea.

- January 2009 Panel Organizer and Speaker, “Regulatory Strategies in Stem-cell and Nano Technology” Beckman Initiative For Macular Research/National Academies Conference. Irvine, CA
- February 2009 Speaker, “Dealing with Multiple Constituencies: A View from the Trenches” AHRPP Annual Meeting, Los Angeles, CA
- June 2009 Speaker, “Doctoral Education in Regulatory Science”, Orange Country Regulatory Affairs Annual meeting, Irvine CA
- October 2009 Speaker and Moderator, “US Regulatory System Update”, Beijing International Healthcare Industry Forum, Beijing, China
- November 2009 Speaker, “FDA Device Primer” Wonju Medical Technovalley Forum, Wonju, South Korea
- July 2009 Speaker, “US Regulation Landscape” Overcoming Commercial Barriers and Exploring Collaborative Opportunities in Regenerative Medicine. Scripps Research institute, La Jolla, July 27
- June 2010 Speaker, “Regulation of BCI Devices” , Telluride Neuromorphic CognitionWorkshop, Telluride, June 28
- July 2010 Speaker, “Stem Cells: From Bench to Clinic”, Scripps Research Institute, San Diego, July 27
- October 2010 Speaker, “Regulatory Science: a Key to Medical Device Commercialization”. Invited presentation at Yonsei University, October 6,
- 2010 Wonju, Korea Speaker, “Research & Development of Medical Devices in US: Regulatory and Quality Assurance”, Yonsei Medical Device Development and Promotion Center, Wonju, Korea
- March 2011 Speaker, “Regulatory Training and Coursework in Higher Education” Society for Quality Assurance, San Antonio, Texas, March 29-31, 2011
- September 2011 Speaker, “The US Regulatory System: An Update”, Development of Sino- American Collaboration in the Healthcare Industry, Sept 19, 2011
- Speaker, "FDA Regulations; An Update", International Cooperation and Development Forum of China Bio-Pharmaceutical Industry, Hangzhou, Sept 20, 2011
- Speaker, "FDA Regulations for Medical Devices", 2011 International Symposium, Challenges in Global medical Device Development, Wonju, South Korea, Sept 27, 2011
- November 2011 Speaker, "Recent Trends in FDA Regulation" 7<sup>th</sup> “FangYuan” Forum of the School of the International Pharmaceutical Business, China Pharmaceutical University, Nanjing, China, December 3, 2011

- December 2011 Speaker, "FDA Regulation of Over the Counter Drugs," China International Summit of OTC Industry Innovation and Development 2011 Boao Forum, Boao, China, December 4, 2011
- February 2012 Moderator, CDRH Top Headquarter Officials Discuss Product Clearances and Quality System Compliance for 2012, MD&M Show
- October 2012 Keynote Speaker, Today's Compliance and Regulatory Challenges OCRA-SDRAN Annual Joint Meeting, San Diego CA
- December 2012 Speaker, Generic Drugs; FDA Approval Process; Regulatory Science Invited Speaker, San Kyon Kwang University, Suwan, South Korea
- September 2013 Invited Speaker, Regulatory Trends and Education , Keio University, Tokyo Japan  
Invited speaker, The US Regulatory System: An Update, SKKU, Seoul, Korea  
Invited speaker, Global regulatory Environment and Market Access, Tianjin International Joint Academy of Biotechnology and Medicine/Tianjin FDA, Tianjin, China  
Invited speaker, US Role in Emerging Markets, China Pharmaceutical University, Nanjing, China
- December 2013 Invited lecturer, Regulations of Drugs and Devices (14 hours), Tianjin University, Tianjin, China  
Invited lecturer, International Regulations of Drugs: Non-CTD Countries, Peking University, Beijing, China
- June 2014 Invited speaker, OCRA, Regulatory Science and You, OCRA, Irvine, California
- September 2014 Course series, Quality and Audits, Tianjin-Binhai FDA headquarters, Binhai, China
- May 2015 Supervision Measures of Biopharmaceutical Innovation in China and US, China-US Biopharmaceutical Innovation Collaboration Forum , Los Angeles, CA

January	2016	Regulatory Science: Are we Coming of Age? San Diego Regulatory Affairs Network, Torrey Pines, CA.
July	2016	Regulatory Management of Neuroadaptive Technologies National Center for Adaptive Neurotechnologies, Albany NY
August	2016	Regulatory Science and Quantitative Drug Development Tools World Conference on Pharmacometrics, Brisbane, Australia
November	2016	Herbal products in the US: Food, Drug, or Dietary supplement? China Pharmaceutical University, Nanjing, China
April	2017	Overview of Medical Device Regulations Pathway to market Postmarket Regulations and Inspections IIT Madras  Five-day course on Quality Systems University of Addis Ababa, Ethiopia
June	2017	Medical Products to Market Biotech Leaders Academy, Los Angeles
July	2017	Regulatory Management of Neuroadaptive Technologies National Center for Adaptive Neurotechnologies, Albany NY
October	2017	2017 Updates: Real World Evidence and Pharmacometrics SKKU-USC Joint Seminar Program, SKKU, Suwon South Korea
October	2017	2017 FDA Updates: Quality Initiatives Keio-USC Symposium, “Regulatory Update in the US and Japan” Keio University, Tokyo, Japan
October	2017	Evidence for Product Commercialization: How do we introduce real-world data? SHFDA CMDEC-USC Symposium, Shanghai, China
October	2017	USC Regulatory System updates: 2017: Generic Drugs CPU-USC Symposium, China Pharmaceutical University, Nanjing, China
November	2017	US Regulatory System Updates:2017 Peking University-USC Symposium, Peking University, Beijing, China
November	2017	Compounding Drugs for Clinical Trials. IND Workgroup Webinar through UTSW

- April 2018 Evolution of Regulatory Science: US Academic Perspective. Utrecht University Symposium, Utrecht
- July 2018 Regulatory Writing Short-course, Zimmer, Warsaw, IN.
- August 2018 Regulatory Science at USC, APEC RHSC meeting, Brisbane Australia
- September 2018 Crossing the Valley of Death: Moving Products toward Commercialization and Clinical Practice. CLINAM Summit, Basel Switzerland
- The Great Divide: Meeting Need for Regulatory Competence in Academia versus Industry. CLINAM Summit, Basel Switzerland
- November 2018 Regulation versus Reimbursement: Can these be divorced? 2018 Asia Pacific Workshop on Social and Administrative Pharmacy. Taipei Taiwan
- Harmonization of Regulatory Science. Lecture to students and faculty at China Medical University Taichung, Taiwan
- US FDA: Changes and Issues. Lecture to students and faculty at China Medical University, Taichung, Taiwan
- Unique Device Identification. Lecture to 30 members of Shanghai FDA
- January 2019 APEC Initiatives in Regulatory Training. Webinar, AGRE

## **Patents: Issued and Pending As Inventor Or Co-inventor**

Method for conditioning pelvic musculature using an implanted microstimulator, Advanced Bionics Ref. No. AB-20, filed November 20, 1996, application number 96941429.1-2305; issued on May 9, 2000 as US Patent No 6,061,596

Implantable Electrode Arrays, Advanced Bionics Ref. No. AB-016C, filed 10/16/97 - Serial Number: 08/951,893 – approved September 18, 1999 as U.S. Patent No. 5,957,958. In continuation-in-part of patent number 5,833,714 issued 11/10/98. 08/784,209

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## Grants

### ***Until 1999 (Canada):***

In Canada, I was funded continuously by the Medical Research Council of Canada since I began my career as an Assistant Professor in the late 1970s. Most recently, in the period from 1994-1999, I was the Director of the MRC Research Group in Sensory-Motor Physiology, funded at a level of about 5 million dollars (direct costs, no investigator salaries) over a 5 year period.

### ***1999-2008 (USC):***

My position until July 2008 was split between directing the regulatory and clinical activities of the Alfred E Mann Institute and directing the Regulatory Science Program in the School of Pharmacy. This unusual position did not require that I apply for grant funds in the usual way, as a Principal Investigator of a single-investigator grant. Our experimental work was funded in a group configuration—either as a part of the core activities of the Mann Institute, or as part of larger group grants for the development of major medical device projects. Most of the writing that I did was contained in confidential business development and regulatory dossiers. Fifty percent of my salary was paid by the Alfred E Mann Institute and 45% of that 50% was covered by grants, below.

### ***2009-present (USC):***

I currently direct the Regulatory Science programs in the School of Pharmacy and am the formal Chair of the Department of Regulatory and Quality Sciences. This group of programs includes a doctoral program, three master's programs, an undergraduate major and minor, and 5 certificate programs, principally funded through tuition revenue rather than grants.

### ***Recent Activities related to Grant-funded Research***

Injectable sensors for control of FES Coinvestigator, Director of Regulatory Core (funded)	NIH \$917,595	6-1-01 to 5-31-083
Bion Rx of neuromuscular dysfunction Scientist, Interface Technology thrust (funded)	NIH \$9,322,983	5-1-02 to 30-07-08
Engineering Research Consortium Scientist, Animal Trials	NSF \$10,000,000	8-1-03 to 30-07-10
Clinical and Translational Science Initiative, NIH, \$67,113,902 Director, Regulatory Knowledge and Support Group		7-1-10 to 6-30-15
USC Tobacco Center of Regulatory Science for Vulnerable Populations Coinvestigator, Research Training and Education Core	NIHP50 \$3,977,518	7-1-13 to 6-30-18
Consortium for Technology Innovation in Pediatrics Member Advisory Board and Regulatory Expert	FDA \$6,600,000	2018-2023

**Activities Related to Teaching**

The MS (Regulatory Science) has grown over a decade and has graduated more than 500 students. The educational activities have recently been brought under the wing of the International Center for Regulatory Science. The current income for that program is estimated to be approximately \$ 4,000,000. At least forty courses are offered each year, some across all three terms.

USC Regulatory Science is a pilot site for a Medical Device Training Event for APEC in advance of consideration as an APEC Center of Training Excellence.

**Advisory Boards**

Editorial Board of Medical Product Outsourcing	2008-2010
Medical Management Systems Council	2009-2012
AACP Graduate Education SIG Curriculum Task Force	2013-2015
ASQ TAG 176 Subcommittee	2012-2014
USP Knowledge, Education and Training on Regulatory and Compendial Science Advisory Group	2013-2015
Drug Information Association Board of Directors	2012 to 2015
AGRE Board of Directors, President	2015 to 2017