



Pictured from left: (front) Nancy Smerkanich, Frances Richmond, Kathleen Rodgers, Stan Louie, Michael Jamieson; (rear) Eunjoo Pacifici, Daryl Davies.

The research arm of the International Center for Regulatory Science (ICRS) is committed to the translation of new medical products to market. The group spans from pharmaceutical experts and engineers to toxicologists and clinical trials experts. Some of its core members include:

Daryl Davies: Daryl L. Davies, PhD, is Director of the Alcohol and Brain Research Laboratories and Associate Professor of Clinical Pharmacy at the Titus Family Department of Clinical Pharmacy and Pharmaceutical Economics & Policy at USC School of Pharmacy. Dr. Davies earned his Bachelor and Master Degrees in Biology at California State University, Dominguez Hills, and his PhD training in the Department of Molecular Pharmacology and Toxicology at USC School of Pharmacy. His dissertation focused on identification of critical targets (sites) of ethanol (alcohol) action in the CNS and how alcohol alters brain function. Alcohol is the number one drug of abuse in the United States with over 17 million persons adversely affected by alcohol. Dr. Davies' laboratory focuses on identifying molecular sites (targets) of alcohol action in the CNS with the goal of identifying specific targets at which therapeutically relevant pharmacological agents can be directed to reduce social problems, loss of lives and economic costs of alcohol misuse. To accomplish this goal, Dr. Davies' group utilizes molecular, electrophysiological, biochemical, pharmacological, computational and behavioral techniques in their alcohol investigations. ddavies@usc.edu
http://www.usc.edu/schools/pharmacy/faculty_directory/detail.php?id=73

Mike Jamieson: Michael Jamieson, DRSc, is an adjunct professor who recently served as Associate Director of the Regulatory Science Program. Dr. Jamieson's research interests include the regulatory support of university based researchers and the commercialization of medical products developed at universities. His teaching focuses on global regulatory issues with an emphasis on Canada, Europe and South America. Dr. Jamieson has built an international reputation around his ability to develop

innovative regulatory solutions which enable companies to get their products and facilities through the regulatory hurdles in a timely fashion. In 1991 Dr. Jamieson founded Pharmacon Research Inc. with the original concept being to assist international companies in the development of integrated new product development programs for the North American market. In the fall of 2003, the company name was changed to InSource Innovations Inc. (Ottawa, Ontario, Canada). michael.jamieson@usc.edu

Gerald Loeb (not pictured): Gerald Loeb received his BA and MD degrees from Johns Hopkins University and trained in surgery before joining the U.S. National Institutes of Health as an intramural neuroscientist (1973-88). He was Professor of Physiology and Director of Biomedical Engineering at Queen's University (1988-99) and has been at the University of Southern California since 1999 as c with adjunct appointments in Neurology and Pharmacy. Dr. Loeb directs the Medical Device Development Facility at USC and is recently served as Deputy Director of the National Science Foundation Engineering Research Center for Biomimetic MicroElectronic Systems. Dr. Loeb has published over 200 journal articles and holds 47 U.S. patents, including key components of commercialized medical products including injectable RFID tags, cochlear implants, spinal cord stimulators, BION neuromuscular stimulators and several types of neurophysiological electrodes. He was Chief Scientist of Advanced Bionics Corp. (1994-1999) and is now President of Biomed Concepts Inc., a consulting and prototyping company, and CEO of SynTouch LLC, developers of tactile sensors for prosthetic and robotic limbs. He was selected as one of Medical Device & Diagnostic Industry Magazine's 100 Notable People in the Medical Device Industry. gloeb@bmsr.usc.edu

Stan Louie: Stan Gee Louie, PharmD is Associate Professor of Clinical Pharmacy and Pharmaceutical Economics & Policy at the USC School of Pharmacy. Dr. Louie received his degrees from the University of California in San Francisco. He then completed a pharmacy residency at California Medical Center in San Francisco. His training includes a fellowship with Dr. Axel Zander while he was in the Kuzell Institute and Sabbatical Training with Dr. Debbie Johnson. Currently, he is an Associate Professor Pharmacy, and has appointments in the Keck School of Medicine. He serves as the Director of Norris Cancer PharmacoAnalytical Core and California Collaborative Trials Group Core Laboratory. He is also member of the Research Advisory Council of AIDS Clinical Trials Group in Pharmacology (TRADD Committee). His interests are wide ranging but include the pharmacometric evaluation of drug actions in diabetes, HIV and other serious diseases. Slouie@hsc.usc.edu

Eunjoo Pacifici: Eunjoo Pacifici, Pharm.D., Ph.D., is currently an Assistant Professor of Clinical Pharmacy in the International Center for Regulatory Science at USC School of Pharmacy. Prior to joining USC, she gained extensive background in clinical research with special focus on Asia Pacific and Latin America region during her tenure at Amgen. She initially worked in the clinical development group managing U.S. investigational sites and central laboratories and then went on to work in the Asia Pacific/ Latin America group interfacing with local clinical and regulatory staff in Japan, People's Republic of China, Taiwan, and Mexico. She represented the regional clinical and regulatory views on project teams and led satellite task forces in order to align local efforts with U.S. activities. Prior to joining Amgen, she completed her B.S. degree in Biochemistry at the University of California, Los Angeles and Doctor of Pharmacy and Ph.D. in Toxicology and Molecular Pharmacology degrees at the University of Southern

California. Her additional professional experiences include community pharmacy practice in various settings and clinical pharmacy practice at the Hospital of the Good Samaritan in Los Angeles.

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Frances Richmond: Frances J R Richmond, PhD directs the International Center for Regulatory Science at USC. She is a professor of clinical pharmacy in the Titus Family Department of Clinical Pharmacy and Pharmaceutical Economics and Policy in the School of Pharmacy. Previously she was on faculty in the School of Medicine at Queen's University, where she was Professor and Director of the Medical Research Council in Sensory-Motor Neuroscience. Dr. Richmond's research interests have included both basic and applied physiological research published in more than 100 journal articles and texts. She has conducted animal and clinical trials of implantable devices and consults on regulatory aspects of medical product development through USC's Regulatory Consulting Center (regulatory.usc.edu/consulting). Her responsibilities at the Center include oversight of Regulatory Science and Drug Development certificate, masters and doctoral programs at the University of Southern California. Her current interests are focused on the regulatory and clinical management of new product development in biomedical areas. fjr@usc.edu

Kathleen Rodgers: Dr. Rodgers received her PhD in Cellular and Molecular Biology at the University of California, Riverside. Rodgers is a member of American Diabetes Association, American Association of Immunologists, Society of Toxicology, Wound Healing Society and Society for Radiation Research. She also is a member of the NIH resource committee to develop Centers for Biomedical Research Excellence and the NIH Dermatology and Neuromuscular Diseases Small Business Innovation Research (SBIR) Study Section. Dr. Rodgers has spent her academic career focusing on the translation of bench top observations to clinical therapies. Throughout the course of 20 years of research, she has made a number of discoveries that has led to patents licensed to the university and assisted in the development of the basic observations into therapies undergoing clinical development.

Nancy Smerkanich: Nancy Smerkanich is an Educational Liaison and Doctoral Candidate, in the International Center for Regulatory Science, School of Pharmacy at the University of Southern California (USC), while continuing to provide regulatory guidance to industry peers. Known for her dedication to education and mentoring across industry, Nancy has designed and conducted regulatory affairs and electronic submissions training across North America, Asia and Europe in both public and private settings. She is recognized for her ability to provide accurate, relevant and dynamic instruction on both the technical and strategic aspects of global regulatory affairs. Ms. Smerkanich continues to consult on regulatory topics and actively contributes to and supports professional organizations such as the Drug Information Association (DIA) and The Organization for Professionals in Regulatory Affairs (TOPRA). As the former Vice President of Global Regulatory Affairs at Octagon Research Solutions, and a senior Consultant in Regulatory Affairs at Accenture, Ms. Smerkanich was responsible for advising sponsors on regulatory filing strategy and submission development. With over 29 years of experience, Ms. Smerkanich has participated in all regulatory aspects of drug development, having served as Regulatory Liaison, US Agent, and Global Regulatory Lead across all therapeutic areas. Prior to joining Octagon, Ms. Smerkanich held various Regulatory Affairs positions within industry, including nine years at Merck and

seven years as an independent consultant. Ms. Smerkanich holds a Bachelor of Science Degree in Microbiology and a Bachelor of Arts in Russian from the University of Connecticut and is working towards completion of her DRSc in 2014. piresmer@usc.edu

Expansion of ICRS has permitted the formalized development in a research subgroup that includes translational researchers, preclinical development experts and regulatory science experts. The goal of this subgroup is to enhance both the stand-alone research and doctoral projects undertaken in the School of Pharmacy.