

# U TRANSLATIONAL MEDICINE SYMPOSIUM

BENCH TO BUSINESS TO BEDSIDE: CLEARING THE HURDLES TO THE CLINIC

Reimbursement  
Clinical Trial  
Product Design  
Financial Plan  
Business Strategy  
Regulatory Path  
Preclinical Plan  
Patent Protection  
Clinical Need



**ABOUT THE SYMPOSIUM**

The Entrepreneurial Faculty Scholars (EFS) program, led by Dr. Glenn D. Prestwich, has teamed up with the HHMI Med to Grad program (U2M2G), co-directed by Drs. Anthea Letsou and Dean Li, to acquaint faculty, student and postgraduate entrepreneurs to understand the complex and non-linear process of commercialization of medical devices and therapeutics. Seven panels of experts will introduce and discuss the basics of the “bench-to-business-to-beside” process.

**PRESENTED BY:**

- The Entrepreneurial Faculty Scholars (EFS)
- The HHMI Med to Grad Program (U2M2)
- The Center for Medical Innovation (CMI)
- The Center for Clinical and Translational Science (CCTS)
- The Center for Engineering Innovation (CEI)

## AGENDA

**TUESDAY, FEB. 11, 2014**

**ARRIVE 11:30 AM, START 12:00 PM: “SYMPOSIUM AND DISCUSSION”**

Each panel topic will be 40 minutes long, with a 20-minute opening presentation by the panelists and 20-minute Q&A with discussion and audience participation.

- 11:30-12:00 ..... Arrive and collect box lunches
- 12:00-12:20 ..... Introductions (Glenn Prestwich, Dean Li)
- 12:20-1:00 ..... Identifying the Clinical Need Panel
- 1:00-1:40 ..... Intellectual Property Panel
- 1:40-2:20 ..... Preclinical Development Panel
- [Break]
- 2:40-3:20 ..... Regulatory Pathway Panel
- 3:20-4:00 ..... Business Strategy & Financing Panel
- 4:00-4:40 ..... Clinical Development and Trials Panel
- 4:40-5:20 ..... Product Development & Reimbursement Panel
- 5:20-5:40 ..... Open discussion and closing remarks
- [Break]
- 7:00 ..... Panelist dinner (Taqueria 27; by invitation)

**WEDNESDAY, FEB. 12, 2014**

**ARRIVAL 8:15 AM, START 8:45 AM: “ELEVATOR PITCH WORKSHOP” (LASSONDE HOUSE PARLOR )**

The final morning features required presentations by the HHMI Med2Grad, MD/PhD, bioInnovate, bioDesign, and B2B student participants. All students should attend all presentations! Panelists and selected mentors will provide feedback.

- 8:30-8:45 ..... Breakfast
- 8:45-10:15 ..... “Elevator pitches” by first seven students, 3 min each, with up to 5 min panel feedback. First group: Med2Grad, MD-PhD
- 10:15-10:30 ..... Break (Snacks, Coffee, Juice at Breaks)
- 10:30-12:00 ..... “Elevator pitches” by additional seven students, 3 min each, with up to 5 min panel feedback. Second group: bioDesign, bioInnovate, B2B

## PANELISTS

### IDENTIFYING THE CLINICAL PROBLEM



**JOHN LANGELL, MD (moderator), Director, Center for Medical Innovation, UU** — John Langell is the Executive Director of the Center for Medical Innovation at the University of Utah. Dr. Langell completed his surgical residency at Stanford University Medical Center and an additional residency in Space and Aerospace Medicine at NASA's Johnson Space Center. Dr. Langell is also a minimally invasive general surgeon at the University of Utah Health Sciences Center and Chief of General Surgery at the George E. Wahlen VA Medical Center.



**ROBERT HITCHCOCK, PhD, Director, bioDesign program, UU Bioengineering** — Dr. Robert W. Hitchcock joined the Department of Bioengineering in 2006 to expand the Department's initiative in medical device design and innovation. He has over 25 years' experience in bringing new products to the marketplace. He is a co-founder of Catheter Connections, Inc.; a former VP of R&D for Sorenson Medical (2002 – 2006); former COO of iSense (2001) and scientific advisory board member for Photokinetics, Inc. (Ogden, UT), MR Board, Inc. (Salt Lake City, UT), Blackrock Microsystems (Salt Lake City, UT) and SMD, Inc. (Wallingford, CT).



**KATHY PETERSON, MD, Assistant Prof. of Gastroenterology, UU** — Dr. Peterson completed her medical degree at the University of Texas Southwestern, followed by an Internal Medicine Residency and GI fellowship at the University of Utah and a Master of Science in Epidemiology from Harvard University. She joined the University of Utah as faculty and is currently an Assistant Professor of Medicine in the Division of Gastroenterology, Hepatology & Nutrition. Dr. Peterson is well known as an outstanding clinical educator who has served as faculty at the University Hospital and SLC VA.

### INTELLECTUAL PROPERTY



**AMELIA SMITH RINEHART, JD (moderator), Associate Professor, College of Law, UU** — Amelia Smith Rinehart joined the S.J. Quinney College of Law faculty in 2010 after several years in practice as a registered patent attorney. Professor Rinehart is a faculty member of the College of Law's Center for Law and Biomedical Sciences and the University of Utah's Center for Medical Innovation. She teaches courses in Contract Law, Patent Law, and Intellectual Property, and her scholarship focuses on patent law and theory.



**LOREN HULSE, JD, Partner, Stoel Rives** — Loren has extensive experience in filing and prosecuting patent and trademark applications. As former in-house IP counsel for NPS Pharmaceuticals and Ceramatec, Inc., Loren has managed domestic and international patent and trademark portfolios. Loren's practice also includes IP diligence and counseling clients on freedom-to-operate and patentability matters. Prior to joining Stoel Rives, Loren was intellectual property counsel for NPS Pharmaceuticals, Inc. from 2006-2007; patent counsel for Ceramatec, Inc. from 2005-2006; and a patent attorney at Madson & Metcalf, P.C. from 2001-2005.



**DAVID MORRISON, MLIS, U Marriott Library** — Dave has been government information librarian and patent and trademark specialist for the J. Willard Marriott Library since January 1987, and Associate Professor since 1994. He is the campus PTRC representative to the USPTO, attends annual training conferences in Washington, and spent 18 months at the USPTO on a Fellowship. He regularly guest lectures on patent searching.

### PRECLINICAL DEVELOPMENT



**BARBARA WIROSTKO, MD (moderator), Moran Eye Institute, CSO Jade Therapeutics** — Barbara Wirostko is co-Founder and Chief Scientific Officer of Jade Therapeutics, developing an ophthalmic drug delivery polymer platform using a novel biodegradable Hyaluronic acid based polymer. Jade, with Dr. Wirostko as the PI, has recently been the recipient of Phase I SBIR grants from the National Science Foundation as well as the Department of Defense. Dr. Wirostko maintains an academic research and clinical practice with the Moran Eye Center, as a Clinical Adjunct Associate Professor in Ophthalmology.



**FLAGG FLANNAGAN, PhD, CEO & Chairman of the Board, Discgenics** — Mr. Flanagan has over 30 years of experience in the medical device field as an entrepreneur, executive and advisor. He founded Flanagan Instruments in 1981 and built it into a leading neurosurgical device distribution business specializing in microscopes, spine products and biologics. He sold the business to Itochu International in 2005. Mr. Flanagan is currently on the board of several medical device and startup companies, including TrueVision Systems and Image Stream Medical. In 2001, he attended the Owner/President Management Program at Harvard Business School.



**ROBERT SELLIAH, PhD, CEO, American Med Chem** — Robert Selliah, Founder, President and CEO of American MedChem Nonprofit Corporation; Adjunct Associate Professor of Medicinal Chemistry, Department of Medicinal Chemistry, The University of Utah. Dr. Selliah has more than 18 years of experience in technology, leadership, and management in drug discovery, medicinal chemistry, and preclinical development in the United States and the global pharmaceutical and biotech sector. He was most recently vice president of Medicinal Chemistry at SAI Advantium Pharma in India, where he led a group of over 200 scientists.

## PANELISTS

### REGULATORY PATHWAYS



**HAVEN MCCALL, DRSc (moderator), Director, Regulatory Affairs Certificate Program, Utah Valley University** — Haven is the Director of the Regulatory Affairs Certificate Program at Utah Valley University. He has over 14 years experience in the medical device industry, specializing in pre market and post market regulatory affairs and quality assurance. He also owns a consulting company that specializes in helping medical device companies in the areas of regulatory affairs and quality assurance. He currently teaches regulatory science courses at Utah Valley University, Arizona State University and guest lectures at the University of Southern California.



**PATRICK BURKE, PhD, VP Emerging Markets, Myriad Genetics** — Dr. Burke is currently Vice President of Emerging Products at Myriad Genetics. In this position, he leads the New Product Planning, Business Development and Project Management functions within Myriad Genetics Laboratories. The Emerging Products team delivers new products for commercial launch in each of Myriad's Commercial Business Units. Dr. Burke's previous positions included VP of Strategic Collaborations at Myriad, Vice President of Corporate and Business Development at Myrexis, Inc. , and Licensing Associate at the University of Utah.



**GREG CRITCHFIELD, Chairman & CEO, Sera Prognostics** — Dr. Gregory Critchfield received a Bachelor's Degree in Microbiology with a minor in Chemistry from Brigham Young University in 1976, an MD degree from the University of Utah in 1980, and a master's degree in Biophysical Sciences at the University of Minnesota in 1985. There he also completed fellowships in Clinical Chemistry and in Health Information Sciences sponsored by the National Library of Medicine and boarded in Clinical Pathology. He served as a reviewer and study section chair for the NIH for over 15 years in biomedical computing programs for SBIR, STTR and R01 programs.

### BUSINESS STRATEGY AND FINANCING



**TROY D'AMBROSIO (moderator), Executive Director, Lassonde Center, U** — Troy D'Ambrosio is the Executive Director of the Lassonde Entrepreneur Institute. Troy D'Ambrosio is co-founder, officer and director of multiple startup companies, which attracted over \$500 million in capital, including: Transworld Telecommunications, which was sold to Sprint in 1996; Convergence Communications, which was sold to Lockheed Martin in 2005; and EPM Mining Ventures, which is listed on the Toronto Venture Exchange. He has served as the VP of Investor Relations and Corporate Communication for American Stores Company.



**DANIEL LEMAITRE, CEO, White Pine Medical, Chairman, Bioventus LLC** — Dan Lemaitre is President and CEO of White Pine Medical, a medical device investment vehicle. White Pine Medical was part of an investor syndicate that acquired controlling interest in Smith & Nephews' clinical therapies business in a transaction valued at \$390 million. Prior to White Pine Medical, Mr. Lemaitre served as President and CEO of CoreValve that was acquired in 2009. Prior to joining CoreValve, Mr. Lemaitre was a Senior Vice President at Medtronic where he headed-up strategic planning and corporate development.



**ANDREW LAVER, Partner, Salt Lake Life Science Angels** — Andrew Laver is a Co-founder and the Managing Director of Salt Lake Life Science Angels ([www.SLLSA.com](http://www.SLLSA.com)), an angel group focused on seed-stage medical investments. Mr. Laver is also the Founder of APL Capital Advisors ([www.APLcapital.com](http://www.APLcapital.com)), a Salt Lake City-based boutique investment bank providing capital raising and merger & acquisition advisory services to early-stage and middle-market companies.

### CLINICAL DEVELOPMENT AND TRIALS



**MICHAEL SPIGARELLI, MD, PhD (moderator), Director, Clinical Trials Office, UU** — Dr. Spigarelli MD, PhD, board certified in Adolescent Medicine, Clinical Pharmacology, Internal Medicine and Pediatrics, was a faculty member at the University of Cincinnati and Cincinnati Children's Hospital Medical Center for almost ten years. During this time he was promoted to the Director of the Clinical Trials Office and the Medical Co-Director for the Office for Clinical and Translational Research. In 2011, he relocated to Salt Lake City to become the Director of the University of Utah Clinical Trials Office. Throughout his academic career, he has been continuously involved in development, implementation and analysis of research projects that help provide insight and understanding of therapeutic approaches, mechanisms of disease development and the role adverse or unanticipated events help to define underlying physiologic processes.

## PANELISTS



**ALONZO COOK, PhD, Associate Professor, Chemical Engineering, BYU** — Dr. Alonzo (Lon) Cook completed his PhD in Chemical Engineering at MIT and joined the BYU faculty in 2012 after 17 years working in the Medical Device Industry. His industry experience was in research and development of Tissue Engineering and Medical Devices, primarily in the fields of Cardiovascular, Ophthalmic and Orthopedic Products. His previous employers include Semprus BioSciences (Teleflex), Johnson & Johnson and W.L. Gore & Associates. He is also an author on numerous peer-reviewed publications and an inventor on 4 issued patents.



**MISHA BACKONJA, MD, Medical Director for Neuroscience, CRI Lifetime Research** — Following neurology residency at the University of Wisconsin Medical School Dr. Backonja completed multidisciplinary pain fellowship training also at UW Medical School, during which he started his research training. Then he held the position of a faculty at the University of Wisconsin School of Medicine and Public Health and a staff physician at the University of Wisconsin and Pain Treatment and Research Center, where he recently retired and now holds the title of Emeritus and Adjunct Professor.

## PRODUCT DEVELOPMENT AND REIMBURSEMENT



**NICHOLAS ANDERSON, MA, MBA (moderator), Health Economist and Market Access Consultant, N C Anderson Consulting LLC** — Nic Anderson is a consultant to medtech firms of every size and shape including the University of Utah and startups on what they should be doing in order to get paid or reimbursed. He is a guest lecturer on medtech commercialization where he illustrates that if companies pursue the wrong payment or reimbursement strategy, VCs lose money, startups struggle or die, growth-stage firms don't grow and large businesses lose market share. Nic also works for Intermountain Healthcare at its insurance company, Select Health.



**S. GEORGE SIMON, PhD, Chief Business Officer, MesaGen LLC** — Mr. Simon has over 20 years of worldwide business development, licensing and product development experience with numerous life science companies. Currently, he is Chief Business Officer of MesaGen, LLC a Salt Lake City-based company focusing on cancer immunotherapy. In addition, Mr. Simon is currently on the board of Olive Medical, Inc., Omixon, and MediMass.



**SCOTT MARLAND, PhD, Director, Bioinnovations Gateway** — Dr. Scott Marland has over fifteen years of experience in innovative research, product development and design. His research and development have been in medical devices, instrumentation and measurement, robotics, outdoor products, automotive and lighting. Dr. Marland has significant experience in product development, manufacturing, supplier management, leading cross-functional teams and project management. Dr. Marland has a Ph.D. in mechanical engineering, an M.S. in engineering science and mechanics and B.S. in mechanical engineering, all from the University of Tennessee.

## HOST



**GLENN PRESTWICH, PhD, Director, Entrepreneurial Faculty Scholars, Presidential Professor of Medicinal Chemistry, UU** — Glenn D. Prestwich created and directs the Entrepreneurial Faculty Scholars program which co-hosts this annual symposium. He is Presidential Professor of Medicinal Chemistry and Presidential Special Assistant for Faculty Entrepreneurism at the University of Utah. His research encompasses drug discovery in cell signaling, synthetic matrices for regenerative medicine, and glycosaminoglycan derivatives as anti-inflammatory agents. He co-founded 8 companies including Echelon Biosciences, Glycosan BioSystems, Sentrx Animal Care, GlycoMira Therapeutics, and Metallosensors. He received the Governor's Medal for Science and Technology for 2006, the 2008 Volwiler Research Award of the American Association of Colleges of Pharmacy, and the 2010 University of Utah Distinguished Scholarly and Creative Research Award. Glenn is also a pilot and sings first tenor in the Utah Symphony Chorus.