

SURFACES IN BIOMATERIALS FOUNDATION

BIOINTERFACE 2014

OCTOBER 6-8, 2014 REDWOOD CITY, CA

Hotel Sofitel San Francisco Bay | 223 Twin Dolphin Drive | Redwood City, CA 94065 | USA

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FROM THE PRESIDENT

Welcome Surface Science Professionals, Colleagues and Friends,

On behalf of the Surfaces in Biomaterials Foundation (The Foundation) I would like to welcome you to BioInterface 2014. The BioInterface Symposium has been presented annually by The Foundation since 1991. This year marks the 24th Anniversary of the Symposium and once again I think we have a very strong and exciting technical program. The Foundation was founded based on the premise that the interface between the body and a medical device is critical to the device's performance. As was the case in previous Symposia, this year's technical program provides a forum where a diverse group of scientists can openly discuss and debate recent innovations and research topics. The BioInterface Symposium has a strong applied focus and brings together engineers, scientists, clinicians, and regulatory experts from all aspects of the biomedical community. Throughout the years, this conference has been characterized by many in the scientific field as a preeminent technical symposium and I am confident that this year's technical program will more than live up to this description.

I encourage you to take this opportunity to engage and interact with your fellow conferees who represent the leading corporations and educational institutions that research and produce the innovative medical devices and products that help people to live longer, healthier and more productive lives.

Thank you for attending BioInterface 2014. We hope your experience at the 2014 BioInterface Symposium stimulates your thinking and provides you with information that will be beneficial in your ensuing scientific endeavors.

Sincerely,
Larry Salvati
President, Surfaces in Biomaterials Foundation

2014 PROGRAM COMMITTEE

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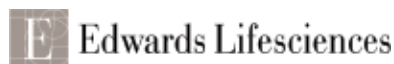
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Monday, October 6

BioInterface Workshop:

“From Entrepreneur to CEO: The Path from an Idea to a Product”

Co-Chairs: Kristen Cardinal, Cal Poly-San Luis Obispo; Mikki Lerner, Plasma Technology Systems, LLC

7:45–8:45am Pre-Registration and Continental Breakfast

8:45–9:00am Welcome and Introduction

9:00–9:45am **Duncan Maitland, Texas A&M University**
 “Embolic Applications of Shape Memory Polymer Foams: Commercialization in Progress”

9:45–10:30am **Kate Garrett, Ciel Medical**
 “The Biodesign Process & BronchoGuard Case Study”

10:30–10:45am Break

10:45–11:30am **Vic McCray, Ocular Dynamics**
 “The Enemy of Good Is Better: Rapid Iteration in Medical Device Development”

11:30am–12:15pm **Casey McGlynn, Wilson, Sonsini Goodrich & Rosati**
 “Insights on Early Stage Funding”

12:15–1:15pm Luncheon

1:15–2:00pm **Leslie Field, Stanford University**
 “IP and Marketing on the Path to Commercialization: Protecting and Communicating Your Product’s Unique Value”

2:00–2:45pm **Kirk Zeller, SI-BONE, Inc.**
 “International Market Entry Strategies for Medical Device Start-ups: Which Markets and Why?”

2:45–3:00pm Break

3:00–4:00pm Applied Technology Workshops
Chair: Josh Simon

3:00–3:30pm **Room:** Bordeaux
CSIRO
Speaker: Laurence Meagher

Room: Champagne
DSM Biomedical
Speaker: John Zupanchich

3:30–4:00pm **Room:** Bordeaux
Christensen Fonder P.A.
Speaker: Colin Fairman

Room: Champagne
Microscopy Innovations, LLC
Speaker: Steve Goodman

4:00–4:30pm Opening Reception

4:30–5:30pm **Keynote Lecture: Kevin Edward Healy, Ph.D.**



About:
 Kevin E. Healy, Ph.D. is the Jan Fandrianto Distinguished Professor in Engineering at the University of California at Berkeley in the Departments of Bioengineering and Materials Science and Engineering. He also serves as Chair of the

Department of Bioengineering. He received a B.Sc. in Chemical Engineering from the University of Rochester in 1983. He obtained graduate degrees in Bioengineering from the University of Pennsylvania (M.Sc. 1985, Ph.D. 1990).

His research interests include the design and synthesis of bioinspired materials that actively direct the fate of stem cells, and facilitate regeneration of damaged tissues and organs. Major discoveries from his laboratory have centered on the control of cell fate and tissue formation in contact with materials that are tunable in both their biological content and mechanical properties. These materials find applications in medicine, dentistry, and biotechnology. Prof. Healy has authored or co-authored more than 350 published articles, abstracts, or book chapters.

He recently co-edited a multi-volume scholarly reference work on the biomaterials field, containing an all-encompassing comprehensive treatise that accurately captures the diversity, breadth, and dimensions of the field.

Dr. Healy is an elected Fellow of the American Institute of Medical and Biological Engineering (AIMBE) and the American Association for the Advancement of Science (AAAS). He has chaired the Gordon Research Conference on Biomaterials and Biocompatibility, and has been honored with the 2011 Clemson award for outstanding contributions to basic biomaterials science. He is a named inventor on numerous issued United States and international patents relating to biomaterials, therapeutics, and medical devices, and has founded several companies to develop these systems for applications in biotechnology and regenerative medicine. He is currently an Associate Editor of the *Journal of Biomedical Materials Research*.

Tuesday, October 7

7:30–8:30am Registration and Continental Breakfast

8:30am President's Welcome

8:30–10:00am **Session 1: Characterization Methods**
Chair: Bill Theilacker, Medtronic

Sponsored by:



8:30–9:00am **Invited Speaker: Ian Gilmore, National Physical Laboratory**
 “Advances in Mass Spectrometry Imaging”

9:00–10:00am **Lara Gamble, University of Washington**
 “ToF-SIMS imaging Investigation of Tumor Micro Environments”

Norman Munroe, Florida International University
 “Surface Responses of Ti Alloys for Orthopedic Implant Materials After Anodization Technique”

Katarzyna Wygladacz, Bausch + Lomb

“Physical, Surface, and Durability Properties Studies of a Silicone Hydrogel Material Designed with Two-Phase Polymerization Processing”

10:00–10:30am Exhibitor Break

10:30am–12:00pm **Session 2: Recent Developments in Materials and Coatings**

Chair: Norman Munroe, Florida International University

10:30–11:00am **Invited Speaker: Nik de Bont, DSM Biomedical**

“Low-particulate ComfortCoat® Coating Allows Ease of Movement of Angioplasty Devices”

11:00am–12:00pm **Laurence Meagher, CSIRO Materials Science Engineering**

“Coatings for the Effective Control of Biointerfacial Interactions”

Laurence Meagher, CSIRO Materials Science Engineering

“Coatings for the Culture of Stem and Progenitor Cells on 2D and 3D Geometries”

Mehdi Golozar, University of Cambridge

“Extending the Application of Plasma Electrolytic Oxide Coatings to Novel Low-rigidity β -Ti Alloys: Applications to Load-bearing Orthopaedic Implants”

12:00–1:00pm Attendee Luncheon & Student Town Hall Meeting

1:00–1:30pm Surfaces in Biomaterials Foundation Annual Business Meeting

1:30–3:00pm **Session 3: Recent Developments in Ophthalmology**
Co-Chairs: Andrew Luk, CooperVision and James Parakka, DSM Biomedical

1:30–2:00pm **Invited Speaker: Lynn Winterton, Better Vision Group, LLC**
 “Material Innovation Leading to Comfortable Contact Lenses – Can a Contact Lens Really Be More Comfortable than No Lens at All?”

2:00–3:00pm **Tejal A. Desai, University of California, San Francisco**
 “Nanostructured Thin Films for Ocular Drug Delivery”

Aylvin Dias, DSM Biomedical
 “Amino Acid Based Biodegradable Polyesteramides for Drug Delivery”

Jeffrey Linhardt, Google
 “New Developments in Contact Lenses: Optimizing Surface, Design, and Moving Toward Smart Contact Lenses”

3:00–4:00pm Reception Featuring The Academic Poster Competition and Industrial Poster Presentations

4:00–5:00pm **Session 4: Point Counterpoint Debate**

5:00pm Free Time to Explore the Area

8:30–9:00am **Invited Speaker: Melissa M. Reynolds, Colorado State University**
 “Metal Organic Frameworks as Mix-ins for Improved Hemocompatibility”

9:00–10:00am **Chelsea M. Kirschner, Sharklet Technologies, Inc.**
 “Bio-inspired Microtopographies Reduce Thrombosis on Blood-Contacting Materials”

Joseph McGonigle, SurModics, Inc.
 “Surface Modification of Medical Devices With Fully Synthetic Coatings For Improved Hemocompatibility”

Bernke Papenburg, MATERIOMICS B.V.
 “Designing Surfaces to Gain Improved Medical Device Functionality”

10:00–10:45am Exhibitor Break & Poster Session

10:45am–12:15pm **Session 6: Cell Response At Nano BioInterface**
Chair: Dimitrios Zeugolis, National University of Ireland – Galway

10:45–11:15am **Invited Speaker: Prof. Michael Sailor, UCSD**
 “Harnessing Silicon Nanomaterials for Medicine”

11:15am–12:15pm **Manus Biggs, National University of Ireland, Galway**
 “Cellular Adhesion on Electron-beam Patterned Surfaces Presenting Nanoscale Heterogeneous Rigidity”

Peter Loskill, University of California, Berkeley
 “Unraveling the Impact of Subsurface and Surface Properties on the Adhesion of Bacterial Cells”

Wednesday, October 8

8:00–8:30am Registration and Continental Breakfast

8:30–10:00am **Session 5: Surface Modification for Improved Hemocompatibility**
Chair: Dave Sogard, American Medical Systems

	<p>Robert S. Kellar, Development Engineering Sciences, LLC “Nanofiber Tropoelastin Provides Unique Material Properties for the Biointerface”</p>		<p>Ryan Looper, Curza “Medical Device Technologies: Potential to Treat and Prevent Biofilm Implant-Related Infections”</p>
12:15-1:30pm	<p>Awards Luncheon: Student Poster Winner Announcement and Excellence in Surface Science Award Presentation</p> <p>2014 Recipient: Thomas J. Fogarty, Fogarty Engineering & the Institute for Innovation “From Beginning to Commercialism: What’s Involved”</p>	<p>3:00–3:15pm</p> <p>3:15–4:45pm</p>	<p>Break</p> <p>Session 8: Technologies and Recent Progress: Percutaneous Heart Valves Chair: Itai Pelled, Edwards LifeSciences Israel</p> <p> Edwards Lifesciences</p> <p>Invited Speaker: Stanton Rowe, Edwards LifeSciences “Development History of the First Percutaneous Aortic Valve”</p>
1:30–3:00pm	<p>Session 7: Anti-Infective Medical Device Technologies Chair: Janelle Gunther, Janssen Global Serices, LLC</p>	<p>Sponsored by:</p> <p>3:15–3:45pm</p>	
1:30–2:00pm	<p>Invited Speaker: Vu L. Truong, Aridis Pharmaceuticals “Gallium-Siderophore Complexes as Anti-Infectives: Synthesis, Gallium Complexation, and Bacterial Inhibition by Siderophore-Based Gallium Compounds”</p>	<p>3:45–4:45pm</p>	<p>William Fearon, Stanford University “TAVR – the Clinician Point of View”</p> <p>Crystal Cunanan, Boston Scientific “Development of a Second Generation TAVI Valve — LOTUS”</p>
2:00–3:00pm	<p>Robert Ward, ExThera Medical Corporation “Removal of Drug-Resistant Bacteria from Whole Blood with a Sorbent Hemoperfusion Device: Carbapenem-Resistant Enterobacteriaceae (‘CRE Superbugs’)”</p> <p>Ethan E. Mann, Sharklet Technologies, Inc. “Microtopographies Limit Bacterial Biofilm Accumulation: A Novel Approach to Decreasing Ventilator-Associated Pneumonia Cases”</p>	<p>4:45pm</p>	<p>Aruna Perera, Direct Flow Medical, Inc. “Direct Flow Medical Trans Catheter Aortic Valve Replacement”</p> <p>BioInterface 2014 Program Concludes</p>

Be it resolved: “Medical device innovation so desperately required to effectively address increasing clinical challenges and costs of biomaterials-associated infections is hindered by lack of clear, consistent regulatory policies and protocols required to accurately assess risk-benefit and economic analyses needed for commercializing new antimicrobial technologies.”



Clark L. Thompson is employed by Boston Scientific Corporation as a Senior Regulatory Affairs Fellow. He has interfaced with the FDA in a variety of venues from face-to-face during the pre-submission meetings and workshops to written correspondence to FDA questions in the review process. He has over 15 years of experience with FDA submissions, providing guidance for Investigation Device Exemptions (IDEs), Pre-Market Approvals (PMAs) and 510(k) medical devices (including combination products). Clark’s experience also includes submission strategy and review of post approval

supplements encompassing: expiration date-shelf life extensions; design, material, manufacturing and sterilization changes. He is active in AdvaMed’s combination products working group and ASTM’s F04 30 06 meetings. He has interest in computational modeling and simulations to: assist in the development and where appropriate design changes of medical devices, to decrease the dependence on animal and human models, to decrease review time, to increase the speed to market. In addition to experience in regulatory affairs, Clark has worked multiple years in research, product development and quality. He earned a BS in Pharmacy from the University of Wyoming and a MS in Medicinal Chemistry and Natural Products from the University of Iowa.



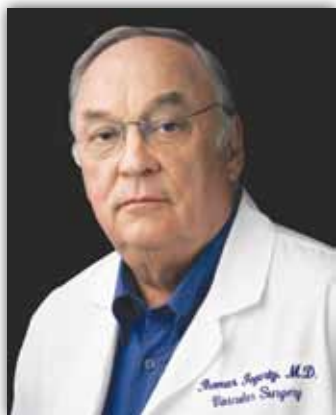
David W. Grainger is the George S. and Dolores Doré Eccles Presidential Endowed Chair in Pharmaceutics and Pharmaceutical Chemistry, Chair of the Department of Pharmaceutics and Pharmaceutical Chemistry, and Distinguished Professor of Pharmaceutics and Bioengineering at the University of Utah. Grainger’s research expertise is focused on improving implanted medical device performance, drug delivery of new therapeutic proteins, nucleic acids and live vaccines, nanomaterials interactions with human tissues, anti-microbial biomaterials, and innovating in vitro diagnostic devices. Additionally, he is an expert in applications of surface analytical methods to biomedical interfaces, including analytical methods development for difficult organic surface patterns and nanomaterials, and also internationally recognized as an expert in perfluorinated thin films and biomaterials. Grainger has won several awards, including the Excellence in Surface Science Award, Surfaces in Biomaterials Foundation

(2013), the Clemson Award for Basic Research from the Society for Biomaterials (2007), and the American Pharmaceutical Research and Manufacturers Associations award for “Excellence in Pharmaceutics” (2005). He has also received several teaching awards for outstanding mentoring and teaching service at all student levels. Grainger is an elected Fellow of both the American Association for the Advancement of Science (AAAS) and the American Institute of Medical and Biological Engineering (AIMBE), and Inducted Honorary Fellow, International Union of the Societies of Biomaterials Science and Engineering. Grainger serves on editorial boards for 6 major research journals in the biomedical materials field, reviewing over 50 manuscripts annually. He is a scientific advisor to several international research centers in regenerative medicine and biotechnology. Grainger has helped found 3 biomedical technology companies, sits on the Scientific Advisory boards for 4 biomedical companies, and actively consults internationally with industries and academic research centers in applications of materials in biotechnologies and medicine.

2014 Excellence In Surface Science Award

Presentation — “From Beginning to Commercialization: What’s Involved”

2014 Recipient: Thomas J. Fogarty, Fogarty Engineering & the Institute for Innovation



Dr. Thomas J. Fogarty is an internationally recognized cardiovascular surgeon, inventor, entrepreneur, and vintner. He has been involved with a wide spectrum of innovations in business and technology. Dr. Fogarty has served as founder/co-founder, and Chairman/Board

Member of over 33 various business and research companies, based on medical devices designed and developed by Fogarty Engineering, Inc. During the past 40 years, he has acquired 135 surgical patents, including the “industry standard” Fogarty balloon catheter and the widely used Aneurx Stent Graft that replaces open surgery aortic aneurysm. Dr. Fogarty has received countless awards and honors; most significantly, he is the recipient of the Jacobson Innovation Award of the American College of Surgeons and the 2000 Lemelson-MIT prize for

Invention and Innovation, and was inducted into the Inventors Hall of Fame and the National Academy of Engineering.

Recently, Dr. Fogarty and his colleagues founded the Fogarty Institute for Innovation at El Camino Hospital. The purpose of the Institute is to create an environment where innovation in medicine is encouraged, supported, and nurtured.

Dr. Fogarty received his undergraduate education at Xavier University in Ohio and his medical degree from the University of Cincinnati. He completed his residency at the University of Oregon and later served as Medical Staff President at Stanford Medical Center, 1973-1975. After 13 years directing the Cardiovascular Surgery Program at Sequoia Hospital, Redwood City, California, he returned to academic life at Stanford University School of Medicine in July 1993 as Professor of Surgery. Dr. Fogarty now spends his time creating new medical devices with Fogarty Engineering and the Institute for Innovation.

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STUDENT POSTERS

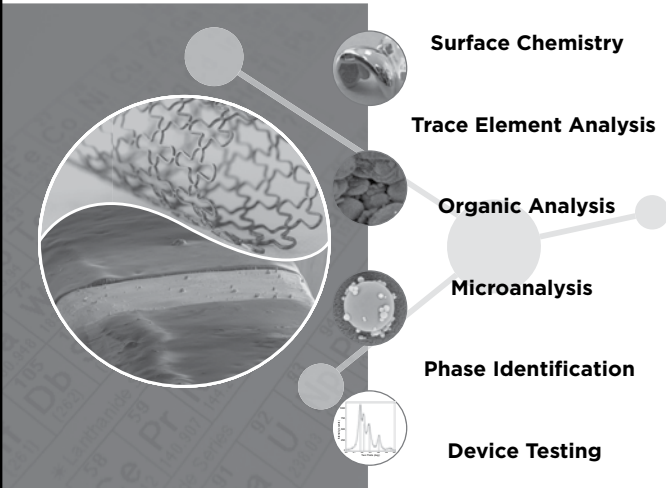
- **“Three-dimensional Semicrystalline Morphology in a PLLA Vascular Scaffold by X-ray Microdiffraction”**
Artemis Ailianou, California Institute of Technology
- **“Sprouting Angiogenesis in Biomimetic Hydrogel Array”**
David G. Belair, University of Wisconsin-Madison
- **“Processing, Microstructure Characterization, and Biological Response of Hierarchical Surface Coatings for Titanium Implants”**
Courtney Gegg, University of California, Davis
- **“Tissue Engineering Skeletal Muscle as a Potential Treatment for Volumetric Muscle Loss”**
Jennifer Go, California Polytechnic State University - San Luis Obispo in collaboration with Stanford University
- **“Surface Patterning of Shape Memory Polymer Surfaces”**
Tina Govindarajan, University of Colorado at Denver
- **“Applications of Accelerometers in Clinical and Home Monitoring: A Survey”**
Janene Grippi, Sonoma State University
- **“Human Umbilical vs Coronary Cell Sources for Tissue Engineered Blood Vessel Mimics”**
Scott Herting & Alex DiBartolomeo, California Polytechnic State University - San Luis Obispo
- **“Shape Memory Polymer Foam-Hydrogel Composite Wound Dressing for Rapid Hemostasis and Infection Control”**
Todd L. Landsman, Texas A&M University
- **“Impact of the Chemistry of Geometrically Designed Titanium on Cell Behavior and Alignment”**
Caroline Mörke, University Medical Center Rostock
- **“Electrospinning as a Method to Create Tunable Scaffolds for Tissue Engineering Applications”**
Jordan Muller, Northern Arizona University
- **“A Synergistic Approach to Attenuate the Neuroinflammatory Response at the Microelectrode-Tissue Interface”**
Jessica Nguyen, Case Western Reserve University

INDUSTRY POSTERS

- **“Biodegradable Polyoxazoline Based Nanoparticles as a Drug Carrier”**
Mengmeng Zong, DSM Ahead
- **“Substrate Effect on Surface Properties of Silicone Hydrogels”**
Meredith Wiseman, DSM Ahead
- **“Nanoscale Craters Induce Cell Migration by Limiting Focal Adhesion Area”**
Willie Mae Reese, University of California at Berkeley

* As of September 20, 2014

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BioInterface Workshop Speakers



J. Casey McGlynn
Partner, Wilson Sonsini
Goodrich & Rosati

J. Casey McGlynn formed the Life Sciences Group at Wilson Sonsini Goodrich & Rosati in 1990. It is a nationally recognized practice representing startups and emerging growth companies in the life sciences field — Medical Devices, Digital Health, Diagnostics and Biotechnology.



Duncan J. Maitland, Ph.D.
Professor, Department of
Biomedical Engineering, Texas
A&M University

Assistant Agency Director for
Commercialization, Texas En-
gineering Experiment Station

Dr. Maitland has worked as an engineer in aerospace, national defense and biomedical applications since 1985.



Kate Garrett
CEO, Ciel Medical

Kate Garrett is the co-founder and CEO of Ciel Medical, a medical device start-up solving major clinical needs affecting mechanically ventilated patients. Prior to Ciel Medical,

Kate worked in strategic marketing at Acclar-ent and as a catheter development engineer at Pathway Medical Technologies.



Kirk Zeller
Senior Director of International
Sales and Market Develop-
ment, SI-BONE

Mr. Zeller is the Senior Direc-
tor of International Sales and
Market Development at SI-
BONE, a position to which he

brings more than two decades of experience in global medical device sales and marketing, channel management, market development, and business development.



Leslie Field
Founder and Managing
Member, SmallTech
Consulting

Dr. Leslie Field is the Founder and Managing Member of SmallTech Consulting, with

more than a dozen consultants working together on a wide range of projects in MEMS, Nanotechnology, and allied fields for large companies, start-ups, entrepreneurs, industry groups and VCs.



Vic McCray, MD
President & CEO, Ocular Dy-
namics

Vic McCray, MD is a general surgeon and President & CEO of Ocular Dynamics, a contact lens R&D company. Vic received formal training in medical device innovation at Stan-

ford University Biodesign, serves as a guest lecturer and consultant in entrepreneurship, and has advised a number of startup companies in all areas of device development.



Save the Date

September 21-23, 2015

Come celebrate the 25th Annual BioInterface 2015 Workshop & Symposium on September 21-23, 2015 at the Fairmont Scottsdale Princess in Scottsdale, Arizona.

