



## KEYNOTE ADDRESS

### SYNTHETIC BIOLOGY AND SYSTEMS BIOLOGY: ENGINEERING GENE NETWORKS FOR BIOMEDICAL APPLICATIONS

**J. J. Collins, PhD**, Center for BioDynamics and the Department of Biomedical Engineering, Boston University



This address will highlight recent advances in designing and constructing synthetic gene networks (synthetic biology) and reverse engineering and analyzing endogenous gene networks (systems biology). We present

a number of case studies, and discuss potential applications of these developments in biomedicine and biomaterials research.

## SYMPOSIA

*A Symposium is designed to focus our attention on a specific topic within the large disciplines that make up the Society's membership. The symposium highlights a well-defined topic that is not addressed by the regular sessions of the Annual Meeting. The format includes a single lead speaker followed by related abstracts. The lead speaker either presents the current concepts of the topic or presents cutting-edge research within the area.*

### BIONANOTECHNOLOGY: THE FUTURE OF BIOMATERIALS

#### "Towards Multifunctional Nanoparticle-based Therapeutics"

Invited Speaker:  
**Sangeeta Bhatia**, Massachusetts Institute of Technology, Cambridge, MA

Co-chairs:  
**J. Zach Hilt**, University of Kentucky  
**Jennifer West**, Rice University

The objective of the symposium will be to examine the impact of nanoscale science and engineering on the biomaterial field. In recent years, nanoscale science and engineering has provided new avenues for engineering materials with macromolecular and even down to molecular scale precision. The resultant biomaterials have been demonstrated to have enhanced properties and applicability, and these materials are expected to be enabling technologies in the successful development and application of nanomedicine. For example, nanoengineered tissue scaffolds and nanostructured coatings for implants and prostheses are leading to better solutions in tissue design, reconstruction, and reparative medicine. Nano- and microarrays are accelerating drug

discovery and assessment of drug candidates. Self-assembly and other nanofabrication methods are facilitating the creation of new biomaterials with well-ordered structures at the nanoscale such as nanofiber peptide and protein scaffolds. Also, nanoparticle systems are enabling a wide range of materials for imaging and/or therapeutic purposes to be easily introduced or injected in the body. This symposium will highlight the unlimited potential of nanoscale science and engineering in biomaterials science and engineering, and it will give a glimpse into the future of biomaterials.

### MODELING BIORESPONSE TO BIOMATERIALS

Assisted by the Biomaterial/Cell Organ Therapy SIG

#### "Rational Computer-aided Design of Biomaterials"

Invited Speaker:  
**William Welsh**, UMDNJ, Piscataway, NJ

Chair:  
**Doyle Knight**, Rutgers University

The advent of High Throughput Combinatorial Synthesis (HTCS) has led to the creation of burgeoning libraries of potential biomaterials. Conventional methods such as Design of Experiments (DOE) are inadequate to fully assess the in vitro performance of these large libraries, leaving little hope for a comprehensive evaluation of their in vivo behavior. Computational modeling of bioresponse to biomaterials offers the potential for dramatically reducing the cost and time required to effectively characterize a typical library of biomaterials (e.g., polycarbonates) by combining experiment and simulation in a synergistic fashion similar to the approach now commonplace in the pharmaceutical industry. A wide range of modeling techniques can be utilized to build models ranging from atomistic simulation (e.g., Molecular Dynamics (MD) simulation) to Quantitative Structure Property Relations (QSPR). The symposium solicits contributed papers on all aspects of computational modeling of bioresponse to biomaterials.

### ORGANIC/INORGANIC HYBRID BIOMATERIALS

Assisted by the Dental /Craniofacial SIG and the Tissue Engineering SIG

This symposium will address key issues related to the design, synthesis, characterization and utilization of organic/inorganic hybrid materials to control biological functions. Biomaterial function depends on processing, composition and structure, at multiple levels of hierarchy, as well as on the hierarchical relations inherent to biology.

One approach to enhance biomaterial function is to control composition and structure via the use of hybrid materials consisting of organic and inorganic phases interacting across dimensional scales, ranging from the molecular level to the whole material level. Such composite materials mimic biological materials designed by Nature and can fulfill different design criteria and function depending upon the size/scale of the organic/inorganic interactions. Nature, has used these same principles to achieve higher complexity and allow adaptation, with a minimal expenditure of energy. This symposium will serve as a forum to present the latest developments in organic/inorganic hybrid materials for biomedical use.

### NEW CONCEPTS AND CHALLENGES FOR THE DELIVERY OF THERAPEUTIC NUCLEIC ACIDS

Assisted by the Drug Delivery SIG

#### "Response of Human Embryonic and Adult Mesenchymal Stem Cells to Nanotopography"

Invited Speaker:  
**Kam Leong**, Duke University, Durham, NC

Co-chairs:  
**Krishnendu Roy**, PhD, University of Texas at Austin  
**Hai-Quan Mao**, PhD, Johns Hopkins University

This symposium will cover current challenges and new advances in the delivery of therapeutic nucleic acids including plasmid DNA, genetic vaccines, RNA, siRNA and oligonucleotides. The talks will focus on biological barriers for nucleic acid delivery and new biomaterials that are designed to overcome these barriers. In addition, pre-clinical and clinical results on nucleic acid delivery as well strategies for combinatorial delivery will be addressed.

### CELLULAR SIGNAL TRANSDUCTION

#### "Signaling Downstream of S1P, VEGF, Shear Stress and Platelet Poor Plasma"

Invited Speaker:  
**Donald L. Elbert**, Washington University, St. Louis, MO

Co-chairs:  
**Carmelita G. Frondoza**, Johns Hopkins University  
**Michael Caplan**, Arizona State University

Response to implants by tissue cells is critically dependent on their ability to recognize the chemical and physical structure of the implant material. Moreover, the type and magnitude of response is modulated by their



biomechanical environment. Cellular recognition of material attributes in context of biomechanical forces involves the transduction of signals that results in the alteration of cell survival, proliferation, differentiation, metabolism and function. This symposium addresses the different genes, molecules and pathways that play a role in signal transduction from material to tissue cells through quantitative modeling. It focuses on the state-of-the-art experiments and quantitative models to evaluate signal transduction mechanisms and predict cell response to biomaterials.

## STEM CELLS: SOURCE, CULTURE AND APPLICATION

Assisted by the Biomaterial/Cell Organ Therapy SIG

### “Developing Human Embryonic Stem Cell for Use in Cell and Tissue Therapies”

Invited Speaker:

**Steve Stice**, University of Georgia, Athens, GA

Co-chairs:

**Krishnendu Roy**, University of Texas at Austin,  
**Karen Burg**, Clemson University  
**Laura Suggs**, University of Texas at Austin

This symposium will overview state-of-the-art research on the isolation, propagation and differentiation of stem cells and their culture on various biomaterials. Basic stem biology will be addressed, including methods for characterizing cells based on various cell surface and genetic markers as well as current challenges and new advances in culturing both adult and embryonic stem cells. Particular focus will be on maintenance and differentiation of stem cells on various biomaterials, 3D culture, and bioreactor-based cultures.

## A TUTORIAL SYMPOSIUM BY THE LEADERS OF BIOMATERIALS

Assisted by the SFB Presidents Advisory Committee

Co-chairs:

**Nicholas A. Peppas**, The University of Texas at Austin, Austin, TX  
**Anne E. Meyer**, University at Buffalo, Buffalo, NY

The objective of the Tutorial Symposium is to examine the impact of biomaterials in biology and medicine. All featured invited speakers of this two-day symposium will be Past Presidents of SFB. In recent years, there has been considerable work in preparing materials and finding new uses for hybrid structures based on biomaterials. Uses such as modified surfaces, stents, carriers for controlled and targeted drug delivery, and microdevices have shown the versatility of these biomaterials. Why do we observe such an explosion of interest in the field? Medical devices now have reached a stage of dimensions comparable to those of biological macromolecules. This raises

exciting possibilities for combining microelectronics and biotechnology to develop new technologies with unprecedented power and versatility. While molecular electronics use the unique self-assembly, switching, and dynamic capabilities of molecules to miniaturize electronic devices, nanoscale biosystems use the power of microelectronics to design ultrafast/ultrascale biocompatible devices—including implants—that can revolutionize the field of bioengineering. For example, polymer surfaces in contact with biological fluids, cells, or cellular components can be tailored to provide specific properties or to resist binding depending on the intended application and environment. The design of surfaces for cellular protection or adhesion and surface passivity encompasses a number of techniques such as surface grafting (ultraviolet radiation, ionizing radiation, electron beam irradiation). Certain techniques can change the chemical nature of surfaces and produce areas of differing chemistry as well as surfaces and polymer matrices with binding regimes for a given analyte. In addition, biomimetic methods are now used to build biohybrid systems or even biomimetic materials (mimicking biological recognition) for drug delivery, drug targeting, and tissue engineering devices. This symposium will concentrate on molecular assemblies and complex polymer structures that exhibit structure, control, recognition and signal transmission of biological properties.

## ADVANCES IN BIOMATERIALS SCIENCE: WHAT'S IN THE FUTURE OF BIOMATERIALS...ADDRESSING BIOLOGICAL PROBLEMS AGAIN!

### “The Marriage of Biomaterials and Biological Science: A Required Alliance”

Invited Speakers:

**Jim Burns**, Genzyme Corp., Waltham, MA

### “Tissue Engineering in Orthopaedic Surgery: Understanding the Clinical Parameters”

**Stuart Goodman**, Stanford University, Stanford, CA  
**Allan Hoffman**, University of Washington, Seattle, WA

## ADVANCES IN BIOMATERIALS SCIENCE: WHAT WE HAVE LEARNED FROM OUR MISTAKES

### “Protein and Cellular Interactions with Biomaterials: Perspectives for Nanotechnology and Tissue Engineering;”

Invited Speakers:

**Jim Anderson**, Case Western Reserve University, Cleveland, OH  
**Jack Lemons**, University of Alabama at Birmingham, Birmingham, AL

### “Nanostructured Surface Modification and Coatings for Orthopaedic and Dental Implants”

**Bob Baier**, University at Buffalo, Buffalo, NY

### “The ‘Theta Surface’ for Biocompatibility: Minimizing Protein Denaturation”

**Buddy Ratner**, University of Washington, Seattle, WA

### “Engineered Biomaterials via Molecular (Nanoscale) Surface Modifications”

The Program Committee extends its deepest appreciation for the dedication of our past Presidents in organizing and donating their time and energy to this very special session.

## GENERAL SESSIONS

*A General Session is on a topic that is familiar to the general membership. Abstracts reflect the most current research in that field.*

## BIODEGRADABLE HYDROGELS FOR TISSUE ENGINEERING

Assisted by the Tissue Engineering SIG

Injectable, biodegradable scaffolds have immense clinical significance in soft tissue reconstruction (including cartilage regeneration) and bone repair. The development of a scaffold (such as a hydrogel) that gels in situ and is biodegradable is a challenge that several researchers have undertaken. The research efforts for biodegradable, injectable scaffolds (both native and synthetic) are increasing each year. As such, the number of researchers, including graduate students and post-doctoral fellows, involved in this field also increases. Additionally, the inclusion of cells within scaffolds is facilitated by development of techniques that allow gelation to proceed in a mild manner, resulting in cell-laden materials formed in situ in a desired target shape. With the advent of stem cell therapies, the need for appropriate cell delivery venues also intensifies.

## FIBRIN SEALANT AND ITS APPLICATION IN TISSUE ENGINEERING

Assisted by the Tissue Engineering SIG

The need to effectively manage hemostasis in vascular procedures; control air leaks in pulmonary procedures; seal cerebrospinal fluid leaks in spinal or neurological procedures; or prevent leaks in gastrointestinal procedures has led to the development of several sealants and adhesives to address the clinical need. The aim of this symposium is to:

1. Present the clinical experience with some of these devices highlighting the materials challenges faced in developing effective sealants and adhesives for these applications.



2. Elucidate future opportunities to develop materials and devices that could effectuate wound care (wound closure, wound healing, tissue regeneration etc.) using sealant and adhesive delivery platforms.
3. The use of these biomaterials to deliver cells or bioactive substances such as peptides or growth factors to treat various diseases such as chronic wounds, bone defects, Alzheimer, Parkinson diseases, etc.

The symposium will be a forum for scientists from academia and industry to present their research, exchange ideas and potentially identify new opportunities to develop new materials and devices to address the clinical need and improve surgical outcome.

## ORTHOPAEDIC BEARING SURFACES

Assisted by the Orthopaedic SIG

Total joint replacement is one of the most common surgical procedures performed worldwide. However, wear of joint replacements has been identified as one of the major factors currently limiting the life of the implants. The design and development of implants with improved performance and durability requires the development of assays that will enable the accurate determination of wear performance of materials, the development of appropriate in vitro models, and development of a deeper insight into the factors that contribute to implant wear. The symposium will bring together leading researchers from academia and industry to discuss recent research on developing novel testing methods and/or conditions to accurately determine implant wear in vitro under simulated body conditions and the factors that contribute to implant wear.

## SYNTHETIC ORTHOPAEDIC MATERIALS

Assisted by the Orthopaedic SIG

Metallic and polymeric biomaterials play a central role in current orthopaedic treatments. Even though these biomaterials combine unique bulk and surface properties that are critically important for their satisfactory performance, further refinements in material properties and the fabrication processes are needed to develop ideal implants. The aim of the symposium is to highlight the current state-of-the-art advancements in metallic and polymeric orthopaedic biomaterials. These include fundamental studies on the properties of the tissue to be replaced, new polymeric and metallic biomaterials, surface modification of existing biomaterials and current understanding of the performance of biomaterials including mechanical behavior.

## BIOMIMESIS IN DRUG DELIVERY

Assisted by the Drug Delivery SIG

Biomimetic materials and systems are exceptional candidates for various controlled drug delivery applications and have enormous potential in medicine for the treatment of disease. This session will highlight recent activities in the field of biomimetic systems and their application in controlled drug delivery. Biomimesis is the process of coordinating molecular recognition and interactions to design biological, biohybrid, and artificial materials that can be structurally similar to and/or function in similar ways as biological structures. In particular, the focus of this session is on current clinical significance for systems that mimic processes where the underlying molecular principles are well understood. We invite topics with emphasis in drug delivery that involve materials consisting of (i) natural biological molecules such as proteins, oligonucleotides and polynucleotides, and/or unnatural biomolecules that have been assembled/synthesized by biological systems; (ii) hybrid structures of synthetic (e.g., polymeric chains, metal particles, etc.) and natural biological molecules (i.e., conjugated biomaterials); or (iii) materials consisting of man-made and in-vitro building blocks, such as synthetic polymers, unnatural amino acids, aptamers, helical coiled coils, materials from configurational biomimesis or molecular imprinting methods, polymerosomes, micelles, etc.

## DENTAL AND ORTHOPAEDIC IMPLANT COATINGS AND MATERIALS: CHARACTERIZATION, IN VITRO, IN VIVO AND CLINICAL ASSESSMENTS

Assisted by the Dental Craniofacial SIG and the Implant Pathology SIG

Dental and orthopaedic materials have become widely successful for use in implants to replace/restore teeth and joint function. Their success has resulted from 30+-year improvement in material design and selection, surface modifications for enhancement of tissue integration, patient selection and clinical protocols. As our understanding of dental and orthopaedic implant science has become more sophisticated, implants have become easier to use, time to completion of treatment has been shortened, biomechanical stability has been improved and aesthetic results have become more predictable. This symposium presents information on the physicochemical properties of novel surface coatings for dental and orthopaedic implants, in vitro and in vivo evaluations of implant-host tissue/cell interactions, and clinical and pathological assessments of implant devices. This program will begin highlight importance of material selection and design and surface modifications on biological and clinical outcomes, and new directions for future designs and strategies for improved patient care.

## INNOVATIVE TECHNIQUES IN BIOMATERIALS EDUCATION

Assisted by the Biomaterials Education SIG

Quality teaching is the backbone of biomaterials education and research. The objective of this symposium is to affect the quality of biomaterials education through providing a forum for educators to share innovative teaching techniques. In the past, these sessions have sparked thoughtful and practical discussions. We believe that those in attendance will have the opportunity to reflect on their own teaching styles. Attendance at this session shows a commitment to effective biomaterials education and helps to foster a proactive culture within the SFB. Topics may include: techniques for teaching to large classes, providing effective mentorship, different learning styles, distance learning, internet courses, and undergraduate research experiences.

## MECHANOBIOLOGY OF SKIN AND BONE

Assisted by the Tissue Engineering SIG

The reciprocal interactions during wound healing between cells, components of extracellular matrices (ECM), cytokines, and other soluble mediators are incompletely understood. Although the overall phenomenology of repair, and correlative patterns of interactions between ECM and cell growth/differentiation, are emerging, the detailed mechanisms that govern cell-ECM interactions await elucidation. Specifically, how do the structural features and mechanical properties of the ECM govern cell behavior during repair? Despite clinical success of engineered tissues to treat patients with cutaneous injury, fundamental questions remain unanswered about the manner in which matrix and structure determine, influence and predict the performance of these materials. In this symposium, studies on the mechanobiology for hard and soft tissues will be presented.

## OPHTHALMIC DRUG DELIVERY

Assisted by the Ophthalmological Biomaterials SIG

The need to provide therapy for multifactorial diseases such as glaucoma, retinal diseases, and cataracts, and for surgical complications such as ocular inflammation and infection, represent growing opportunities for ophthalmic drug delivery. Strategies for specific localized and effective delivery of therapeutic and regenerative agents to the various segments of the eye must address barriers to drug delivery such as tissue, blood-aqueous, and blood-retina barriers and ultimately improve the ocular penetration of drugs. The scope of this symposium is to present clinical needs along with industrially relevant strategies for improving ophthalmic drug delivery. Emphasis will be placed on drug delivery to the posterior segment of the eye.



## CELL RESPONSE TO MICRO/NANOPATTERNED BIOMATERIALS

Assisted by the Proteins and Cells at Interfaces SIG and the Surface Characterization and Modification SIG

Nanopatterning of biomaterial surfaces has emerged as promising surface modification strategy to manipulate protein activities, cellular functions and tissue responses. A key characteristic of these approaches is that the nanoscale features elicit different or enhanced responses compared to smooth and micropatterned substrates. By focusing on the nanopatterning theme, this symposium will cut across different biomedical applications to concentrate on fundamental issues related to nanoscale interactions.

## UROLOGICAL TISSUE ENGINEERING AND BIOMATERIALS

The aim of this session is to introduce the attendees of the biomaterials community to the current clinical needs and issues associated with reconstruction and tissue engineering of the urinary tract. The scope, however, will not be limited to research on tissue engineering, but include various biomaterials and devices used for the treatment of urological complications such as urinary incontinence and pelvic organ prolapse. Submission of abstracts from both academic and industry laboratories is encouraged for discussion and exchange of ideas on the topics of: bladder/urethra tissue engineering scaffold materials, stem-cell therapy, biologically-derived and synthetic biomaterials for incontinence and female prolapse treatments, biomechanical evaluation of urological tissues, etc.

## SURFACE MODIFICATION AND CHARACTERIZATION OF BIOMATERIALS

The modification of the outermost surface of biomaterial constructs continues to drive the evolution of implant functionality. Such treatments include those that regulate the elution of therapies, reduce the inflammatory response, resist thrombus or biofilm formation, and those that induce specific biological responses such as cell anchoring and tissue in-growth. Development of ever more sophisticated treatments demands the ability to characterize ever subtler structures within the top nanometers of a surface. Today's new surface characterization methods permit the biomaterial scientist to probe the orientation and structure of proteins and other molecular features with greater detail than just a few years ago. This session will provide contributors with a venue for presenting the latest developments in both surface modification and characterization of biomaterials. Presenters are invited to highlight developments in such characterization

methods as Electron Spectroscopy for Chemical Analysis (ESCA), Time-Of-Flight Secondary Ion Mass Spectrometry (TOF-SIMS), scanning probe microscopies (AFM, SNOM), Near Edge Absorption for Fine Structure (NEXAFS), Sum Frequency Generation (SFG), Surface Plasmon Resonance (SPR), etc.

## WORKSHOPS

### VASCULARIZATION AND INNERVATION OF TISSUE ENGINEERED CONSTRUCTS

Assisted by Tissue Engineering SIG

Tissue engineering of thick tissues or whole organ engineering remains a significant clinical need. The latest research has demonstrated that every tissue, with the exception of cartilage, has both a blood supply and is innervated, including bone, heart valves, and skin. Vascularization and neural ingrowth are important in healing, tissue regeneration, and tissue and organ function. The engineering of replacement tissues or organs will require complex systems to be integrated into or generated after implantation. Two of the important challenges will be to provide 1) a stable blood supply to the implanted construct and 2) neural integration with the host tissues. Although angiogenesis and neural regeneration are active areas clinically, bringing these complex systems together with other cells or tissues and biomaterial scaffolds to create an integrated, fully functional tissue engineered product that is vascularized and innervated still remains a major barrier to thick tissue and organ engineering.

### MICROSCOPY: BASIC PRINCIPLES AND APPLICATIONS FOR BIOMATERIAL ANALYSIS

Assisted by Implant Pathology SIG

The applications of microscopic principles and analysis of biomedical devices (materials) is fundamental in understanding device/tissue interactions and remodeling and regeneration at the tissue, cell and molecular levels. At each level there are core areas of physiology, engineering, biology and modeling that can be discovered by the application of various microscopic techniques. A basic understanding of microscopic principles and optical tools enables the researcher to apply these in the studies of biomaterial surfaces and microstructure, which would provide data to further elucidate mechanisms of biocompatibility. Sophistication in digital and electronic technology has greatly enhanced the microscope to provide images that can be correlated to failure modes and analysis of biomedical devices. Drug coatings, distribution, concentrations and release profiles warrant sophisticated methods to

explain and view mechanisms of action. A knowledge of when to use the various microscopes would be useful. There are numerous microscopes for the various applications, such as two photon microscopy, acoustic microscopy, scanning tunneling microscopy, scanning electron microscopy, atomic force microscopy, Raman spectroscopy, fluorescence microscopy, confocal microscopy, etc. This workshop will provide an overview of the different microscopes useful for biomaterial analysis. This workshop will answer the basic questions of a) what is... b) when to use it, c) why a particular scope, d) how to... e) analysis of results (what the results mean).

### WHAT FITS YOU BEST, ACADEMIA OR INDUSTRY, AND HOW DO YOU GET THERE?

Assisted by Biomaterials Education SIG

To enhance the professional development of graduate students as well as provide knowledge about academia and industry through invited speakers. This workshop will be divided into three sections. In the first section we will have invited speakers who have started in academia and switched to industry, and vice versa. The intent is that students will be more informed when it comes time to choosing either pathway. The second section will focus on how to develop a budget and there will be invited speakers from both academia and industry to address the differences in this process. The intent of this section is to provide information that is not generally given a classroom setting. The last section will focus on developing the students interviewing skills so that they have more confidence when going on their first interview.

## PANEL DISCUSSIONS

*Panel Discussions are a format that foster open debate on a topic. The invited guests include renowned experts in the area of focus and the chair allows time for open discussion with the audience.*

### ENTREPRENEURSHIP AND BIOMATERIALS/MEDICAL DEVICES

Assisted by the Biomaterial Availability and Policy SIG

Entrepreneurial small business start-ups are being increasingly recognized and supported by federal, state and local governments, and by universities as a mechanism for successful technology commercialization. "Biotech" start-ups based on biomaterials technology utilized for medical device applications have a unique set of challenges and rewards. Our Society has previously examined the business models used by large corporations; this forum will address many of the issues faced by entrepreneurial individuals such as faculty members or graduate students as they



attempt to bring their biomaterials technology to the market through a start-up business.

## CLINICAL EXPERIENCE WITH ORTHOPAEDIC AND DENTAL BIOMATERIALS

Assisted by the Dental/Craniofacial Biomaterials, Implant Pathology, and Orthopaedic Biomaterials SIGs

Materials science and engineering is about the processing-structure-property relationship of various materials. The above relationship of biomaterials is ultimately tested in clinics. The development of biomaterials should have the goal of successful clinical applications. This panel discussion will invite leading medical doctors who have a lot of clinical experience with biomaterials in areas such as orthopedics, dentistry and tissue engineering. The objectives of this panel discussion are (1) present the clinical applications of currently available biomaterials and (2) discuss the improvement and directions of new biomaterials in different clinical areas.

## THE ROLE PLAYERS IN THE DRAMA OF ANTI-BIOMATERIAL IMMUNITY: THE MACROPHAGE, THE DENTRITIC CELL, THE B CELL AND THE T CELL

Assisted by the Implant Pathology SIG

Each panelist will review the role of one of the players as an immunological cell in general and as an antagonist of implants. The reviews will end with an explanation of how the investigations of the reviewer improve our understanding of these roles. Then the panelists will convene as a panel to discuss how the roles become parts in a drama featuring player interaction. Finally, the floor will be opened for questions from the audience. The purpose of the presentation is to make all SFB researchers aware of the scope of immune cell activity as it applies to implants and to help those specializing in one small area of host response to relate their work to the larger picture of host recognition of non-self.

## TUTORIALS

*The purpose of a Tutorial is to teach the attendees about a specific technology or focus area. It may include up to two presenters and time for questions and answers.*

## ADVANCES IN SURFACE CHARACTERIZATION METHODS

Assisted by the Surface Characterization and Modification SIG

During this tutorial, leaders in the field will survey state-of-the-art advancements

in surface characterization methods. Speakers will emphasize how these advancements enhance our understanding of biomaterials, and how materials interact with their biological environments. Furthermore, each speaker will be asked to look beyond the horizon to describe methods that are currently under development, or are being adapted for use on biomaterials from other scientific fields. To investigate molecular orientations at surfaces, Sum Frequency Generation and Near Edge X-ray Absorption Fine Structure will be presented. Recent advances in measuring mechanical modulus of soft materials using AFM will be updated. A variety of methods for imaging composition at the surface and near-surface will be described. These methods will include: imaging ESCA, TOF-SIMS and MALDI-TOF, scanning near optical microscopy, and confocal Raman. Presenters will emphasize the strengths and limitations of each application, why one might choose a given tool over others, important details regarding sample preparation, and the benefits of applying surface analysis methods in combination.

## PRODUCT LIABILITY LAW AS PART OF THE PRODUCT DESIGN PROCESS: WHAT EVERY SCIENTIST SHOULD KNOW

Assisted by the Biomaterial Availability and Policy SIG

Learn realistic product design principles to build in success against product liability lawsuits. Product liability lawsuits are practically unavoidable for a successful medical product. Device designers can take realistic steps to enhance the success of a product against product liability challenges. And businesses can use specific principles to manage product liability lawsuit risks. This tutorial will explain the legal principles that underpin medical product liability law and realistic design principles that anticipate potential legal challenges. Legal experts in medical device design and experienced designers will describe best practices for medical device design with respect to product liability. The tutorial is intended to provide scientists with tools they want and need to make the best products possible.

## TECHNOLOGY & TRAINING FORUMS

*These Forums will be technically-based educational opportunities hosted by SFB corporate supporters.*

1. “Using Novel High Performance Polyetheretherketone Biomaterials for Implantable Medical Devices”  
Invivio Inc.

2. “Coatings for Medical Device Applications”  
IonBond LLC
3. “Alginate Technology Workshop”  
FMC BioPolymer/NovaMatrix
4. “Long Term Biostability of Polymeric Biomaterials”  
Medtronic Inc.
5. “A New Approach for Tailoring Biomaterials Properties: Polymers with Self Assembling End Groups”  
Polymer Technology Group

1. “Using Novel High Performance Polyetheretherketone Biomaterials for Implantable Medical Devices”  
Invivio Inc.

### Description

This forum will discuss the novel uses and performance profile of Polyetheretherketone with carbon fibres added to make commercial FDA cleared and CE marked medical devices. The forum will present accepted theories and practices of fibre reinforcement and address issues of functional performance and biocompatibility.

Participants are encouraged to bring real-world applications for the workshop and discussion with our expert panel.

Polyetheretherketone is an important biomaterial that is selected in preference to metals in some common implantable devices. While the base polymer has excellent mechanical properties compared with other materials of its class, the addition of reinforcing carbon fibres can further increase its strength, stiffness and wear resistance.

### Agenda

- Polyetheretherketone composite products
- Biocompatibility and tissue interactions of Polyetheretherketone composites and carbon fibre compounds
- Polyetheretherketone composite materials and processing
- End-user perspective
- Workshop and case history discussion with panel of experts

### Goals

1. To introduce to a new audience an important biomaterial.
2. To describe the use of carbon fibres as a means of enhancing the mechanical properties of the base polymer and give examples of successful applications.
3. To describe the theory and practice of fibre reinforcement and production processing capabilities of this class of materials.
4. To describe the achievable mechanical properties in comparison with traditional materials used for medical implants.



5. To provide participants with the opportunity to discuss real-life ideas and applications with leading experts in device design.

**Who Should Attend?**

Surgeons, medical device engineers, students and academia. Anyone interested in alternatives to traditional materials that offer performance benefits and features not otherwise available. Someone who designs medical devices, or specifies materials, or is involved in the manufacture of medical devices.

**2. “Coatings for Medical Device Applications”**

IonBond LLC

**Description**

Surface enhancement technologies are a viable, cost effective solution for the improvement of the physical properties of biomedical materials. This forum will summarize the capabilities, products and services of the IonBond LLC Medthin Medical Group. It is intended to stimulate thought and discussion about potential applications for commercialization.

Physical Vapor Deposition (PVD), Chemical Vapor Deposition (CVD) and Plasma Assisted Chemical Vapor Deposition (P A CVD) describe a group of surface enhancement technologies used to deposit wear-and-abrasion-resistant thin film coatings with excellent adhesion. Medical and dental applications include orthopedic implants, cardiovascular implants, dental implants, catheters, surgical and dental instruments.

Various PVD deposition technologies are discussed together with product features and applications for medical grade coatings. More recent additions to the Medthin portfolio are a variety of diamond-like carbon (DLC) based coatings, a solid lubricant film and a 'patented' nano-textured biologic growth surface (TST).

**Agenda**

- Advantages of IonBond® Coatings as Biomaterials
- PVD and P ACVD Coating Deposition Technologies
- Implant and Surgical Instrument Applications
- New Coating Developments
- Medical Business Unit Capabilities

**Goals**

Surface enhancement technologies can provide biocompatibility, wear-and-abrasion resistance and reduced costs through improved performance for the medical device industry. The goal of this corporate forum is to provide a foundation for all participants to learn about the technologies, products and applications possible through the use of coating surface enhancement technologies. Coating deposition technologies and

practical application examples that take advantage of the properties offered by thin film coatings are presented. In addition, newly developed carbon based films, solid lubricant films and biologic in-growth nano-structured surfaces are discussed.

**Who Should Attend?**

Individuals involved in the development, design or improvements of medical devices are invited to attend to learn how this powerful technology can be utilized to improve the performance and properties of accepted biomaterials. Members of research and development teams, product development team design engineers and application specialists are invited to attend and afterwards discuss application-related items with our experienced team.

**3. “Alginate Technology Workshop”**

FMC BioPolymer/NovaMatrix

**Description**

The Alginate Technology Workshop will begin with a “lecture-style” overview of alginate structure and function and how this biopolymer can be formulated for use in cell encapsulation and tissue engineering applications. Three technology platforms will be presented: immobilization of cells in alginate gel beads, self-gelling alginate systems, and alginate foams. The Workshop will then offer attendees “hands-on” experience with the different alginate technologies. Furthermore, practical demonstrations relating to strength and degradability will show the flexibility inherent in using alginate in such applications. The Workshop will also review current Guidelines and Standards for alginate used in Tissue Engineered Medical Products. A new alginate product will be launched: RGD-alginate.

**Agenda**

- Alginate structure and function
- Encapsulation in alginate gel beads
- Self-gelling alginate systems
- Alginate foam
- New Products
- Hands-on session

**Goals**

The Workshop is intended to give attendees an overview of several alginate-based technologies for tissue culture, cell therapy and tissue engineering applications. Attendees will gain an understanding of alginate structure and function and how such knowledge can be put to use in developing biomaterial applications. A review of current regulatory information regarding alginate will be useful to those considering commercialization of alginate-based products. The “hands-on” session will give participants an opportunity to make and handle different alginate formulations specifically designed for cell immobilization and tissue engineering

applications.

**Who Should Attend?**

The prospective attendee would be a researcher with experience in biomaterial, scaffold and/or matrix formulations. Those interested in cell therapy (cell encapsulation) and tissue engineering scaffolds will also benefit by attending this Workshop.

**4. “Long Term Biostability of Polymeric Biomaterials”**

Medtronic Inc.

**Description**

Biostability is critical for biomaterials in general, but it is much more critical for those biomaterials used for chronic implantation. This is not only because these materials require long term functional and mechanical integrity, but also because biostability can affect chronic biocompatibility. For example, chemical degradation may result in the loss of material properties and functions, but could also lead to the release of toxic degradation products into surrounding tissues. In this lecture, we will first discuss some common chemical, physical, and combined factors that can lead to degradation of polymeric materials. Secondly, we will discuss in vitro and in vivo chemical stability tests for material screening. Lastly, we will discuss the selection of polymeric materials for long term implantation.

**Agenda**

- Biostability, biocompatibility, and their relationships for chronic implant materials.
- Common causes for materials to degrade.
- In vitro and in vivo chemical stability test for polymers.
- Material selection guidelines for chronic implant applications.

**Goals**

The goal of the tutorial is to help participants learn the basic principles of biostability of polymeric materials and to understand the in vitro and in vivo material stability tests.

**Who Should Attend?**

Students and industrial researchers who are interested in biomaterials for chronic implant applications should attend the tutorial. The principles and test methods presented in the lecture should be beneficial to their research, development and use of biomaterials.



## 5. “A New Approach for Tailoring Biomaterials Properties: Polymers with Self Assembling End Groups” Polymer Technology Group

### Description

Self-assembling monolayers (SAMs) are useful in research because they create well defined surfaces for optional attachment of biologically-active molecules, but their use in applications is limited by their fragility. New thermoplastic biomaterials are built from backbone segments and surface-modifying end groups (SME). Recent work demonstrates similarities between SME polymer surfaces and those created from analogous self assembling thiol monomers on gold. The more robust polymer systems can be fabricated by high-speed processing methods and have the potential to serve in many applications: bulk properties are determined by the polymer mid-block, while surface properties are dominated by the SMEs. This versatile architecture offers a seamless transition from R&D results with SAMs to manufacturing of new polymers tailored for biomedical applications.

### Agenda

- Parallel optimization of device and materials
- Nature of polymer surfaces
- A versatile polymer structure for separately tailoring bulk and surface properties
- Similarities between SAMs and SME polymers
- Existing biomaterials with SMEs
- Future potential in biomaterials development and applications
- Control of surface nanostructure with amphipathic SMEs

### Goals

To review progress in the science and technology of high-performance biomaterials, and to instruct device developers in the optimization of materials for new/demanding applications.

### Who Should Attend?

Physicians, scientists, engineers and technicians involved in the design or manufacturing of medical devices who desire to learn more about state-of-the-art materials and their optimization.

