

BIOMATERIALS

# FORUM!



OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

Second Quarter 2014 • Volume 37, Issue 2



# BIOMATERIALS FORUM!

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 37, Issue 2

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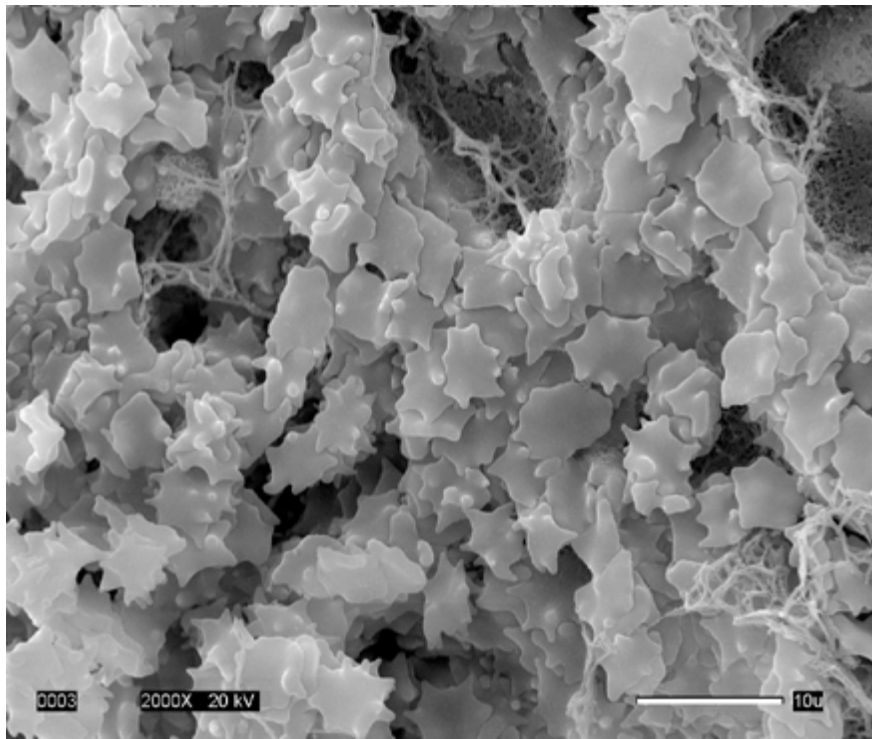
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# Departments



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**On the cover:** This electron micrograph shows activated platelets and fibrin fibers as part of a blood clot on a chitosan hemostatic patch manufactured by HemCon® Medical Technologies. Fresh whole blood from a pig was placed on the chitosan fabric for five minutes where it formed a thrombus, before fixation with gluteraldehyde, dehydration through a series of ethanol solutions, and osmium tetroxide and gold sputter coating to prepare the specimen for scanning electron microscopy (SEM) imaging. The image was captured by a JEOL SEM, Model JSM-5900LV under a 20 kV accelerating voltage at a magnification of 2000x. The scale bar is 10  $\mu$ m. The image was modified by Adobe Photoshop to adjust gamma levels. The image was obtained by Xinyue Lu from the College of Textiles at North Carolina State University, while enrolled in the graduate level course “Biological Scanning Electron Microscopy,” MB705, under the instruction of Dr. John M Mackenzie Jr. and Mrs. Valerie Knowlton Lapham in the Department of Molecular & Structural Biochemistry.





### GREETINGS FELLOW BIOMATERIALS SCIENTISTS,

Welcome to the summer issue of the Society For Biomaterials (SFB) news magazine. The *Biomaterials Forum* provides a platform for discussion of scientific, business, philosophical, and legislative matters related to

biomaterials, and allows members to share news outside of our annual meeting. In case you weren't able to attend the recent annual meeting in Denver, Colo., this issue contains a few highlights from the meeting, as well as other news of interest to you as a biomaterials scientist:

- » The Biomaterials Education Challenge was judged during the 2014 SFB Annual Meeting and first prize (\$2,500) went to Sandeep Ramineni at the University of Kentucky with faculty advisor Dave Puleo. See page 10 for more information about the event and the other award winners.
- » Other news about the SFB annual meeting is reported by the Proteins and Cells at Interfaces SIG and the Student Chapter President Jordan Gilmore in the SIG News section as well. Don't miss the update about the Business Plan Competition, which truly embodied the theme of the meeting, "Pioneering the Future of Biomaterials."
- » The front page cover art is from a student who became enamored with scanning electron microscopy during a course he took. He sent us this image for consideration as cover art. It was selected! Congratulations to Xinyue Lu from the College of Textiles at North Carolina State University. Please encourage your students or staff to forward us their favorite biomaterials-related image for consideration as cover art.
- » Based on the historical review of the SFB that was presented by Guigen Zhang from Clemson University at the annual meeting, the *Forum* has a new Historical Flashback column describing the beginning of the SFB traditions and its founders. Learn more about the origin of the Clemson Awards and the SFB Biomaterials Bash in the Historical Flashback column.

- » There is increasing momentum within the U.S. Food and Drug Administration (FDA) on the topic of standardized protocols for conducting test methods that can help regulate tissue engineered medical products. Read about two standardization initiatives in the Government News column.
- » A successful international collaboration included student exchanges between the U.S. and India and is described in the Education News column.
- » Read Industrial News for an overview of the latest mergers, acquisitions, and other notable corporate product releases.
- » Our SFB members continue to receive prestigious professional awards, advancements and other new opportunities. Read the member news column to find out more. Send us your noteworthy news for inclusion in a future issue.

Help us make sure this publication reflects news of interest to you within the diverse and fascinating field of biomaterials. I invite you to prepare a biomaterials-related article or opinion piece or cover art and send it to me at [Lkuhn@uchc.edu](mailto:Lkuhn@uchc.edu) for inclusion in one of the next issues of the *Biomaterials Forum*.

Best wishes,



### LIISA KUHN

Biomaterials Forum Executive Editor  
Associate Professor  
University of Connecticut Health Center



This issue of the *Forum* serves as my first presidential letter for the coming year. I would like to begin by thanking our Past President, Dr. Tony Mikos, for his outstanding effort this past year and for guiding our Society to again, another fiscally sound year. His leadership and guidance have been most important for me to have a smooth transition for the coming year.

This past year has been quite eventful, culminating in our outstanding meeting in Denver this past April. I would like to express my sincere gratitude to our numerous sponsors and exhibitors who helped make this meeting a success. The Program Committee and its Chair, Dr. Joo Ong, did an exceptional job in covering the wide range of interests of our Society's members, as well as introducing some new and invigorating ideas. Some highlights of the meeting were the opening ceremony, in which Dr. Rena Bizios received the Founders Award and Dr. Michael Yaszemski gave the keynote address. There were a number of workshops, including the second U.S. vs. China regulation, standards, and innovation discussions; women in biomedical engineering luncheon; and technology/training forums sponsored by Sanofi and Anton Paar.

We continued to have the Student Education Design Competition, which was won by the students from the University of Kentucky. A new and exciting addition to our meeting was the Business Plan Competition, sponsored by our Biomaterials and Medical Products Commercialization SIG and chaired by Eric Sussman. The event was well attended and we appreciated the support of Dow Corning Corporation (Jim Curtis) and Tephra Inc. (David Martin), who provided the awards that were given to MEM|MESH and MetastaticPrecision. I am hopeful that we could continue this competition for our future meetings. Our SIG meetings were generally well attended, and continue to generate strong interest into putting forth ideas for the upcoming meeting. In addition, to help promote our SIGS and offer some value to joining and maintaining membership in our society, we implemented a change to this year's registration/membership fees: one could join one SIG free of charge. Another highlight of the meeting was our annual Bash, which was held in the Pinnacle Club of the Grand Hyatt and offered a wonderful view of the

Rocky Mountains as well as provided an opportunity for networking and some relaxation. Finally, it is important to recognize those individuals from Association Headquarters (AH), especially Dan Lemyre and Leslie Clark, for helping us organize and plan our Denver meeting.

This coming year our Society will be quite engaged as we continue to implement the long range plans that were initially brought forth during Joel Bumgardner's presidency. Many ideas from this plan have generated task forces, with much discussion and input from our members. I am happy to report that some ideas have already been implemented, such as membership and dues changes this past year, education and industry design challenges implemented for the past meeting, and a significant website redesign. There are discussions with other societies to co-sponsor a meeting in the future. Finally, we are already planning our themes and program for our meeting next April, in Charlotte, N.C. The Program Chairs, Helen Lu, Peter Edelman, and I met in Denver and I was excited to hear about their ideas for the upcoming meeting, which should be another resounding success.

Our Society is vibrant, engaged, and fiscally sound, but there still remain challenges to keep our membership strong and ensure that SFB remains the major society for our diverse group of people from academia, industry, and government. We must continue to offer a valued membership and keep our members engaged. Two years ago, as Member-At-Large, I sent an "SFB Wants to Hear from You" memo and, as I believe communication is important, I would encourage you to keep in touch with us. I look forward to working with you this coming year, and please feel free to contact me ([npz@case.edu](mailto:npz@case.edu)) if you have any questions, thoughts, or ideas concerning our Society.



**NICHOLAS P. ZIATS, PH.D.**

Case Western Reserve University  
President, Society For Biomaterials

# Staff Update

BY LESLIE CLARK, ASSISTANT EXECUTIVE DIRECTOR



Hello from Society For Biomaterials headquarters! The work of your committees was in evidence at SFB's 2014 Annual Meeting in Denver. Following is a recap of their activities.

## AWARDS, CEREMONIES AND NOMINATIONS

{ 2013-14 CHAIR NICHOLAS PEPPAS }

Those planning to nominate a student for a 2015 student research award are encouraged to start thinking about it now because a paper is required for submission and it would help the student to have the summer to prepare one. The process to nominate new Fellows to the International Union of Biomaterials Science and Engineering (IUSBSE) is beginning.

## BYLAWS

{ 2013-14 CHAIR JIRO NAGATOMI }

Possible amendments to the bylaws to extend the term of the Presidency or add an additional Member-at-Large are under consideration. Research into the pros and cons of such a change is being conducted.

## DEVICES & MATERIALS COMMITTEE

{ 2013-14 CHAIR ANDY DORAISWAMY }

A joint U.S – China Workshop was organized for the Denver annual meeting as were several other sessions.

## EDUCATION AND PROFESSIONAL DEVELOPMENT

{ 2013-14 CHAIR WILLIAM MURPHY }

The committee conducted the 2<sup>nd</sup> Annual Biomaterials Education Challenge in which student chapters competed by creating and presenting study modules aimed at eighth grade science students. Following are the winners of the competition:

- First prize (\$2,500): University of Kentucky
- Second prize (\$1,500): Case Western Reserve University
- Third prize (\$750): Texas A&M
- Fourth prize (tie - \$250): Vanderbilt
- Fourth prize (tie - \$250): University of Texas

Other activities undertaken by the committee included final selection of the STAR award recipients (candidates nominated by the SIGs), choosing the C. William Hall

Scholarship recipient, handling meeting endorsement requests from other societies, overseeing the Biomaterials Days grants, and granting student chapter awards.

## FINANCE

{ 2013-15 CHAIR LISA FRIIS }

Total reserves (both operating and long term) are healthy and have enabled the Society to invest in a new website and allow all members to join one Special Interest Group for free. Two new policies were approved by Council. The first is a Start-Up Exhibitor Policy, providing start-up companies with a first-time discount on a regular exhibit booth during the initial five years of their formation. The second is a Contract Signing Policy, putting in writing the process by which contracts for SFB may be signed. Council also approved giving invited speakers a one-year complimentary SFB membership along with the usual complimentary meeting registration.

## LIAISON

{ 2013-15 CHAIR DAVID PULEO }

The joint task force with TERMIS-NA resulted in a proposal by the Tissue Engineering SIG for a full-day workshop to be held in conjunction with the 2016 TERMIS meeting in San Diego, Calif. Registration and sponsorship will be sought in order to make this a revenue-neutral event, with details to be worked out in the coming months. Council approved this proposal and is now asking all SIGs to consider similar proposals as options for SFB's 2016 off-year meeting plans. The benefits are content-rich workshops of interest to SFB's members and the opportunity to introduce other societies to SFB, perhaps generating additional membership.

## LONG RANGE PLANNING

{ 2013-14 CHAIR NICHOLAS ZIATS }

Many of the items in the long range plan are complete or have been undertaken. The new website, which went live just prior to the annual meeting, was one of the goals in the plan.

## MEETINGS

{ 2013-14 CHAIR ANTONIOS MIKOS }

Council approved having SFB try something different in 2016, such as a stand-alone symposium or an event that follows the model of the Tissue Engineering SIG/TERMIS workshop approved for San Diego. The SIGs will be asked to collaborate in creating proposals for 2016. The proposals should avoid events that take place in the same month as each other or within one month of the World Biomaterials Congress, and should strive to remain revenue neutral. Details on what the proposals should contain will be sent out.

**MEMBERSHIP**

{ 2013-14 CHAIR HORST VON RECUM }

For the first time, the 2013-2014 committee consisted of appointed, not elected, members. Other changes to SFB membership included the elimination of the associate member category for all but students and post graduates, the collection of dues along with meeting registration, and giving members one free SIG membership. Under early consideration now is an incentive whereby student chapters would be given free memberships in SFB based on a percentage of their own membership numbers.

**2014 PROGRAM**

{ 2013-14 CHAIR JOO ONG }

Late-breaking abstracts, for poster presentations only, were accepted. The final program book for 2014 was redesigned to make all of the information easier to find and the program easier to follow. A call for ideas for 2015 will be going out from the 2015 Meeting Co-Chairs Peter Edelman and Helen Lu.

**PUBLICATIONS**

{ 2013-15 CHAIR ALAN LITSKY }

*Biomaterials Forum* (Editor Liisa Kuhn):

Ways are being sought on how to index issues of the *Forum*. SIGs will be encouraged to create an index listing the articles they have contributed and post it on their websites.

*Website* (Editor Tom Webster):

The new Society website launched prior to the annual meeting. It is designed to scale well on smart phones and tablets, and contains both public-facing and private-facing pages for all SIGs and committees.

*Biomaterials Bulletin* (compiled by Multibriefs):

The *Bulletin* e-newsletter continues to feature a compilation of relevant articles about the field of biomaterials from across the Internet. It is sent to members bi-weekly.

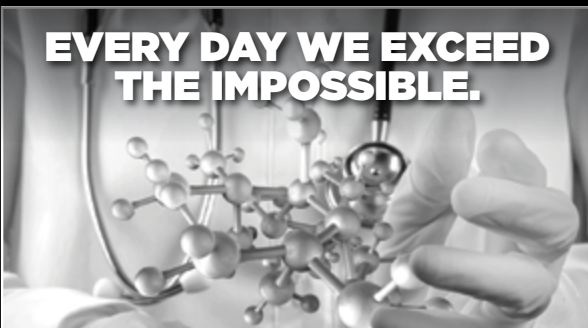
*JBMR-A and B* (Editors Jim Anderson and Jeremy Gilbert):

The editorial board is undergoing reorganization. A full list will be provided when it is complete. Manuscripts are getting too long and the editors will be requiring strict adherence to the allowed length. Plagiarism continues to be a problem and is being closely monitored. First time violators are warned but repeat offenders will no longer be allowed to submit manuscripts.

**SPECIAL INTEREST GROUPS**

{ 2013-15 REPRESENTATIVE STEVE LITTLE }

The most important change this year was the inclusion of a SIG membership with each new or renewing SFB member. The *SIGnal* newsletter was updated with a visual redesign and is now sent to all SFB members. A rotation for submission of articles to the *Forum* has been set up to ensure timely materials. A new SIG, Immune Engineering, was founded and an existing SIG, Implant Pathology, changed its name to Biomaterial-Tissue Interaction. The SIGs will be asked to submit proposals for 2016 workshops or symposia in response to Council's desire for a different approach to meetings in a World Congress year.



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# Members in the News

BY JAN STEGEMANN, 2013-14 MEMBER-AT-LARGE



It was great to see so many colleagues and new members at the SFB Annual Meeting in Denver! The scientific sessions were excellent and the networking outstanding as usual. The meeting also marked the end of my tenure as Member-at-Large, so I would like to take this opportunity

to convey what a pleasure it was to serve the Society, and to learn so much about how it works. The membership is fortunate to have such an engaged, dedicated, and thoughtful group of leaders at the helm. I'd also like to take this opportunity to convey my thanks to the many SFB members who contacted me about Society issues and provided material for this column.

It is my pleasure to announce that **Dr. Horst von Recum** from Case Western Reserve University has been elected as the SFB Member-at-Large for 2014-15. I can think of no one better suited to this position than Horst: an active, approachable and responsible young leader in the field. I am sure Horst will do a great job in representing the Society membership. He will also be taking over this column, and you can send your news for future issues directly to him at [Horst.vonRecum@case.edu](mailto:Horst.vonRecum@case.edu).

I hope this column helps you keep track of what is happening in our community, and to see how our membership is impacting the field.

## HONORS AND AWARDS

**Dr. Susmita Bose** will receive a 2014 Richard M. Fulrath Award from the American Ceramic Society for her exceptional contribution in the field of bioceramics as applied to bone tissue engineering and drug delivery. These awards recognize individuals for their excellence in research and development of ceramic sciences and materials, and promote technical and personal friendships between professional Japanese and American ceramic engineers. The awardee must be 45 years of age or younger, and travels to Japan to receive the award and visit academic and industrial laboratories. Dr. Bose is Professor of Mechanical and Materials Engineering at Washington State University.

**Dr. Jindrich (Henry) Kopecek** was awarded a Doctor of Philosophy honoris causa degree from the University of Helsinki, Finland, for his many contributions to the study of relationships between the structure of synthetic macromolecules and their interaction with living tissue. The insignia of the Doctor's degree was presented at a conferment ceremony on May 23, 2014. Dr. Kopecek is Distinguished Professor of Bioengineering and Pharmaceutics and Pharmaceutical Sciences at the University of Utah.

**Dr. Liisa Kuhn** received the Award of Merit from the American Society For Testing and Materials (ASTM) International at the 2014 Spring F04 Committee meeting in Toronto, Canada. The award was established in 1949 by the ASTM International Board of Directors and is the highest society award granted to an individual member for distinguished service and outstanding participation in ASTM International committee activities. Recipients also receive the honorary title of Fellow. The plaque inscription reads:

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For outstanding leadership and high productivity in fostering the development and promulgation of surgical implant standards in ASTM Committee F04 for Medical and Surgical Materials and Devices.

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**Dr. Tony Mikos** received a 2014 Distinguished Engineering Alumni Award from Purdue University. This award is presented annually to men and women who have distinguished themselves in any field in ways that reflect favorably on Purdue University, the engineering profession, or society in general. Dr. Mikos is a past recipient of the Clemson and Founders Awards, and currently serves as First Past President of the Society. Dr. Mikos is the Louis Calder Professor of Bioengineering and Chemical and Biomolecular Engineering at Rice University, Director of the J.W. Cox Laboratory for Biomedical Engineering, and Director of the Center for Excellence in Tissue Engineering at Rice University.

**Dr. David K. Mills** received the 2014 College of Applied and Natural Sciences Outstanding Research Award from Louisiana Tech University for his research in designing novel and dynamic nanofilms. In his 20-year career at Louisiana Tech University, Dr. Mills has been recognized by several awards for his scholarly activity, mentorship, and excellence as director of undergraduate/graduate research projects. Dr. Mills is Professor of Biological Sciences and the Institute for Micromanufacturing at Louisiana Tech University.

**Dr. Syam Nukavarapu** received an M1 Mentoring Award from the Connecticut Institute for Clinical and Translational Science at the University of Connecticut. This award is given to successful research-funded faculty who serve as mentors, with the goal of increasing the presence of minority students otherwise underrepresented among academic scientists. Awardees receive \$50,000 per year for three years for mentoring activities. Dr. Nukavarapu is an Assistant Professor in the Department of Orthopedic Surgery, Biomedical Engineering and Materials Science & Engineering at the University of Connecticut.



**Dr. Xingdong Zhang** was elected a Foreign Associate in the National Academy of Engineering (NAE). Professor Zhang was elected “for contributions to musculoskeletal medical therapies and biomaterial product development.” Professor Zhang is the current President of the Chinese Society for Biomaterials (CSBM) and he also served the President of the 9th World Biomaterials Congress in Chengdu, China 2012. Dr. Zhang is Professor and Honorary Director of the National Engineering Research Center for Biomaterials at Sichuan University, Chengdu, China.

The following SFB members were inducted as 2014 Fellows of the American Institute for Medical and Biological Engineering (AIMBE): **Dr. Sarit Bhaduri** (U. Toledo), **Dr. Justin Hanes** (Johns Hopkins U.), **Dr. Erin Lavik** (Case Western Reserve U.), **Dr. Bill Murphy** (U. Wisconsin), **Dr. Todd McDevitt** (Georgia Tech), **Dr. Kishore Udipi** (Biopolymer Designs Inc), **Dr. Guigen Zhang** (Clemson U.). AIMBE is “an organization of leaders in medical and biological engineering, consisting of academic, industrial, professional society councils and elected Fellows.”

## OTHER NEWS AND RECOGNITIONS

**Dr. Eben Alsberg** has been selected to the editorial board of two prominent journals in the field: *Tissue Engineering* and *Scientific Reports*. Dr. Alsberg was also elected to the Americas Council of the Tissue Engineering and Regenerative Medicine International Society (TERMIS) for a three-year term. Dr. Alsberg is Associate Professor of Biomedical Engineering at Case Western Reserve University.

**Dr. Allan Hoffman** was feted at the “Hoffman Family Symposium II” March 24-25, 2014 in Tsukuba Japan. The symposium was organized by Mitsuhiro Ebara, Takao Aoyagi, and Kyu Park and was attended by over 80 of Dr. Hoffman’s close colleagues, friends, and former students. This event follows the first Hoffman Family Symposium held in Tsukuba in 2010, as well as 60<sup>th</sup>, 70<sup>th</sup>, and 80<sup>th</sup> Birthday Symposia held to honor Dr. Hoffman’s many contributions to the field of biomaterials, held in Maui, Hawaii in 1992, 2002, and 2012. Dr. Hoffman is a past recipient of a Clemson Award and the Founders Award, and is a past President of SFB. Dr. Hoffman is a member of the National Academy of Engineering and is Emeritus Professor of Bioengineering at the University of Washington.

### IN MEMORIAM

It is with great sadness that we impart the news of the recent passing of two of our esteemed colleagues in the field of biomaterials.

**Dr. Roger Marchant** passed away January 31, 2014 in Cleveland, at age 62. Dr. Marchant was Professor of Biomedical Engineering and Director of the Center for Cardiovascular Biomaterials at Case Western Reserve University (CWRU). He was one of the earliest and most respected members of the CWRU Biomaterials Faculty and made significant contributions to science and engineering in drug release, atomic force microscopy, biomimetic materials, and cardiovascular implant devices.

Professor Marchant received a B.Sc. (Honors) in Polymer Science and Chemistry in 1978 from the University of Sussex in England. He subsequently received his M.S. and Ph.D. degrees (1982 and 1984, respectively) in Macromolecular Science and Engineering, specializing in biomaterials, from CWRU in Cleveland, Ohio, under research advisor Professor James M. Anderson. He received the award for outstanding research from the SFB in 1984. He was a visiting scientist at the University of Washington, University of Utah, and University of Paris. Dr. Marchant joined the primary faculty in the Department of Biomedical Engineering and the Department of Macromolecular Science at CWRU in 1988, rising to the rank of Professor by 1998.

Professor Marchant was internationally recognized for his research contributions in biomaterials, reflected by his visiting professorships in Chongqing, China, and Bangkok, Thailand. His seminal research contributions include using concepts from nature that mimic cellular structures, like endothelial cells and platelets, to develop new materials for medical use. He developed cell-targeted liposomes for drug delivery and biomimetic coatings on artificial blood vessels to allow better tissue healing. He was also a pioneer in atomic force microscopy, and developed techniques to image proteins and vascular cells at a molecular scale. He was the holder of 10 patents and brought in over \$23 million in National Institutes of Health and National Science Foundation research grant support to CWRU from 1988 to 2014, with \$19 million attributed to him as a principal investigator. He had published 135 peer-reviewed scientific papers, 18 book chapters and had presented over 250 papers and invited lectures. His co-investigator on most of these projects was his former graduate student colleague and wife, Kandice Kottke-Marchant, MD, PhD, who is Chair of the Robert J. Tomsich Pathology and Laboratory Medicine Institute at the Cleveland Clinic.

Professor Marchant was also revered as an educator and mentor. He taught courses on the Structure of Biomaterials and Polymers in Medicine, among others, at CWRU for 20 years, educating a generation of biomedical engineering students. During his tenure at CWRU, he personally mentored 22 postdoctoral researchers, 27 graduate students, 15 master's students and 54 undergraduate students in his research laboratory. Many of his former students are now research professors, research scientists, and physicians in Cleveland, throughout the U.S., and internationally.

Roger Marchant was born in Birmingham, UK, on March 8, 1951, the son of Eric and Audrey Marchant. He was a competitive fencer who was a member of the English national fencing team in the 1970s. He was also an avid football (soccer) player, who was a life-long supporter of Aston Villa Football Club. He was a devoted father and husband who loved traveling, especially long road trips in his Z28 Camaro. He became a U.S. citizen in 2014. He is survived by his wife of 32 years, Kandice Kottke-Marchant, MD, PhD; two children, Eleanor Marchant (b. 1983) and Alexandra Marchant Lederer (b. 1986); and by his sister Janet Johnson, niece, Samantha Johnson, and parents Eric and Audrey Marchant. A lectureship in biomaterials is being established in his memory at CWRU.

*Originally appeared at: <http://brown-forward.com>*

**Dr. Leo Vroman** passed away February 22 in Fort Worth, Texas at age 98. Dr. Vroman is known to the biomaterials world for his original studies, beginning in 1958, of the behavior of proteins and plasma at interfaces. These attracted great interest in the biomaterials world and culminated in the postulation, by Brash and Horbett, of the Vroman Effect<sup>1</sup>. The consequences of his findings continue to reverberate in studies of thrombogenicity and the immune response to foreign surfaces.

Dr. Vroman published a perspective on this research in 2008, at age 92.<sup>2</sup> The modest title, "Finding seconds count after contact with blood (and that is all that I did)," is supplemented in the abstract by another admission: "It took me about 30 years to discover that." Dr. Vroman further describes this work as "a series of grand mistakes made as a means of reaching for the truth."

Dr. Vroman was known to a wider world as a distinguished poet and artist/illustrator. He was named poet laureate of the Netherlands, having received every honor that art could bestow. His output was impressive: 3,000 poems, collected in 60 volumes. One respected Dutch critic considered him the greatest poet ever in his country. News of his passing was a major news and television event in the Netherlands.

His often whimsical sketches decorated not only his volumes of poetry; they also appeared, with effect, in his scientific articles (see references 2 and 3).

Dr. Vroman gave a series of interviews, including his last days, to reporter Tim Madigan, with permission to publish them. The resultant articles weave additional texture into the layers of his life.<sup>4</sup> They tell a remarkable story of courtship and separation in prewar Holland, incarceration in a Japanese Prisoner of War camp for most of World War II, and being reunited with Tineke, his beloved-intended, in postwar New York. All this before his scientific studies commenced. As he approached life's end he reconsidered his opinion about the Vroman effect, saying that he valued it especially because it was part of scientific knowledge, "there for posterity." And so it is: a recent tally lists 38,000 Google searches of the Vroman Effect.

These scientific, literary, and newspaper publications give unusual insight into the life of this polymath: a gifted, articulate, humble, and very human man.

1. Slack SM, Horbett TA. The Vroman Effect: A Critical Review. In: Horbett and Brash, eds. *Proteins at Interfaces II*, ACS Symposium series 602; 1995:112-128.
2. Vroman L. BioInterface perspective. In: *Colloids and Surfaces B: Biointerfaces* 62. 2008:1-4.
3. Vroman L. Methods of investigating protein interactions on artificial and natural surfaces. In: Leonard, Turitto, Vroman, eds. *Ann NY Acad Sci*. 1987:516:300-305.
4. Madigan T. The epic journey of Holland's beloved poet ends in Fort Worth. 2014. <http://www.star-telegram.com/2014/03/08/5632799/the-epic-journey-of-hollands-beloved.html?rh=1>

*Contributed by:*

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Dr. Edward Leonard, Columbia University

# The Beginning of Two of the Society For Biomaterials (SFB) Traditions

If you have an interesting historical tidbit or photo to share with our members please forward them to: Professor Zhang at [GUIGEN@clemson.edu](mailto:GUIGEN@clemson.edu).

## Historical Flashback



**{ GUIGEN ZHANG }**  
Clemson University

At this year's Society For Biomaterials (SFB) opening ceremony, Professor Guigen Zhang of Clemson gave a brief flashback about the beginning of two traditional events of the SFB – the Clemson Awards and the Biomaterials Bash. Although this part of history is known to many who have been members of SFB for several years, it is unclear to many recent and new members. The positive response to his presentation led to the formation of this new column in the *Forum* that will be continued in future issues.

The SFB was officially formed in 1974 and the first SFB meeting was held at Clemson in 1975, but the first set of awards (known later as the Clemson Awards) was actually given in 1973. Since then, the Society has continued to recognize three distinguished scholars each year with the prestigious Clemson Award for Applied Research (originally called Clinic Research), for Basic Research and for Contributions to the Literature.

The tradition of the Biomaterials Bash started in 1972, three years before the first official SFB meeting. Professor Zhang's brief flashback helped make this part of SFB history more clear and was well appreciated by many attendees, including some pioneers of SFB, previous Clemson Award winners and newcomers.

Before the formation of the SFB, Clemson University hosted an annual gathering, starting in 1969, of biomaterials enthusiasts, known as the International Biomaterials Symposium (IBS) led by Drs. C. William Hall and Samuel F Hulbert. The IBS evolved to become the SFB in 1975 and for several years Dr. Hall would call the annual meeting an SFB and IBS joint meeting. He would call the first and second SFB meetings as the seventh and eighth IBS meetings, respectively.

Thus the Biomaterials Bash actually began at the IBS. Now you know the real story!

## Tracing back to the beginning at Clemson



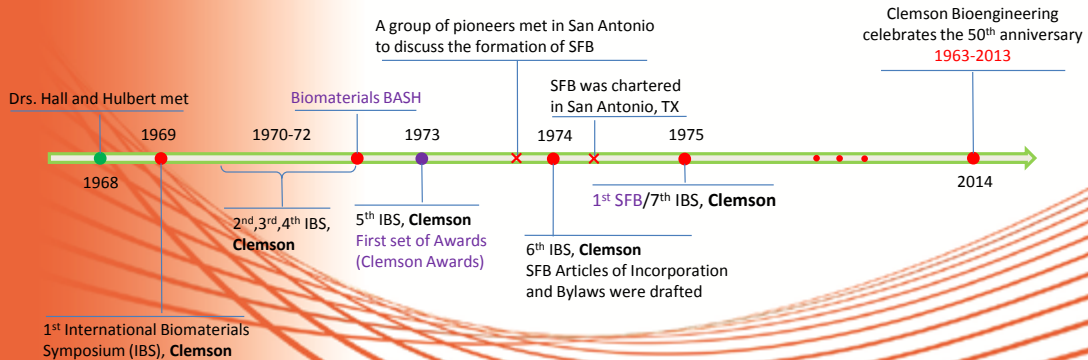
Dr. C William Hall Dr. Samuel F Hulbert

Hulbert: "Dr. C. William Hall is truly the father of the Society." ... he "is a great clinician, a great engineer, and a great humanitarian."

Hall: "Sam, rather than I, should have been receiving all the accolades as the 'grandfather' of our Society. Besides, he's older than I!"



Dr. Hall's sketch of the SFB logo





# Second Annual Biomaterials Education Challenge

BY GREG HUDALLA, DEPARTMENT OF BIOMEDICAL ENGINEERING, UNIVERSITY OF FLORIDA

## FROM THE BIOMATERIALS EDUCATION SIG

This year marked the second annual Biomaterials Education Challenge organized by the Society For Biomaterials Education and Professional Development Committee. The event was made possible by a generous grant from the Burroughs Wellcome Fund, which was given to the Society For Biomaterials (SFB) specifically to support this competition and a regenerative medicine panel discussion. The design competition tasked SFB student chapters from around the country with developing innovative, practical approaches to biomaterials education. Specifically, each SFB student chapter was asked to develop a hands-on educational module designed for a 45-minute middle school science class period.

Overall, the key goals of the education challenge were to create a module that can:

- Demonstrate a fundamental biomaterials concept.
- Describe scientific principles at a level that is understandable to a middle-school audience.
- Feature hands-on components that are easily incorporated into typical middle school science courses.
- Use easily obtainable materials and provide a basis for module sustainability and cost-effectiveness.

This year's competition featured five entries from five different SFB student chapters, which were judged during a special session on the second day of the 2014 SFB Annual Meeting in Denver, Colo. The competition's judges represented a cross-section of biomaterials educators, including junior faculty and senior faculty from multiple universities. The entries covered a range of topics, from controlled release to design of an artificial joint, and were uniformly outstanding. Each had clear educational goals, which were often further refined through direct interaction with middle school educators. In addition to module design, many of the chapters implemented these modules at local middle schools, and provided assessments of module effectiveness in the classroom. Winners were selected based on the potential for educational impact, with an emphasis on innovation, practicality, and likelihood of widespread adoption in middle school classrooms.

Congratulations to this year's winners. A group photo of all the teams and judges together is shown below. SFB is excited to broadly disseminate each of your education modules, and we have high expectations that all will be broadly adopted. We eagerly anticipate the third annual Biomaterials Education Challenge to be held at the 2015 SFB conference. Stay tuned for more information about entering the 2015 Challenge!

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Following a very difficult selection process, the winning teams were:

**First prize (\$2,500):** University of Kentucky, Student contact: Sandeep Ramineni, Faculty Advisor: Dave Puleo

**Second prize (\$1,500):** Case Western Reserve University, Student contact: Christa Modery-Pawlowski, Faculty Advisors: Nicholas Ziats and Anirban Sen Gupta

**Third prize (\$750):** Texas A&M University, Student contact: Kirsten Brink, Faculty Advisor: Elizabeth Cosgriff-Hernandez

**Fourth prize (tie - \$250):** Vanderbilt University, Faculty Advisor: Amanda Lowery

**Fourth prize (tie - \$250):** University of Texas, Student contact: Jeehyun Park, Faculty Advisor: Nicholas Peppas

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### { FIRST PLACE TEAM }

The winning team with session organizer Dr. William Murphy: Front Row (l-r), Dr. William Murphy, Theodora Asafo-Adjei, Paul Fisher, Sandeep Ramineni. Back row (l-r), Bryan Orellana, Nicholas Anderson. Missing from photo: Matt Brown.

BY SUMONA SARKAR

## HIGHLIGHTS OF “MOLECULAR MECHANISMS GOVERNING PROTEIN-SURFACE AND CELL-SURFACE INTERACTIONS” GENERAL SESSION AT THE 2014 SFB CONFERENCE IN DENVER, COLO.

SESSION CO-ORGANIZERS:

Robert A. Latour (Clemson University) and Christopher Siedlecki (Penn State University College of Medicine)

This general session, sponsored by the Proteins and Cells at Interfaces SIG, featured eight oral and nine poster presentations. Highlights for the session included presentations on state-of-the-art experimental methods to probe the orientation, conformation, and bioactivity of adsorbed peptides and proteins, and on molecular mechanisms that mediate the contact activation of proteins on biomaterial surfaces and their influence on thrombus formation and cellular response. Presenters also

addressed molecular mechanisms governing the behavior of stimuli-responsive “smart” materials for the control of protein-surface and cell surface interactions as well as the development and function of artificial platelets for blood transfusion applications and their interactions, with adsorbed protein. Attendees took part in several interesting discussions focused on furthering our understanding of the basic molecular and cellular mechanisms controlling behavior at biomaterial interfaces.

## Industrial News

News & Updates

BY STEVE LIN, INDUSTRIAL NEWS CONTRIBUTING EDITOR



**Stryker** (Kalamazoo, Mich.) recently announced that it will pay about \$120 million, or \$2.22 per share, for **Patient Safety Technologies** (Irvine, Calif.) and its bar code tracking technology meant to prevent medical professionals accidentally leaving sponges and other items inside

of patients post-surgery. Stryker is obviously making a bet that preventing costly operating room mishaps is also good business. Patient Safety Technologies has a proprietary Safety-Sponge System and SurgiCount 360 compliance software. It saw \$14.9 million in revenue during the first nine months of its 2013 fiscal year. According to Stryker, sponges are the most common object retained during surgery, with about 2,300 incidents reported annually at an average cost per incident of over \$400,000.

**Smith & Nephew** (London, U.K.) announced the execution of a definitive agreement to acquire medical device company **ArthroCare Corp** (Austin, Texas) for \$48.25 per ArthroCare share in cash, a total consideration of approximately \$1.7 billion and an enterprise value of \$1.5 billion. “This is a compelling opportunity to add ArthroCare’s technology and highly complementary products to further strengthen our sports medicine business,” Olivier Bohuon, chief executive officer of

Smith & Nephew, stated in a company press release. Smith & Nephew anticipates closing the transaction in mid-2014.

**Baxter International Inc.** (Deerfield, Ill.), which has about 61,000 employees worldwide including some 5,700 in northern Illinois, has announced that it intends to split itself into two individually operated companies in 2015. One is to concentrate on the pharmaceuticals and biotechnology business while the other will retain the firm’s medical devices operations. CEO Robert Parkinson will continue in his role on the medtech side, while Ludwig Hantson, currently president of Baxter’s BioScience unit, will lead the as-yet unnamed biotech and pharmaceuticals company. The biopharmaceuticals operations that will constitute the new company generated about \$6 billion in revenues in 2013.

2013 was not a great year to be in the business of medical technology, according to a recently published report, “Medtech 2013 in Review,” by EP Vantage. “With less money coming in,” the report explains, “large firms are avoiding risky acquisitions of early-stage companies. Venture capitalists are following suit, with most awarding investments cautiously to companies with approved products.” Mergers and acquisitions, the report says, were down only 16 percent in number from 2012, but the total value of those acquisitions totaled \$19.3 billion, which was less than half the amount

spent in 2012. While EP Vantage reports that device makers raised just over \$3.6 billion in venture capital investments in 2013, the MoneyTree Report that Thomson Reuters compiles for PriceWaterhouseCoopers (PwC) and the National Venture Capital Association only counts \$2.1 billion in VC financing rounds in 2013 in their Medical Devices and Equipment category. US Food and Drug Administration (FDA) has its own numbers on how bad it was. The agency granted only 23 Premarket Approvals (PMAs) in 2013, compared with 41 in 2012. AdvaMed says that nearly 40 of its member companies reported that the tax forced a total of 14,000 layoffs, and big reductions in research and development and start-up company investment.

A new study by the **Brigham and Women's Hospital** and **Harvard Medical School** examined what kind of testing has been done on medical devices meant for kids, since an act of Congress incentivized their development seven years ago. The researchers considered the 25 medical devices that were approved by FDA for use in patients age 21 and under between 2008 and 2011. They looked at data from the main clinical trial that was used to get each device approved. According to those data, 11 of the 25 devices were not tested on any patients age 21 and under. Only four of the devices had been tested on patients under age 18. "Children are not simply small adults, and a device found to be safe and effective in adults may have a very different safety and effectiveness profile when used in a pediatric population," said fellow Thomas J. Hwang, one of the study's authors.

The production of blood on an industrial scale could become a reality once a trial is conducted in which artificial blood made from human stem cells is tested in patients for the first time. **Professor Marc Turner**, the principal researcher, has devised a technique to culture red blood cells from induced pluripotent stem (iPS) cells – cells that have been taken from humans and 'rewound' into stem cells. Biochemical conditions similar to those in the human body are then recreated to induce the iPS cells to mature into red blood cells – of the rare universal blood type O-negative. This is the first time anybody has manufactured blood to the appropriate quality and safety standards for transfusion into a human being. There are plans in place for the trial to be concluded by late 2016 or early 2017.

While it produces less than one microwatt of power, researchers have figured out how to harvest electricity from human saliva. Using the oxygen in the air as the cathode and graphene as the anode, scientists at the **King Abdullah University of Science and Technology** (Thuwal, Saudi Arabia) and **Penn State University** (State College, Penn.) have harnessed bacteria into a 25- $\mu$ l microbial fuel cell (MFC). Although saliva does not have the type of bacteria necessary for the fuel cells, it can

be inserted in the device by a manufacturer. As the bacteria digest organic material in the saliva, they give off electrons that are deposited on the graphene anode for harvesting. The researchers said they had tried using a carbon cloth anode, but found that graphene was 40 times more efficient. One potential use for their power source might be as a fertility signaling device, small enough to be attached to a tooth, that could predict a woman's ovulation from changes in her saliva's electrical conductivity, which is known to plummet five days before ovulation.

A paper published by three researchers at the **Korea Advanced Institute of Science and Technology** (KAIST; Daejeon, Republic of Korea) has been generating considerable buzz in the wearables space. The scientists have formulated and screen printed thermoelectric generators on a flexible glass fabric. The glass fabric generator produces an order of magnitude more electricity than previous flexible thermoelectric generators and is said to have a bending radius as low as 20 mm. The assembled generator is sufficiently flexible to bend 120 times without losing its electrical generation capabilities, the researchers say.

**Aastrom Biosciences Inc.** (Ann Arbor, Mich.) announced that it has entered into a definitive agreement to acquire Sanofi's **Cell Therapy and Regenerative Medicine** (CTRM) business for a purchase price of \$6.5 million, with \$4 million payable in cash at closing and \$2.5 million payable in the form of a promissory note. Through the CTRM acquisition, Aastrom is acquiring global commercial rights to three marketed autologous cell therapy products. Carticel (autologous cultured chondrocytes) is an autologous chondrocyte implant (ACI) currently marketed in the United States for the treatment of articular cartilage defects. Epicel (cultured epidermal autografts) is a permanent skin replacement for full thickness burns greater than or equal to 30 percent of total body surface area, and is marketed in countries around the world. MACI (matrix-induced autologous chondrocyte implant) is a third-generation ACI product currently marketed in the European Union. Revenues of those three products were \$44 million in 2013. Aastrom will also acquire global manufacturing and production centers located in the United States and Denmark.

**Zimmer Holdings Inc.** (Warsaw, Ind.), a maker of artificial hips and knees, agreed to acquire rival **Biomet Inc.** (Warsaw, Ind.) for \$13.4 billion to become the second-largest company in the rebounding market for treating muscle and orthopedic injuries. The purchase will end a planned initial public offering by closely held Biomet's parent, Biomet Group Inc. It's the latest in a spate of deals, led by Novartis AG and GlaxoSmithKline Plc, that show medical companies are adding depth and expertise as the focus on cost and



innovation in health care intensifies. The acquisition will help Zimmer take on Johnson & Johnson, the No. 1 manufacturer in the now-growing \$45 billion market, and Stryker Corp. Sales and profit have started to accelerate after the recession led patients to delay elective surgeries and insurers to crimp prices.

The **Chinese government** and **The China Food and Drug Administration (CFDA)** have been working on significant revisions to their medical device laws and regulations,

some of which will go into effect on June 1, 2014 and others throughout the year. The revised regulations call for increased compliance with good manufacturing practices (GMP) for manufacturers and good supply practices (GSP) for distributors. Government regulations and systems will be strengthened to monitor device recalls and adverse events, trace high risk products and re-evaluate devices. Penalties for manufacturers and distributors that are not following the applicable regulations have been expanded and could include criminal charges.

## Education News

### INDO-US PROGRAM ON CELL TARGETED DIAGNOSTICS AND THERAPY USING NANOMATERIALS

Shantikumar Nair, Antonios G. Mikos, F. Kurtis Kasper, Lakshmi S. Nair, Shireen Vali, Mark E. Wong, Sarah Heilshorn, Manzoor Koyakutty, Deepthy Menon and Krishna Prasad Chennazhi

In 2010, Amrita University in Kochi, Kerala, India; Cellworks, Bangalore, India; Rice University, Houston, Texas; University of Texas School of Dentistry; UConn Health, Farmington, Conn.; and Stanford University, Calif., began a substantial collaboration with the support of the Indo-U.S. Science and Technology Forum (IUSSTF) on cell-targeted diagnostics and therapy using nanomaterials. IUSSTF is a non-profit organization established in 2000, under an agreement between the governments of India and the U.S., to foster Indo-U.S. bilateral collaborations in science, technology, engineering, and biomedical research through substantive interaction among government, academia, and industry. The principle objective of IUSSTF is to “provide opportunities, exchange ideas, information, skills, and technologies, and to collaborate on scientific and technological endeavors of mutual interest that can translate the power of science for the benefit of mankind at large.”

The foundation of the collaborative effort was the recognition that nanomaterials in many structural forms have specificity for cells and that this behavior could be exploited for diagnostics and therapy, including the use of targeted structures in scaffolds that can tune the properties of tissues generated from them. Some of the areas of focus were cancer diagnostics, cancer therapy, and regeneration of complex tissues and quantification of directed regeneration based on targeted flow of factors in a milieu using micro-fluidics. Although six institutes officially were part of the collaboration, the Rice University effort included contributions from another institute at the Texas

Medical Center, MD Andersen Cancer Center, Houston, Texas. Thus the overall collaboration grew to a seven institutional collaboration. Amrita was the lead university led by Professor Shantikumar Nair, director of the Centre for Nanosciences and Molecular Medicine at Amrita University, Amrita Institute of Medical Sciences and Research Centre, India. In the U.S. the lead PI was Professor Antonios G. Mikos, Louis Calder Professor of Bioengineering and Chemical and Biomolecular Engineering at Rice. The other investigators were Dr. Mark E. Wong (DDS), Chair of the Department of Oral and Maxillofacial Surgery of the University of Texas School of Dentistry; Professor Sarah Heilshorn from Stanford University; Dr. Lakshmi S. Nair from UConn Health; Dr. Shireen Vali from Cellworks; Dr. F. Kurtis Kasper from Rice University; Dr. Manzoor Koyakutty, Dr. Krishna Prasad Chennazhi and Dr. Deepthy Menon from Amrita. Dr. Jorge Cortes (MD) of MD Andersen Cancer Center also contributed to the collaboration.

Significant accomplishments included development of nanoscale layered structures for bone tissue engineering, combination of micro- and nanostructures to enhance tissue regeneration, development of nanoribbons of recombinant elastins, microfluidic setup to quantify factor gradients and how it affects tissue regeneration from nano-sources in the form of factor-encapsulated nanoparticles, use of gel-based nanostructures for drug delivery to oral giant-cell cancer, use of protein nanoparticles for drug delivery to overcome drug-resistant leukemia, osteochondral tissue engineering using nanoparticle in nanofiber structures

# Education News *(continued)*

and nanocomposite gels, computational systems biology to understand the interaction of nanoparticles and factors on intra-cellular pathways of action. These collaborations have significantly raised new avenues of collaborations of both a fundamental and applied nature.

The center has facilitated more than 14 exchange visits of faculties and doctoral students between India and the U.S. Graduate students from Rice University, UConn Health Center and Stanford University visited Amrita University, India, during 2011-2013. The students were trained in electrospinning of multiscale fibers, processing of fibrin nanofibrous materials, electrospinning of nanoparticle in nanofiber polymers with and without drugs and electrospinning of recombinant protein nanomaterials. Likewise, students from Amrita visited all of the above three universities in the U.S. At Stanford University, training in microfluidics experiments to study the effect of growth factor gradients took place, while at Rice, Amrita students addressed the problems of biomaterial-based drug delivery design for treatment of giant cell oral carcinoma and also were trained in in vivo studies using Amrita's layered scaffolds for bone tissue engineering. At UConn Health, the visiting student was trained in human embryonic stem cell culture and methods to develop injectable hydrogels as cell delivery vehicles to support tissue regeneration. Students also were introduced to MD Andersen Cancer Center for planning nanomedicine development, which may lead to a strong future collaboration.

The participating institutions thank the Indo-US Science and Technology Program for providing the funds for this program and, more important, for recognizing the wisdom of such multi-institutional collaborations in the cutting-edge interdisciplinary areas of engineering, biology, and materials sciences. The interactions resulted in a dozen publications and one potential patent, pointing to the promise of such collaborations between the two countries to foster exchange of talent and expand the educational opportunities for their students.



Dr. F. Kurtis Kasper, Professor Antonios G. Mikos, Professor Shantikumar Nair and Dr. Mark E. Wong

## DEPUTY DIVISION DIRECTOR DIVISION OF MATERIALS RESEARCH

*National Science Foundation (NSF), Arlington, Va.*

The Directorate for Mathematical and Physical Sciences (MPS) announces a nationwide search to fill the position of Deputy Division Director, Division of Materials Research (DMR). Appointment to this Senior Executive Service position will be on a career basis with a salary range of \$157,000-\$174,100. Information about the Division's activities may be found at <http://www.nsf.gov/materials>.

The successful candidate will possess an established record of significant achievement in research administration as well as leadership responsibility in academe, industry, or government. In addition to having a strong record of research and education accomplishments within his or her technical communities, the Deputy Division Director must be experienced and competent in technical, financial, and administrative management. He/she must work well with people, be an effective communicator, and act as a mentor to continuously develop the diversity of talents and skills of his or her colleagues at all levels.

Announcement DMR-2014-0003, with position requirements and application procedures, is located at <https://www.usajobs.gov/GetJob/ViewDetails/371147100>.

Applicants may also obtain the announcement by contacting the Executive Personnel Staff, 703-292-4345. Hearing impaired individuals may call TDD 703-292-5090. Applications must be received by the closing date.

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# National Student Chapter Report on the 2014 Annual Meeting

## Student Chapter News

BY NATIONAL STUDENT CHAPTER PRESIDENT JORDAN GILMORE, CLEMSON UNIVERSITY



Student chapter representation and involvement at the recent Society For Biomaterials (SFB) Annual Meeting was another huge success, as student members from across the country convened in Denver, Colo. to present exciting research, network with industry and academic professionals,

and fellowship with colleagues. Student highlights from this year's meeting include the student participation in the SFB Business Plan Competition, Student Education Design Competition, Student Chapter Business Meeting, and the Student Mentoring Luncheon.

Students participating in the Business Plan Competition truly embodied the theme of the meeting, "Pioneering the Future of Biomaterials," by presenting their novel and innovative concepts to a group of judges holding industrial, entrepreneurial, and academic experience. Several student chapters were represented, including students from Clemson University, University of Pittsburgh, and Vanderbilt University. The competition was spirited as each team discussed the scope of their technology, market opportunities, and business projections. In the end, a technology entitled MemMesh took home the first place prize, with the audience-based award going to the Metastatic Precision technology.

The second annual Student Education Design Competition also showcased student work. Students representing chapters from across the Society presented interactive outreach modules focusing on the dissemination of biomaterials knowledge to younger students. A variety of modules were displayed ranging from a focus on the structure and function of hydrogels to bone fixation demonstrations.

The annual Student Business Meeting was certainly productive as members of student chapters from Duke University, University of Texas at Austin, University of Florida, University of Connecticut, North Carolina State University, Clemson University, and the University of Washington discussed best practices for putting on Biomaterials Days at their respective institutions and strategies for recruiting new members into their chapters. A number of ideas for the upcoming year and next

annual meeting were offered, such as funding assistance for chapters wanting to collaborate on professional development events and the highlighting of a Student Member of the Month similar to the award given monthly on the SFB website for general members.

The highlight of the meeting from a student standpoint was easily the Student Mentoring Luncheon where Paul Attar, President of Bridge PTS, spoke to attendees regarding tips on successful navigation through an industry career. Students also had the chance to connect with industry and academic professionals from across the Society, gaining insight into ways to maximize their educational experience and leverage their skills for a smooth transition into the professional domain. The event allowed students to communicate their thoughts and concerns to individuals who had an earnest desire to see the students succeed. Many students considered this event to be one of the most helpful of the meeting because of the opportunity to expand their personal networks by speaking with such esteemed mentors.

The recent annual meeting added much value to the students who attended and participated. But students not only received from the conference, they also gave in tremendous ways through the presentation of their research. As student chapters continue to grow, students will continue to grow the Society through their attendance and research. The many positive outcomes from this meeting and the fresh ideas for the new direction and interaction bode a bright future for the student members of the SFB.



{ TEAMS AND JUDGES FOR 2014 BIOMATERIALS EDUCATION CHALLENGE AT THE ANNUAL MEETING IN DENVER, COLO. }

BY CARL G. SIMON JR., GOVERNMENT NEWS CONTRIBUTING EDITOR

### FOOD AND DRUG ADMINISTRATION HOSTS WORKSHOP ON STANDARDS DEVELOPMENT FOR CELL THERAPIES



On March 31, 2014, the U.S. Food and Drug Administration (FDA) hosted a workshop entitled “Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine” at the FDA campus in White Oak, Md.

The potential for tissue engineering and regenerative medicine (TERM) to have broad and far-reaching impact in many aspects of medicine has generated intense interest and the need for standards to advance the field is becoming widely accepted. Many organizations that actively produce standards for TERM were represented, including: FDA, NIH, ATCC, NIST, USP, FACT, AABB, TERMIS, ISCT, ASTM, ARM, ICCBBA and ISO. The goal was to get all the active groups in the same room so that collaborations could be formed and to explore opportunities for synergy. The broad array of TERM standards activities was overwhelming and the need for better coordination was clear. A TERM standards network was forged that can help to facilitate harmonization and involvement. The workshop announcement can be found here:

<http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm364114.htm>

A copy of transcripts for all FDA Biologics workshops can be found here:

<http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>

### THE FOOD AND DRUG ADMINISTRATION’S MSC CONSORTIUM

The U.S. Food and Drug Administration (FDA) has received hundreds of applications for clinical trials using mesenchymal stem cell (MSCs). However, there is wide variability in how MSCs are prepared and characterized, making it difficult for stakeholders to understand what to measure to predict safety and effectiveness of MSC-based products. In order to address this concern, the FDA has formed an internal consortium whose goal is to improve characterization of MSC-based medical products by discovering MSC characteristics that are more predictive of their clinical effectiveness and safety than those currently in use. The consortium uses MSCs derived from human bone marrow and is developing a wide range of quantitative methods to measure their properties. These measurements include colony forming unit assay, *in vitro* differentiation assays (osteogenic, chondrogenic, and adipogenic lineages), proteome measurements, transcriptome measurements, epigenome measurements and *in vitro* immunogenic assays. The current outcomes from the consortium activities can be found in the list of articles below. Please contact Steve Bauer at FDA ([steven.bauer@fda.hhs.gov](mailto:steven.bauer@fda.hhs.gov)) for more information.

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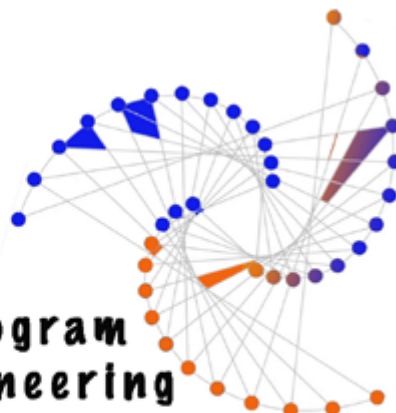
Nazarov C, Lo Surdo JL, Bauer SR, Wei C-H. Assessment of immunosuppressive activity of human mesenchymal stem cells using murine antigen specific CD4 and CD8 T cells *in vitro*. *Stem Cell Research & Therapy*. 2013; 4:128.

Mindaye ST, Ra M, Lo Surdo JL, Bauer SR, Alterman, MA. Global proteomic signature of undifferentiated human bone marrow stromal cells: Evidence for donor-to-donor proteome heterogeneity. *Stem Cell Research*. 2013; 11: 793-805.

Lo Surdo JL, Millis B, Bauer SR. Automated microscopy as a quantitative method to measure differences in adipogenic differentiation in preparations of human mesenchymal stem cells. *Cytotherapy*. 2013; 15:1527-40.

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Lo Surdo, JL, Bauer, SR. Quantitative approaches to detect donor and passage differences in adipogenic potential and clonogenicity in human bone marrow-derived mesenchymal stem cells. *Tissue Engineering: Part C*. 2012; 18:877-889.



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