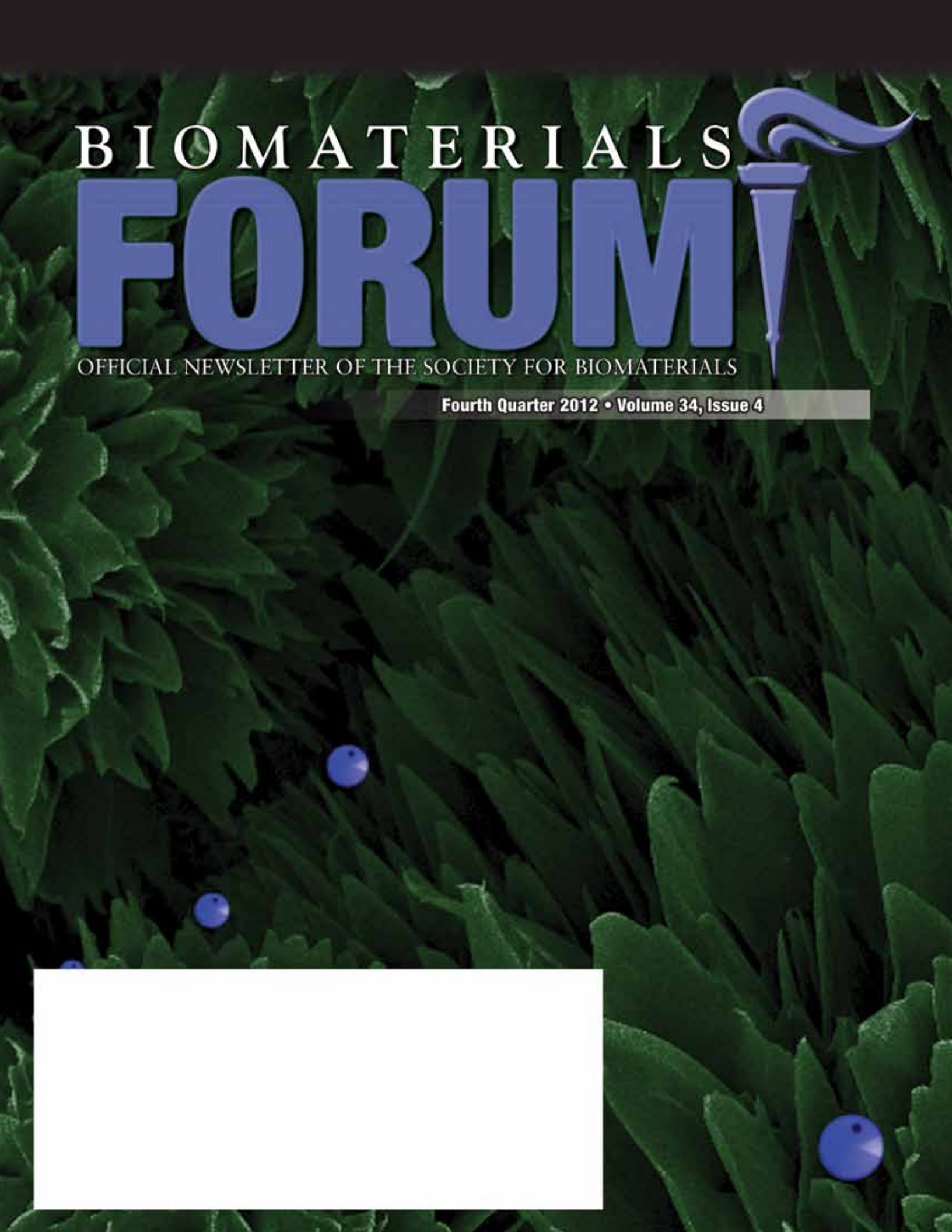

BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

Fourth Quarter 2012 • Volume 34, Issue 4

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BIOMATERIALS FORUM

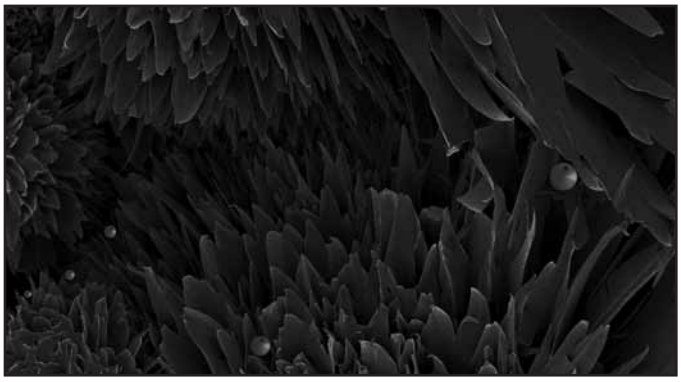
The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 34, Issue 4

Special Interest Group Reporters

BIOMATERIALS FORUM

Fourth Quarter 2012 • Volume 34, Issue 4

Departments



On the cover: Nano-grass: In an aqueous media, self-assembly of low-molecular-weight amphiphilic agent selected from the United States FDA's generally recognized as safe (GRAS) list was used to produce this hydrogel that can entrap and release anti-inflammatory agents in response to enzymes that are present during inflammatory conditions. This is a scanning electron micrograph of the dehydrated xerogel that has been color enhanced. The blue dots represent incorporation of anti-inflammatory agents. These enzyme-responsive
hydrogels may find application as next-generation biomaterials for the treatment of proteolytic disease.

Contributed by Jeffrey Karp and Praveen Kumar Vemula
Center for Regenerative Therapeutics
Department of Medicine, Brigham and Women's Hospital
Harvard Medical School

From the Editor

Greetings fellow biomaterials scientists,

In this issue we have assembled a selection of interesting articles about biomaterials technology, biomaterials industrial news, biomaterials education and Society For Biomaterials member news. If you are interested in biomaterials, you're reading the correct news magazine!

Here are the highlights of this issue:

- The University of Memphis Biomaterials Day 2012 was a well-attended event with participation from 12 different universities. A description of the speakers and activities can be found on page 18. Congratulations to the student chapter for the initiative that made this Biomaterials Day a success, and congratulations to the new student chapter formed at the University of California, Los Angeles, under the guidance of Prof. Howard Winet.
- A letter of introduction from our new Member-at-Large, Nick Ziats, with announcements of new awards and professional relocations of various SFB members, is found on page 6.
- Learn about issues with *in vitro* testing of Mg-based alloys for orthopaedic applications that complicate the analysis, and learn how to avoid them on page 9. Without standardized methods it is difficult to compare any test results. If you're interested in standardized testing, The American Society of Testing and Materials will host a workshop next spring about tissue engineering scaffolds. Read more on page 12.
- The education column discusses how intellectual property management in the classroom can be both stimulating and stifling. This article is timely, given the continuing expansion of biomedical engineering departments into the realm of commercialization. Read more on page 8.
- Deciding where to put your research efforts is a critical question–read the Industrial News section on page 15 to find out the international statistics for burgeoning diabetes populations that continue to drive biomedical product development. Did you know the affordable medical care act contains a 2.3 percent medical device excise tax? Find out how some companies are reacting and attempting to change legislation in the Industrial News section. China's healthcare industry continues to expand with plans for a new International Medical Service Area in Beijing.
- Some helpful time management tips can be found in the book review section on page 13.

I hope you enjoy this issue of the *Biomaterials Forum*. If you have suggestions for content to be used in an upcoming issue, please send it to me at Lkuhn@uchc.edu.

Best wishes,

Lisa Kuhn

University of Connecticut Health Center
Biomaterials Forum Editor

From the President

I have just returned from our 2012 Fall Symposium "Grand Challenges in Biomaterials" held in New Orleans, and would like to give a big shout-out to Dr. Monty Reichert, Program Chair, and his committee for a fantastic job! The meeting capitalized on different meeting program elements that engaged leaders (including this year's Clemson awardees) and innovators at the beginning of a session followed by typical, more project-focused, 15-minute or rapid fire oral presentations. This format enabled participants to get a great primer on the current state of a particular biomaterials area as well as identify key directions and opportunities in meeting today's biomaterials and clinical challenges. This format worked particularly well with the focused and intimate aspect of the meeting. Many attendees commented to me that this was a major benefit in meeting and networking with the many keynote and invited speakers and other attendees. It seems to me that our ability to create environments for supporting and advancing professional networking activities is one of our Society's great strengths and benefits.

It is anticipated that we will see many of these activities being initiated during the 2013 SFB Annual Meeting in Boston– stay tuned, and make plans to attend the 2013 meeting!

In the last issue of the *Forum*, I was able to report to you on efforts of the 2011-2012 Long Range Planning Committee in revising/developing mission, vision, goals and plans for the Society. These documents are now posted on the SFB website for member review and input. Because of the importance of our meetings in providing a resource and forum for biomaterials information and in professional networking, these activities are major components of many aspects of the Society's draft goals and long range plans. Indeed, the special and non-traditional meeting format of the 2012 Fall Symposium and the enhanced professional networking opportunities it provided may be viewed as already advancing on several of the goals and activities outlined in the draft plan. In addition, during the SFB Board and Council Meetings held at the symposium, many other initiatives to advance and promote our Society were discussed and/or are being developed that are also a direct consequence of the draft long range plan. These include, but are not limited to, launching a biomaterials design competition by the Education and Professional Development Committee, highlighting the local impact of our meetings and sessions via local press releases, a re-vamping of the SFB website by the Publications Committee, and capturing and disseminating information from special programs to enhance the long-term impact of the meetings beyond the meeting dates by the Program Committee. It is anticipated we will see many of these activities initiated during the 2013 SFB Annual Meeting in Boston—stay tuned, and make plans to attend the 2013 meeting!

Finally, I would like to thank Anthony Celenza and his team at AH, the management group that helps run our Society, not only for the excellent management and success of the 2012 Fall Symposium, but for his many years (since 2004) in organizing, growing and making sure our meetings run smoothly! Having worked as the then Program Chair with Anthony during the 2005 annual meeting, I can attest to his professionalism, creativity, resourcefulness and witty style that have made the meetings great and fun! Anthony's role at AH is changing, and changing in a good way, and, as such, he will be leaving as SFB's meeting manager. Join me again in thanking Anthony for his great service to the Society. I want to also take the opportunity to warmly welcome Cheryl Gallagher as our new meetings manager. Cheryl has worked closely with Anthony and she was at our fall meeting, so she is well informed and equipped to take us on and to new successes! Welcome, Cheryl, and we look forward to a great 2013 Annual Meeting in Boston with you!

Joel D. Bumgardner, PhD
University of Memphis
President, Society For Biomaterials

Staff Update

Leslie Clark, Assistant Executive Director

Hello from Society For Biomaterials headquarters! The Society's Board of Directors and governing Council met October 3, 2012, in New Orleans and shared the following updates on committee activity:

Awards, Ceremonies and Nominations – Chair Lynne Jones

The committee is reviewing the officer and award nominees and will be presenting them for Council approval before announcing the results in the first quarter 2013 issue of *Biomaterials Forum*. It was clarified that the committee has the right and responsibility to ensure that a qualified slate of officers and award nominees is presented, as the bylaws state that soliciting nominees is part of the committee's duties. Members' interests are well represented as the Awards, Ceremonies and Nominations Committee members are elected by the membership.

Bylaws – Chair Jiro Nagatomi

The committee has been asked to work with the Membership and Long Range Planning Committees to find ways to remove barriers to membership categories and recommend any amendments to the bylaws necessary to accomplish this. Council has agreed an interest in the biomaterials field and a desire to join SFB should be the criteria for membership. Checks and balances are provided by the Awards Committee, which screens nominations to prevent a new member from being allowed on the officer or awards slates before having proved him/herself.

Education and Professional Development – Chair William Murphy

The committee is developing a new Biomaterials Education Challenge for competing student chapters to create study modules aimed at eighth grade science students. Research has shown eighth grade as the best time to introduce information about career possibilities. SFB students will design outreach materials including instructions to eighth-grade science teachers, materials for handouts and ideas for introducing the subject of biomaterials. The chapters will then be encouraged to work with local schools in implementing the study modules. Details on the competition, including any budgetary impact, are being completed with the goal of announcing it before the annual meeting in Boston. In other news, the committee reviewed applications for Biomaterials Days grants and recommended five applicants to Council: Rice/Texas A&M/Univ. of Texas; Univ. of Florida; Univ. of Kentucky/Purdue/Case Western; Univ. of Memphis/Vanderbilt; and Univ. of South Dakota. These five were approved to receive the 2013 Biomaterials Days grants. Also, the response to the Women's Luncheon and Student Luncheon scheduled for the Fall Symposium was excellent, with all available seats sold out, and both events will be repeated in some form in Boston.

Finance – Chair David Kohn

There is more than half a year's operating expense in the Long Term Reserve Fund, and a similar amount is in the operating reserve. SFB is financially healthy. Though 2012 is a World Congress year, which means a negative budgeted net income, 2013 budget planning is underway and will endeavor to ensure the Society's continued success.

Long Range Planning – Chair Antonios Mikos

The mission and vision statements, as well as related goals and action items, have been posted on the homepage www.biomaterials.org for members' review and comment. The final draft will be voted upon at the annual meeting in Boston.

Meetings – Chair Joel Bumgardner

Proposals for potential 2014/2015 meeting sites have been reviewed, but more discussion is needed before a final decision is made. It was noted that attendance from members in industry has declined slightly. The reasons for this could be associated with fewer companies sending their employees to educational meetings. Companies seem to only have enough money to send people to one meeting, and some companies are sending people to meetings with a more targeted focus, such as cardiovascular or orthopedic meetings.

Membership – Chair Horst Von Recum

The current membership number stands at 925, with 122 new members having joined since November 2011. Membership figures are lower, and were expected to be lower, because it is a World Biomaterials Congress year. Ideas to increase membership include asking student chapters to have Biomaterials Days and hold a membership drive at the same time (possibly with the Board providing an incentive) and requiring organizations who want SFB meeting endorsement to make SFB membership applications available. Banner ads were placed on the TERMIS, MRS and BMES websites in the months leading up to the Fall Symposium in hopes of attracting more attendees and interest in joining.

Program – Chair Tim Topoleski

2012 Fall Symposium: The World Biomaterials Congress in China reduced available travel budgets for some institutions, so Fall Symposium attendance was slightly lower than had been hoped. Though budget goals for exhibits, sponsors and advertising were met, some of the larger exhibitors that participated in the World Congress in China could not afford to attend in New Orleans. However, they and many others have already said they plan to exhibit or be a sponsor at the annual meeting in Boston. These contacts will be followed up before the end of the year.

2013 Meeting: The website and prospectus were online by late October. Because of the World Biomaterials Congress, SFB is about a month behind its normal meeting timetable. For example, this year the abstract submission deadline was November 30.

Publications – Chair Alan Litsky

Social Networking: SFB's LinkedIn site has 2,700 members, and the Facebook fan page has 650 "likes." Efforts will be made to give more advance publicity to the meeting in Boston by using these and other social media.

***JBMR-A* (Editor Jim Anderson):** As of August 19, 706 manuscripts were submitted and 275 published. An anti-plagiarism software, iThenticate (provided by Wiley), is being used to find potential plagiarism cases but the software does not identify plagiarism in data, tables, figures etc. This issue needs to be addressed.

***JBMR-B* (Editor Jeremy Gilbert):** Anti-plagiarism software is now being run on all submissions. When self-copying or other copying is found, the manuscript is rejected and an explanation is sent with an admonition not to do it again.

One Hundredeth Volume of *JBMR* (Jim Anderson and Jeremy Gilbert): Twenty-five articles published since the inception of *JBMR* in 1965 have been identified for inclusion in the 100th volume, and a short foreword introducing them has been written by the editors.

***Biomaterials Forum* (Editor Liisa Kuhn):** To continue to provide content of technical interest, more articles written by SFB members are needed. The valuable content of previous issues of the *Forum* is currently not searchable. Research is being done on what the cost and process would be to have past issues indexed. A simple search function would be sufficient. This would build on the accessibility to Society-based information, which increased when meeting abstracts were made searchable. More interviews and "Where are they now?" articles are planned.

Website (Editor Tom Webster): Several website development proposals were considered and a contract is being drawn up with the company selected. Development of a new Society website will begin shortly and is expected to be completed in 2013.

Book Series (Editor Jeffrey Hubbell): The first book will be going to the publisher at the end of this year with three more to be sent next summer. Care is being taken to create consistency and branding so all are readily identifiable as SFB books. Volunteers are still being sought for more book series.

***Biomaterials Bulletin* (compiled by Multibriefs):** A new SFB e-newsletter called *Biomaterials Bulletin* has launched. This product searches out and compiles relevant articles about the field. The first issue was sent to more than 5,000 contacts, former and current members and non-members who have attended SFB meetings. It contained a notice that all future issues will be sent to members only and encouraged readers to join or renew their SFB membership in order to continue receiving the e-newsletter. Ads are being sold, and it is anticipated this will become a revenue source for the Society.

Abstracts: Omnipress will be providing SFB's abstract collection site for the 2013 meeting. They have been publishing the annual meeting transactions for some time now, and the new abstract website will be much more user-friendly and robust once members have adjusted. The learning curve is expected to be short and simple.

Liaison – Chair David Puleo

A new form for liaison subcommittee special project proposals was developed, and two proposals have been submitted. One, a proposal to conduct a joint half-day symposium on the day the GRIBOI and SFB meetings overlap in Boston was approved by Council. It will be held at SFB's meeting site on the morning of Wednesday, April 10. The AIMBE congressional briefing in June was very good, with interest expressed in supporting under-represented minorities. Research for America has a lot of information regarding government affairs, including letter templates. A link will be posted on the SFB website.

National Student Chapters – President-elect Beth Pollot

The Student Mentoring Luncheon was sold out once again, and it is a valuable event at the Society's meetings. New student chapters were added in 2012, for a total of 19 chapters now involved. Several more universities have inquired about forming or re-activating chapters. Biomaterials Days continue to be important chapter events, which have helped educate students about the field of biomaterials.

Special Interest Groups – Representative Jeff Schwartz

The STAR award process was changed this year to allow for SIG co-sponsorships of awards. This idea came from the SIG officers and proved successful. Some minor changes in the process have been recommended for next spring to make it run more smoothly. A monthly e-newsletter, *The SIGnal*, is sent to all SIG members to inform them of upcoming events, deadlines, and provide them with timely information. SIG officer elections will be taking place soon, for terms running 2013 – 2015.

If you have any questions, require any information or have suggestions for improved services, please feel free to contact the Society's headquarters office:

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Member News

Nicholas P. Ziats, PhD, Society Business and Membership News Contributing Editor

I am the current Member-At-Large for the upcoming year, and I am the voice for the Society's members. The Member-At-Large serves the Society in many capacities, including serving on the Society for Biomaterials Board of Directors as well as Council. Therefore, I can directly convey any information/ concerns to these governing bodies from you. In addition, the Member-At-Large serves on the Program and Meetings committees so that members may have input into the most current plans as well what happens in the future. The recent meeting in New Orleans in October was exceptional due the outstanding program put forth by **Monty Reichert, Ph.D.,** from Duke University. I'm sure the meeting in 2013 in Boston, chaired by **Tim Topoleski, Ph.D.,** from the University of Maryland, will be just as exciting. Please send me your thoughts for this upcoming meeting.

It is an honor to have been selected for the position of Member-At-Large, and I am willing to serve as an active participant for the Society's members. Having served on the Council in recent years, I have seen the Member-At-Large position become more important on the Board and Council, as well as to our Society. In my vision statement over a year ago, I mentioned a few things I felt were important to the Society. For example, having served as Membership Chair for three years, when our membership numbers were declining, we tried creative ways to improve it. We increased our Student Chapters from a few to the present 19, and they are more active within the Society. Also, having recently served as Program Chair for the Orlando meeting in 2011, I evaluated our survey results and heard a number of positive and negative aspects about the meeting as well as the Society and how both can be as improved. I would encourage you to continue to express your concerns, as well as positive aspects, to me, as I can relay them to the Board and Council. The role of the Member-At-Large should be as an active participant in the Society, as the most recent Members-At-Large have done, and I hope I may do this for you. I have sent out an e-mail (from the Society headquarters) asking for any input, and I received a number of responses. I will report these in this issue as well as upcoming ones. If I may, I will remind you quarterly so I can continue to report on the outstanding achievements from our members. I look forward to the challenge of developing new ways to better meet the needs of our Society through discussions with you. You can contact me by e-mail (Nicholas.Ziats@case.edu) or by telephone at (216) 368-5176. Here are some recent outstanding achievements by our members:

The role of the Member-At-Large should be as an active participant in the Society, as the most recent Members-At-Large have done, and I hope I may do this for you.

James M. Anderson, M.D., Ph.D., has been selected by Case Western Reserve University as a Distinguished University Professor, recognizing his outstanding contributions as a full-time, tenured professor with an exceptional academic record of research, scholarship, teaching and service. This title is the highest honor bestowed upon professors at Case Western Reserve University. As a Professor of Pathology, Macromolecular Science and Biomedical Engineering, Dr. Anderson has spent the last 44 years at Case Western Reserve actively engaged in research, teaching and service that have bridged both medicine and engineering. A member of the Institute of Medicine of the National Academy of Sciences, Dr. Anderson is a sought-after consultant to the Federal Drug Administration and NIH as well as medical device and pharmaceutical companies. He has won numerous national and international awards, including an honorary degree from the University of Geneva, the 2005 Elsevier Gold Medal, the 2006 Chugai Mentoring Award from the American Society of Pathology and a Case Western Reserve University School of Medicine Distinguished Alumnus Award in 2007. He is a member of the Association of American Physicians and a fellow of the American Association for the Advancement of Science. Among his many contributions to the field of biomaterials are his well-known studies on inflammatory and foreign body giant cell reactions with materials, tissue/materials interactions, cellular degradation of polyurethanes and recent development of a microchip implant that administers medication according to directions delivered wirelessly from outside the body. School of Medicine Dean Pamela B. Davis had this statement about Dr. Anderson: "His students are distinguished, independent scientists, and his collaborators are the who's who of American medicine—and his own work is stellar and a driver of today's medical advances." Above all his personal accomplishments, Dr. Anderson is most proud of the students who have come through his laboratory and what they have achieved. He states, "I expect my students in my laboratory to collaborate. I set up projects so that's what occurs… because when they leave the sheltered environment of the university, they're going to have to communicate and collaborate. That's reality; that's real life."

Barbara D. Boyan, Ph.D. will become the fourth dean of the Virginia Commonwealth University School of Engineering January 1, 2013. Currently, Dr. Boyan is an Associate Dean for Research and Innovation in Georgia Tech's College of

Engineering. She also holds an endowed chair in Tissue Engineering and is a Professor of Biomedical Engineering at both Georgia Tech and Emory University. Dr. Boyan is a fellow of the American Association for the Advancement of Science and in the American Institute of Mechanical and Biomedical Engineering. She was elected this year to the National Academy of Engineering, one of the national academies, and inducted into the Fellows of the World Congress of Biomaterials. President Michael Rao of VCU said in a statement, "…Bringing someone of Dr. Boyan's national stature, particularly given her standing in the National Academy of Engineers, signals VCU's commitment to engineering and its move toward becoming one of the nation's great research universities."

Jeffrey R. Capadona, Ph.D., an Associate Professor of Biomedical Engineering at Case Western Reserve University, recently received a Presidential Early Career Award for Scientists and Engineers (PECASE), one of the highest honors the U.S. government bestows upon promising scholars beginning their careers. This honor is bestowed upon the nation's 96 most promising young scientists. President Barack Obama presented Dr. Capadona with his award at the White House this past July. Dr. Capadona's work in biomaterials research is in neurologic disease and implants, specifically developing fabrication techniques that produce biologically inspired polymer nanocomposites that change from rigid to flexible and vice-versa, depending on cues from the environment.

President Barack Obama presented Dr. Capadona with his award at the White House this past July.

Karen L. Christman, Ph.D., Assistant Professor of Bioengineering at the University of California, San Diego, recently had her work highlighted in a number of news articles concerning VentriGel. Dr. Christman found a way to remove heart muscle cells from cardiac tissue of pigs and turn it into a liquid that becomes a semi-solid gel when it enters the body. She and her colleagues have reported early success in limiting tissue damage in rats that suffer heart attacks. Dr. Christman has also received a number of awards in 2012 including, the American Heart Association Western States Innovative Sciences Award, the Tissue Engineering and Regenerative Medicine International Society Young Investigator Award and an NIH Director's Transformative Research Award.

Anne George, Ph.D., Professor of Oral Biology at University of Illinois at Chicago College of Dentistry was conferred with Docteur Honoris Causa from University Paris Descartes in Paris in November 2011. Dr. George holds the Allan G. Brodie Endowed Professorship, and her research is focused on identification and characterization of acidic proteins involved in dentin mineralization, dentin matrix proteins and is working on cloning phosphophoryn genes.

Shu-Tung Li, Ph.D., has been selected for induction into the New Jersey Inventors Hall of Fame, co-sponsored by Stevens Institute of Technology and Greenberg Traurig, LLP. Dr. Li is President and Chief Executive Officer of Collagen Matrix, Inc., and his award recognition is for "Patented technology related to collagen-based medical implants for the repair and regeneration of soft tissue and bones." Dr. Li has more than 40 years of experience in connective tissue research and collagen-based implant development. This includes 10 years of basic science research experience at the University of Connecticut Health Center related to the structure and function of collagen fibrils in mineralized and non-mineralized tissues and 30 years of experience in collagen-based and mineral-based medical implants development in the medical device industry. Dr. Li holds 30 U.S. patents, has authored more than 95 publications and has developed more than 30 collagen and mineral-based implants currently on the market.

Kacey G. Marra, Ph.D., Associate Professor in the Departments of Plastic Surgery and Bioengineering at the University of Pittsburgh was awarded the 2012 TERMIS Educational Award at the TERMIS World Congress in Vienna, Austria in 2012. This award recognizes her dedication to the education of tissue engineering, including biomaterials, to the next generation of scientists and engineers.

Other members in the news:

Thair Latif Alzubaydi, Ph.D., from the Ministry of Science and Technology in Iraq, reports doing research this past year, as a visiting scientist at Syracuse University with **Jeremy L. Gilbert,** trying to develop different surface engineering techniques for modifying orthopedic and dental implants.

Kagya Amoako, Ph.D., a postdoctoral research associate working in **Dr. Shaoyi Jiang's** laboratory in Chemical Engineering at the University of Washington, Seattle, received a NIH T32 fellowship.

Noam Eliaz, Ph.D., an Associate Professor in Mechanical Engineering at Tel-Aviv University Israel and Research Affiliate at the Department of Materials Science and Engineering at M.I.T., wishes to inform our Society members that he has edited a book entitled *Degradation of Implant Materials* (Springer). This book is now available both online (at

continued on page 20

Intellectual Property (IP) in the Classroom: Stimulating or Stifling?

Entrepreneurship and new venture creation have become increasingly important topics in higher education over the past decade, as our country and its academic institutions strive to promote innovation and the economic and social benefits it can bring. Students are learning more about the practical applications of their work, including how to protect and commercialize their ideas. I teach in an engineering environment, and "product realization" courses have sprouted in many of the disciplines. Similar trends are occurring in other areas, including the biomedical sciences.

A key part of creating a product and a company is securing the intellectual property (IP) that is needed to protect the inventor from competitors for a period of time, often in the form of a patent. This mechanism allows development costs and investments to be recouped and usually further provides for a period of essentially unchallenged profit-making. A related and similarly important concept is to ensure a company has "freedom to operate," meaning a product can be commercialized without infringing on the IP rights of others. These IP concepts are central to the creation of a company, and for this reason it is important students who are working on product realization understand their implications. In addition, it is important students understand their rights and roles as they move products toward the market.

The U.S. patent system was developed to provide inventors with the right to exclude others from selling the product they have invented. In return, the inventor must publicly disclose the details of the invention through the issuing of a patent document. The latter half of this bargain is sometimes not appreciated. The purpose of public disclosure is to allow other inventors to inspect new ideas and technologies, which, in turn, will allow them to create newer and even better technologies. Therefore the theory behind patent protection was to provide both temporary protection to the inventor, as well as information to the public to spur further innovation. However in practice, patents are often used as weapons to inflict delay and financial harm on competitors, while the beneficial effect of the information they provide is less evident.

I have been involved in several academic design classes, in which students work in teams to come up with innovative solutions to clinical problems. An exciting component of such courses is the possibility of generating new IP, which can be protected and then developed or licensed in the commercial space.

This column is motivated by experiences I have had in the classroom over the past several years. I have been involved in several academic design classes, in which students work in teams to come up with innovative solutions to clinical problems. An exciting component of such courses is the possibility of generating new IP, which can be protected and then developed or licensed in the commercial space. When students generate new IP, it is important to ensure their rights are protected. Other inventors, whether part of the academic community or external, need to be similarly protected, and there are generally accepted guidelines as to what constitutes inventorship on a patent. At my institution, IP generated by

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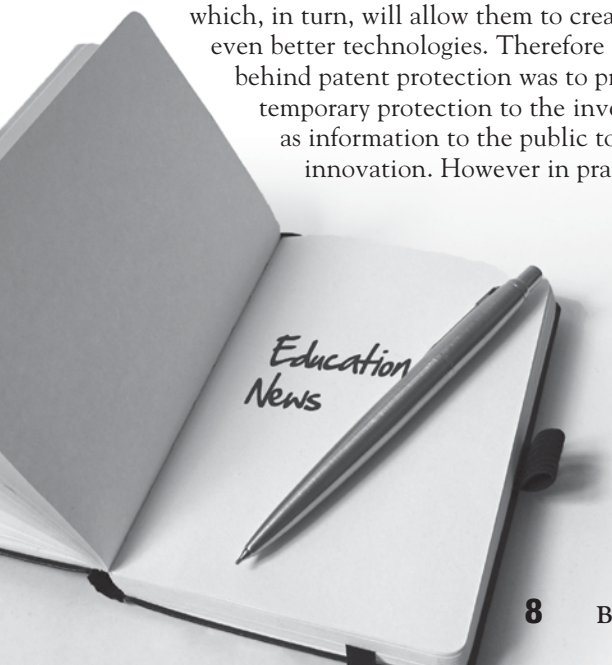

Education Quote of the Quarter:

"A patent, or invention, is any assemblage of technologies or ideas that you can put together that nobody put together that way before. That's how the patent office defines it. That's an invention."

— Dean Kamen

In vitro Evaluation of Magnesium-based Metallic Biomaterials and the Need for Standardization

By Ian Johnson, Huinan Liu
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Introduction

Magnesium (Mg) alloys are promising biodegradable metallic materials for orthopedic implants due to their many desirable properties. Magnesium has a mechanical strength and elastic modulus similar to cortical bone[1], and the degradation products can be naturally metabolized.[2] Furthermore, increased bone growth has been observed surrounding Mg derived implants *in vivo*.[3] However, rapid Mg degradation *in vivo* leads to rapid loss of mechanical properties of implants and acute increase of the local pH, thus limiting clinical translation of Mg alloys to orthopedic implants.[4] Significantly increased pH is often the primary reason for Mg cytotoxicity *in vitro*.[5] Many different experimental techniques have been used to investigate the cytocompatibility of Mg-based biomaterials and their *in vitro* interactions with cells. However, the results of different experimental techniques are often not directly comparable to each other, even if the same question is studied. The ability to compare experimental results among different literature reports is important to advance the field rapidly towards clinical translation. Therefore, this article will first review and compare various *in vitro* techniques used to investigate cellular interactions with Mg-based biomaterials (Table 1) and then emphasize the urgent need to establish standardized procedures for *in vitro* evaluation of Mg-based biomaterials.

Cytocompatibility and Bioactivity of Mg-based Biomaterials

Characterizing the effects of Mg on *in vitro* cell proliferation is one way to determine the cytocompatibility of Mg and its degradation products. Both direct contact and indirect contact methods have been reported in literature to describe cell adhesion and proliferation in the presence of Mg alloys. For the direct contact method, cells are incubated directly upon the surface of Mg-based biomaterials. The direct method more closely represents the cell-implant interaction at the interface, which plays a critical role in implant success. Alternatively, for the indirect contact method, Mg-based samples are first degraded in water or buffer solutions since the amount of solubilized degradation products in the cell culture media depends on the degradation rate of Mg-based samples. Cells are then incubated with the soluble degradation products. In contrast to the direct contact method, the indirect contact method precisely controls the exact amounts of degradation products added into the cell culture media, and can allow the media pH values to be normalized across multiple groups.

When selecting an appropriate assay for Mg-based materials, it is necessary to consider the compatibility of the assay with Mg. The 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenoltetrazolium bromide (MTT) assay measures the conversion of MTT and other tetrazolium salts to formazan by cellular metabolism. The rate of conversion can be tracked by absorbance of formazan. The standard MTT assay assumes only the metabolic activity of cells converts MTT to formazan, and more cells will lead to more formazan production. Mg alloy degradation releases soluble Mg ions and increases the pH, both of these interfere with the MTT assay.[6] The interference induced by Mg degradation products can be minimized by using a control and subtracting the background from the experimental samples.[7,8] The advantages of the MTT assay are its ease to use and high testing efficiency. The PicoGreen and bromodeoxyuridine (BrdU) assays are used to determine the amount of dsDNA in a sample. The PicoGreen assay uses a fluorescent nucleic acid stain that preferentially binds to existing dsDNA.[9] The BrdU assay measures incorporation of BrdU into replicating dsDNA. Both of these assays quantify cell proliferation by measuring the amount of dsDNA in the sample. As Mg ions do not interfere with the PicoGreen and BrdU assays; and thus these two assays offer more reliable alternatives to quantify cell proliferation than the MTT assay. The compatibility of the BrdU assay with Mg alloys has been verified.[6]

Characterization of Cell Adhesion and Morphology

Fluorophores have been used to visualize the adherence, morphology, structure, viability and protein expression of cells. The choice of fluorophores and fixation method is dependent upon the cells, cell media and biomaterials tested. Alexa Red Phalloidin stains the actin cytoskeleton and Hoechst 33342 stains the nucleus, respectively.[10] Calcein acetoxymethyl stains the cytoplasm of live cells. Ethidium homodimer-1 stains the nuclei

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of dead cells.[5,11] The use of counter stains that distinguish between live and dead cells can differentiate cytotoxic from cytostatic effects. Giemsa stain binds to the phosphate groups of DNA and differentially stain human and bacterial cells[12], making them particularly useful for studying biomaterials with antimicrobial properties.

An alternative to the addition of fluorophores is to genetically engineer cells that express fluorescent proteins[13,14]. However, green fluorescent protein (GFP) expression may alter cell behavior, and thus caution must be taken.[15] Visualization and versatility are the greatest advantages of fluorescence microscopy. In many cases, an image can provide valuable information that cannot be obtained from raw numbers of cell count or protein expression data. For example, a fluorescence image can provide information about multiple phenomena such as adhesion, morphology, structure, distribution of proteins and viability of cells. Moreover, fluorescence microscopy allows the differentiation between cytotoxic and cytostatic effects on cell populations. However, cell proliferation is less accurately quantified using fluorescence microscopy, and the results are somewhat subjective.

Characterization of Cell Differentiation

Even if cells survive, adhere and have the proper morphology, they still may not have desired functions. For this reason, it is important to monitor the differentiation of cells and their gene and protein expression thereafter. Alkaline phosphatase (ALP) activity increases with osteogenesis, making it a useful test for osteogenic differentiation.[12] However, this test does not provide information about what genes or proteins are expressed. Reverse transcription polymerase chain reaction (RT-PCR) can be used to track RNA expression levels.[8] Enzyme-linked immunosorbent assay (ELISA) or Western blots can be used to track protein expression levels.[16] RNA and protein expression assays are most reliable when they are used to complement each other, as the expression of a specific gene does not always directly correlate to the type or level of protein expression, and *vice versa*.

Characterization of Bone Mineralization

Mineralization is vital to the functions and mechanical properties of bone. Von Kossa stains[3,17] can reveal phosphate deposition. Alizaran red stains can reveal the presence of calcium (Ca).[12] Alternatively, Ca chelating fluorophores (such as calcein green and calcein blue) can capture images of mineralization in live cells *in vitro*; and these images can be taken in sequential time points from the same cells to track mineralization over time. Some Ca chelating fluorophores can be used with minimal influence on cell proliferation or mineralization.[3,17] Many of these Ca chelating fluorophores are not completely specific to Ca. Some will also interact with Mg ions and other metallic ions in Mg alloys.[18] Combining the stains for phosphate and the stains for Ca will increase the reliability of the results.

Suggestions for Establishing Standard Procedures for the Evaluation of Mg-based Biomaterials

The lack of standardized procedures is a major obstacle for comparing literature results on Mg-based biomaterials. Cell growth is affected by cell type, age and health of the donor[19], culture media composition [20], passage number[19,20] and many other parameters. Experimental procedures also influence the results of investigations and can sometimes lead to contradictory conclusions, as shown in the following examples.

Zhang *et al* used the indirect contact method to test Mg cytocompatibility.[21] The extraction media was prepared by immersing 10x10x1 mm 99.9 percent pure Mg substrates in RPMI-1640 at 37°C for 24 hours. Immersion occurred at a ratio of 3 cm^2 Mg per mL media. Human osteosarcoma cells (U2-OS) were cultured in the extraction media for 48 hr under standard cell culture conditions (37°C, five percent CO_2). Cell population size was determined using cell counting kit-8 (CCK-8; a tetrazolium salt assay similar to MTT). RPMI-1640 without Mg extract was used as a control. This investigation found the cell viability in the extraction media was around 10 percent of the control, demonstrating significant cytotoxicity due to Mg degradation.

X.N. Gu *et al* also used the indirect contact method to test Mg cytocompatibility.[22] The extraction media was prepared by immersing 10x10x10mm 99.9 percent pure Mg substrates in DMEM for 72 hr. Immersion occurred at a ratio of 0.2 g Mg per mL. Murine fibroblast cells (L-929) were cultured in DMEM for 24 hr under standard cell culture conditions to allow time to adhere. The media was then replaced with extraction media and incubated for one, three and five days. Cell population size was determined using the MTT assay. DMEM without Mg extract was used as a control. This investigation found the cell viability in the extraction media was around 85-95 percent of the control, demonstrating only minor cytotoxicity due to Mg degradation.

The results of these investigations are clear when we read them individually, but are ambiguous as to the cytotoxicity of Mg degradation when we try to compare them. One investigation demonstrated Mg degradation caused major cytotoxicity (~10 percent of the cell viability observed), but the other investigation demonstrated that Mg degradation only caused minor cytotoxicity (~85-95 percent of the cell viability observed). The differences in experimental design and procedures led to these conflicting conclusions. One cell type may have been more sensitive than the other. Different media, exposed sample surface area and immersion duration could have altered the media pH and dissolved Mg ion concentration. Allowing the cells time to adhere before adding the extraction media may have been a major factor in the increased cell viability observed by X.N. Gu *et al*. Standardization of experimental procedures could prevent such ambiguity in future investigations, and increase comparability of literature reports on Mg and Mg-based alloys for biomedical applications.

Some extent of standardization should not be difficult to implement in investigations. The combination of direct contact methods (such as PicoGreen or BrdU assay) and fluorescence microscopy to visualize cell adhesion and morphology may provide valuable, comparable information on cytocompatibility and cellular interactions with the biomaterial surface. Moreover, experimental conditions such as the type of cells used and cell-culture protocols (e.g. incubation time, type of media, frequency of media change, etc.) should be standardized to enable direct comparison of results in literature. Finally, consistent controls

Table 1: *Assays used to characterize cellular interactions with Mg-based biomaterials.*

Biological Characterization	Methodology	Process/Structure Observed	Capabilities and Limitations
Cell Proliferation	MTT [6-8]	Cell metabolism	Mg ions interfere with the absorbance results
	PicoGreen [9] or BrdU [6]	dsDNA	Measures dsDNA in a cell population; Mg ions do not interfere with the assays
Cell Morphology/ Viability	Calcein-AM [5, 11]	Intracellular Ca, Zn	
	EthD-1[10,11]	Nucleus of dead cells	
	Alexa Red Phalloidin [10]	Actin cytoskeleton	
	Hoechst 33342 [10]	Nucleus of cells	
	Giemsa stain [12]	DNA	Distinguishes between mammalian and bacterial cells
	GFP expressing osteoblasts [13-15]	Cell morphology	Enables tracking of living cells, but may also alter their behavior
Cell Differentiation	ALP [12]	Alkaline phosphatase	Assay for osteogenesis
	RT-PCR [8]	Quantifies RNA expression	
	Western Blot or ELISA [16]	Quantifies protein expression	
Bone tissue Growth/ Mineralization	Von Kossa stain [12]	PO_4	
	Alizaran red stain) [12]	Ca	
	Calcein blue and green [3, 17, 18]	Ca, Mg, Cd, Fe, Ag, Zn, Cu, F, SO_4	Other metal ions (e.g. Mg) interfere with the stains

could provide benchmarks to compare cytocompatibility in different publications. Standardized cytocompatiblity testing procedures can potentially enhance comparability of current literature reports on Mg-based biomaterials, promote worldwide data sharing, advance the field of biodegradable metals with more synergy and accelerate clinical translation of Mg based biomaterials for biomedical implant and device applications.

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AIMBE Holds Human-on-a-Chip Validation Workshop

By Carl Simon, NIST, Biosystems and Biomaterials Division
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The American Institute for Medical and Biological Engineering (AIMBE) held a workshop at NIH September 17-18, 2012 entitled "Second AIMBE Workshop on Validation and Qualification of New In Vitro Tools and Models for the Pre-Clinical Drug Discovery Process." The workshop was built on recent momentum to streamline the therapeutic development pipeline through efforts sponsored by the new NIH National Center for Advancing Translational Sciences (NCATS), FDA and the Defense Advanced Research Projects Agency (DARPA). Drug development requires the screening of thousands of compounds, takes 14 years from idea to clearance and typically costs more than one billion dollars. NCATS aims to eliminate the bottlenecks in the translation process by developing improved 3D *in vitro* models for preclinical screens. The goal is to augment or replace current models, especially animal models, in the FDA drug approval process and 17 awards were recently made to support this work. The goal of the workshop was to develop guidelines on how to validate these new technologies so that they become useful, meaningful tools.

Much discussion focused on the meaning of "validation" for tissue chips, including what performance metrics must be characterized for regulatory acceptance, whether a standardized set of test chemicals should be defined for toxicity testing, and defining the process for determining whether the *in vitro* test is giving the "right" answer. The workshop was chaired by James Hickman (University of Central Florida), who won one of the tissue chip awards in collaboration with one of the workshop speakers, Michael Shuler (Cornell). Other workshop participants included Anne Plant (NIST), Christine Kelley (NIH/NIBIB), Ping Zhao (FDA/CDER), Sonja Beken (European Medicines Agency), Rosemarie Hunziker (NIH/NIBIB), William Warren (Sanofi Pasteur), Jack Reynolds (AnaBios Corporation), Danilo Tagle (NCATS/NIH) and Michael Jackson (Sanford Burnham). Part three in this series of workshops is being scheduled for spring 2013.

More information on the NCATS/FDA/DARPA tissue chip initiative can be found here: http://www.ncats.nih.gov/research/reengineering/tissue-chip/tissue-chip.html

More information on the AIMBE Validation Workshop can be found here:
http://www.aimbe.org/events/aimbe-event/2012/08/second-joint-aimbe-workshop-on-validation-and-qualification-of-new-in-vitro-tools-and-models-for-the-pre-clinical-drug-discovery-process/

Tissue Engineering and Dental/Craniofacial SIGs Announce Poster Winners

The Tissue Engineering and Dental/Craniofacial Biomaterials SIGs are pleased to announce new awards created for the benefit of their SIG student members who are poster presenters. Winners are determined by evaluation scores achieved by combining original abstract scores (from the program planning review process) with scores on each poster's appearance and elements, the presenter's understanding of the subject and skill of presentation, the research and the overall content. These awards are intended to complement the existing STAR awards in bringing attention to the importance of poster presenters at SFB meetings.

The following Tissue Engineering SIG poster presentation winners were selected at the 2012 SFB Fall Symposium in New Orleans:

First Place - Mary Beth Browning,
Texas A&M University

Second Place - Paul Turner,
University of Mississippi Medical Center

Third Place - Nassir Mokarram,
Georgia Institute of Technology

Third Place - Cristina Fernandez,
Duke University

The following Dental/Craniofacial Biomaterials SIG poster presentation winners were selected:

Bonnie Culpepper, University of Alabama at Birmingham

Nina Vollmer, Colorado School of Mines,
Metallurgy & Materials Engineering

Book Review

Review by Lynne C. Jones,
Associate Professor, Johns Hopkins University

Taking a break from science…

In today's competitive world, there is an ever-increasing emphasis being placed on efficiency and productivity. We keep hearing "Do more with less." Given the wide variety of job responsibilities and individual personalities, this can mean different things to different people. With this in mind, I bring you reviews of two books I believe provide a very pragmatic approach to increasing efficiency and productivity through effective time management skills.

Many of you have read *Seven Habits of Highly Effective People* by Steven Covey. For those of you who have not or would like to review some of the principles championed by the Covey Leadership Center, there is *Connections: Quandrant II Time Management* by A. Roger Merrill and Rebecca R. Merrill (1987; Publishers Press; ISBN 0-9622363-0-60). This book begins by segmenting our activities into four quadrants:

I. Urgent and important.
II. Important, not urgent.
III. Urgent, not important.
IV. Not urgent, not important.

Quadrant I includes crises, pressing problems and deadline-driven problems. One would like to think we have no control over what goes into Quadrant I, but frequently our mismanagement of Quandrant II and III activities results in pushing non-urgent or activities of lesser importance into stressful urgent situations that could have been prevented or handled better.

The authors urge the reader to become more proactive and less reactive in order to become more effective. Understanding the driving and resisting forces underlying our current level of effectiveness enables us to develop strategies to push towards our desired or optimal level of effectiveness. It is important to understand productivity is not just getting more things done but getting the right things done with quality and integrity. Frequently, effectiveness and efficiency are confused. In judging effectiveness, the authors suggest we need to ask ourselves "Does it bring the desired results?" With efficiency, the questions include "Does the outcome justify the input?" and "Is there a better way?"

In organizing ourselves, we need to look broadly and then focus on a weekly strategy. First, the book discusses the importance of writing a personal mission statement. This helps to establish the framework for deciding what is important and our end goals. We are encouraged to take time to plan our week by organizing a schedule around Quadrant II (important) activities. The book provides us with 10 strategies to improve effectiveness and efficiencies including synergizing and segmenting our big projects. We are given concrete tools to help us accomplish this including a questionnaire to assess our time management skills, a questionnaire to identify our vision, identity and purpose and a weekly worksheet.

There are two take-home messages I believe are especially enlightening. First, it is important to appreciate that we may not be able to have an effect on all of the circumstances concerning us. By identifying our "circle of influence," we can manage our time and resources more effectively. Second, it is important to find balance–not only between our different roles in our professional life, but also between our professional life and our personal life.

The second time management book is entitled *Getting Things Done: How to Achieve Stress-Free Productivity* by David Allen (2001; Pistkus Books; ISBN 978-0-7499-2264-1). Again, this book addresses personal and organizational productivity. As best stated by the author:

> "On the one hand, we need proven tools that can help people focus their energies strategically and tactically without letting anything fall through the cracks. On the other, we need to create work environments and skills that will keep the most invested people from burning out due to stress."

The book reinforces the idea that today's world has new demands and insufficient resources, and we need to develop strategies to overcome these challenges. David Allen emphasizes it is important to keep a clear head and be completely present. He introduces the concept of giving 100 percent to what you are doing at that time and pushing away distractions. He also proposes that our greatest efficiency occurs when we are relaxed.

Allen proposes the "Natural Planning Model." This model encompasses defining purpose and principles, outcome visioning, brainstorming, organizing, and identifying next actions. Again, this reminds me of some of the principles espoused by the *Seven Habits of Highly Effective People*–concepts such as "Begin with the End in Mind."

He describes the "Collection Habit" and the importance of not letting things pass through the cracks. Allen describes five stages for managing workflow—collect, process, organize, review and do. There are chapters dedicated to each of these stages. He describes ways of handling e-mail, including the "If it takes less than two minutes to do something, just do it" concept. A workflow diagram is provided to assist us in organizing our office and projects by setting up "buckets." List-making is advocated not just to organize yourself but to enable you to put your thoughts on paper and out of your mind. The book also includes a chapter acting as a practical guide to getting projects under control.

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Upcoming ASTM Workshop on Scaffold Standards

By Carl Simon (NIST, Biosystems and Biomaterials Division, Gaithersburg, Md., carl.simon@nist.gov)

The ASTM will host a workshop on standards and measurements for tissue engineering scaffolds entitled "Standards and Measurements for Tissue Engineering Scaffolds: What Do We Have, and What Do We Need?" Standards accelerate innovation and translation by providing a common base for comparison of results from different research groups, by enabling the establishment of quality control criteria and by creating a shared language to facilitate communication between scientists, regulators and product developers. The workshop will be held May 21, 2013 during ASTM Standards Week in Indianapolis, Ind., and the target audience is those involved in developing scaffolds-based tissue-engineered medical products (TEMPs). The goal is to identify high-priority items for future standards work for scaffolds for TEMPs. The workshop will bring together government, academia and industry to discuss how standards for scaffolds are currently being used and what opportunities exist for the future. Leaders in the field, including clinicians, regulators and product developers will discuss how their organizations use current scaffold standards and the standards they need to accelerate future scaffold development. Needs for standards (as revealed by both basic research and clinical experience) will be discussed. The workshop will focus more on discussion of future needs than on presentation of past accomplishments.

The workshop is being sponsored by ASTM Committee F04 Medical and Surgical Materials and Devices and the organizing committee includes Carl Simon (NIST), Michael Yaszemski (Mayo Clinic), Anthony Ratcliffe (Synthasome), Paul Tomlins (European Standards Consultant), Reto Luginbuehl (Robert Mathys Foundation) and John Tesk (Consultant). In addition to the organizers, confirmed participants include Barbara Boyan (Georgia Tech), Michael Dornish (FMC Biopolymer), Jed Johnson (Nanofiber Solutions), Antonios Mikos (Rice), Jayesh Doshi (eSpin Technologies), Wing Lau (3DBiotek), Byron Hayes (Gore), Gregory Brown (Park Nicollet), Steve Lin (Exactech), Michael Hiles (Cook Biotech), Joy Dunkers (NIST), Eugene Smit (Stellenbosch Nanofiber Co.) and Ted Wakatsuki (InVivoSciences). Workshop conclusions will be summarized in an article that will be published. More information can be found at the following link: http://www.astm.org/F04Wrshhp0513.htm or by contacting Carl Simon (carl.simon@nist.gov, (301) 975-8574). We hope to see you in Indianapolis in 2013!

Special Interest Group News

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Book Review

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Both of the reviewed books place an emphasis on following principles. The Merrills call this the "Principle of Principles," defined as "A person who understands principles can use or create a variety of implementing practices in different circumstances to accomplish his or her purpose." They state that principles are timeless, self-validating and empowering. The principles discussed include vision, identity, purpose, order, concentration, integrity, harmony and progression. David Allen also discusses the "Power of the Key Principles" of time management and organization including the collection habit, the next-action decision and outcome focusing.

These are two easy-to-read books that still pack a punch. For the disorganized, frequently procrastinating individual, these books can be transformative. For others that are more organized, you will still find enough pearls of wisdom to make an impact on your day-to-day activities.

Updates In Industry

Steve T. Lin,
Industrial News Contributing Editor

China and India, with their burgeoning diabetes populations, are expected to be big consumers of medical devices and propel the global diabetes device market to $25.3 billion in 2018, up from $17.7 billion in 2011. A new report from GBI Research states global firms such as **Roche, Sanofi, Novo Nordisk** and **Eli Lilly** are trying to focus on these two populous Asian nations with analysis showing the Chinese diabetes devices market will see a 5.9 percent compound annual growth rate over the seven years to $1.1 billion in 2018. India is on an even faster track, and showing that the market, while much smaller than China, will see a 10 percent CAGR to $285.2 million in 2018.

There is one single category of device that will dominate the market, according to GBI Research —the glucose monitoring device. The firm found that in 2011, glucose-monitoring products were worth $9.7 billion of the $17.7 billion overall market for diabetes devices. It remains to be seen if the world will be any closer to having a working artificial pancreas, the Holy Grail for all diabetes patients.

Cook Medical President Kem Hawkins said at the opening of the company's new $19 million manufacturing facility in Canton, Ill., where he shared speaking duties with U.S. Sen. Dick Durbin, (D-Ill.), among others, that unless the Senate follows the lead of the House and votes to repeal the 2.3 percent medical devices excise tax contained in the Affordable Care Act, Cook Medical will not build any more plants in the U.S. Cook has estimated the impact of the new tax on the company will be approximately $20 million a year—the cost of one of those Canton plants, which combined will employ about 350 people. Hawkins said if the tax goes into effect next year, as scheduled, the private, family-owned company based in Bloomington will be forced to use revenue that would have financed expansion to preserve the jobs of current employees. Hawkins said Cook has shelved plans for five additional U.S. manufacturing facilities until it sees what is going to happen with the proposed excise tax. Cook produces more than 70 percent of its products in the U.S.

Developing an alternative approach to blood glucose monitoring that does not rely on lancets and pinpricks has been a primary goal of diabetes device R&D in recent years. Contributing to this effort, researchers at Purdue University have engineered a noninvasive, low-cost biosensor capable of detecting glucose in concentrations as low as 0.3 micromolar in blood, urine, saliva and tears. While initial development of the biosensor has focused on glucose monitoring, the biosensor could potentially be employed for other medical tests by simply swapping out the enzyme. Using glutemate oxidase in lieu of glucose oxidase, for example, could enable testing for such conditions as Parkinson's or Alzheimer's.

Medical device mergers look poised to take off in 2013 as the industry compensates for shrinking reimbursements, a new U.S. tax and executive shake-ups at its biggest companies. Merger and acquisition activity in the sector has fallen near the lows reached in 2009, during the global financial crisis, but industry executives and bankers say the situation is changing. The value of announced deals totaled $20 billion. That is down from a year-earlier $53.32 billion, including **J&J's** $21 billion agreement to buy surgical tool maker **Synthes**, which closed in June. **Medtronic Inc.**, the world's largest medical device maker, has been viewed as a likely buyer, but Chief Executive Officer Omar Ishrak has said the company will be careful not to acquire anything that will hurt profits. In the orthopedic market, analysts say public companies at the center of takeover speculation include **Nuvasive Inc.**, **Wright Medical Group Inc.** and **Tornier Inc**. In the heart sector, they include **Edwards Life Sciences Corp.**, **HeartWare International Inc.**, **Thoratec Corp.** and **Volcano Corp**. Physician groups and hospitals are also consolidating, giving them even stronger buying power at a time when all segments of the healthcare market are under pressure to cut costs.

A promising approach for producing medical images with enhanced soft tissue visibility—grating-based x-ray phase contrast—has now advanced from bench-top studies to implementation in an *in vivo* preclinical computed tomography scanner. A German, Swedish and Belgian team led by scientists at the **Technische Universität München** (TUM) published the first experimental results demonstrating the practical potential of this technology, which can significantly improve the contrast in CT scans. This work, reported in the *Proceedings of the National Academy of Sciences*, could mark a critical step in moving beyond proof-of-concept experiments to applications—including *in vivo* preclinical imaging with small animal models in the mid-term future, and, in the long-term, medical CT scanning.

Following the 2008 Summer Olympics in Beijing, the Chinese government announced plans to build a modernized city in the Tongzhou District in the southeast part of the capital. Plans for the Beijing International Medical Service Area were officially announced in Beijing September 17, 2012. The project hopes to attract leading global clinical, research and educational institutions and investment agencies dedicated to the development of China's healthcare industry. Part of the new city of Tongzhou, the centre will encompass a "medical and industrial chain" able to meet the diverse healthcare requirements of the surrounding population and beyond. The first phase of the **Beijing International Medical Service Area** will occupy three square kilometers. It ultimately will represent 30 percent of the city's overall 48-square kilometer radius. Key phase I infrastructure projects will be completed by 2018. When completed, the new city reportedly will fully integrate consumer technology with healthcare services, allowing residents to access healthcare information at all times.

Boston Scientific Corporation (Boston) has signed a definitive agreement to acquire **BridgePoint Medical, Inc.,** a privately held company based in Minneapolis, Minn. The company has developed a proprietary, catheter-based system to

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Steve T. Lin,
Industrial News Contributing Editor

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treat coronary chronic total occlusions (CTOs). The transaction is expected to close in the fourth quarter of 2012 subject to customary closing conditions. The BridgePoint Medical CTO system is comprised of the CrossBoss™ CTO Crossing Catheter and the Stingray® CTO Re-Entry System, and is designed to navigate highly diseased (occluded) coronary arteries as a means of blood flow restoration. The system has received both U.S. Food and Drug Administration clearance and CE Mark and is currently the only crossing and re-entry system cleared in the U.S. for use in coronary CTOs. CTOs are chronically occluded coronary arteries—typically for three months or longer—that prevent blood circulation to critical areas of the heart. CTO devices are designed to permit endovascular treatment in cases that otherwise might require a patient to undergo invasive intervention, such as coronary artery bypass surgery.

A team of Ukranian students has developed a glove that can transform sign language into verbal communication. The device could help people with hearing and speech impairment to communicate. The team won the Microsoft Imagine Cup 2012 and has launched a website (http://enabletalk.com/abstract.html) detailing the project, which they call "Enable Talk," and the business plan. The prototype glove has sensors that measure the degree of bending. A compass, accelerometer and gyroscope also help determine the motion of the glove, while a microcontroller on the glove processes the data. Software (developed under Windows Phone 7/Windows 8) transforms the information into a soundwave. The data is then sent via Bluetooth to a cell phone. The projected price is US $400 for two gloves.

The following is a notification from the U.S. Census Bureau

To: Biomaterials Forum readers

In November and December, more than four million American businesses, including 170,000 manufacturers, will receive 2012 Economic Census forms. Responses to the questionnaire are required by law (Title 13, U.S. Code), to be returned by February 12, 2013.

Every five years, the Economic Census develops a comprehensive portrait of American business, from the national to the local level. Timely and accurate data are vital to effective public policy and important to your publication and your readers.

What Businesses Need to Hear…and When	
Sep-Oct 2012	The Economic Census has information that benefits your business, at business.census.gov.
Nov-Dec 2012	Watch for your form - coming to most businesses in mid-December
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We've created a special Web page at business.census.gov to explain the Economic Census, and provide statistics you can use to assess and grow your business operations.

First International PEEK Meeting—April 2013

The Implant Research Center of Drexel University, in collaboration with Exponent Inc., is pleased to announce the first International PEEK Meeting:

April 25-26, 2013
Union League
Philadelphia
USA

The purpose of the meeting is to bring together engineers, scientists and clinicians from academia and industry to present leading-edge research on advancements in medical grade PEEK technology and clinical applications. The focus of the first International PEEK Meeting is on bioactive PEEK composites.

University of Memphis Biomaterials Day 2012

by Matt Goodhart

The University of Memphis (UM), in conjunction with the University of Tennessee Health Science Center (UTHSC) and Vanderbilt University, hosted Biomaterials Day 2012 for the second year in a row. Biomaterials Day was a one-day symposium held Feb 17, 2012, focusing on the past, present and future of biomaterials innovations and research from clinicians, industry professionals and students. This event was held at the FedEx Institute of Technology on the University of Memphis campus and was sponsored by the Society For Biomaterials, the FedEx Institute of Technology (FIT), UM Student Event Allocations, the UM Herff College of Engineering and the UM Biomedical Engineering department.

For this event, there were more than 215 attendees, a major increase from the 175 last year. The event hosted 12 different universities including The University of Memphis, The University of Tennessee Health Science Center, Vanderbilt University, The University of Tennessee (Knoxville), The University of Alabama, The University of Alabama (Birmingham), Mississippi State University, Harding University, The University of Kentucky, Clemson University, The University of Arkansas and The University of Michigan. There were representatives from numerous companies including Smith and Nephew Inc., Medtronic Inc., Wright Medical Technology Inc., Dow Corning Corporation, Bionova Medical Inc. and Evonic Degussa Corporation.

Biomaterials Day 2012 started with a panel discussion featuring five industry professionals from five biomedical companies. They spoke about their current biomaterial uses and where they see the most pressing needs in biomaterials research. Topics ranged from tissue engineering improvements to implant materials to more effective antibiotic applications. Following the panel discussion, the attendees could choose between two research sessions: drug delivery or nanotechnology in biomaterials. Students and faculty presented current research in these respective areas.

The networking luncheon was great. Each table had at least one industry professional and one clinician available to answer questions about careers and medical school. Students were able to make many connections and gain answers to many of their burning questions.

Our second panel session consisted of five clinicians/surgeons in orthopedics and cranial/maxillofacial reconstruction. They spoke and answered questions about their most immediate biomaterial needs. Their needs were very diverse, spanning needs for molding materials, better tools and, as always, better ways to fight nasty infections. A second research session followed in the areas of tissue engineering and drug delivery from scaffolds. The highlight of the day started at 3:30 with a keynote address from Dr. Buddy Ratner from the University of Washington (Seattle).

The conference facilities at the University of Memphis

A student design competition was held.

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University of Memphis Biomaterials Day 2012

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Dr. Ratner is a professor in the Department of Bioengineering and Chemical Engineering at the University of Washington, the Michael L. and Myrna Darland Endowed Chair in Technology Commercialization and the director of the University of Washington Engineered Biomaterials Group. He is the past president of the Society For Biomaterials, the author of more than 400 scholarly works and the recipient of countless other honors and awards, including the 2011 Pierre Galletti Award from the American Institute of Medical and Biological Engineering. We were very excited to have him as he spoke about the past, present and future of biomaterials.

The day ended with a poster research session and catered closing reception. We awarded winners for best oral research presentation, best graduate research poster presentation and best undergraduate research poster presentation to Christopher Nelson (Vanderbilt), Jonathan Page (Vanderbilt) and Jason Brewer (University of Memphis), respectively. We had excellent feedback about this event, and we look forward to hosting another Biomaterials Day in the future.

Dr. Ratner receives a plaque commemorating his address to the conference. Pictured left to right: Matt Goodhart (2011-2012 SFB student chapter President), Dr. Buddy Ratner, Marvin Mecwan (Program Chair).

Dr. Buddy Ratner gave the keynote address.

Panelists from the Industrial Panel Discussion. Pictured left to right: Ann Burgess, Dr. Kelly Emerton, Dr. Kevin Weaver, Dr. Scott Noel and Jim Curtis.

New Student Chapter at UCLA Announcement

by Helena Chia

Founding members of UCLA SFB student chapter (L to R): Helena Chia, Arnold Suwarnasarn, Prof. Howard Winet, Chase Linsley and Abigail Corrin.

We are excited to announce the formation of a student chapter of the Society For Biomaterials at the University of California, Los Angeles. Approved during the summer of 2012, the purpose of the UCLA student chapter is to encourage the development, dissemination, integration and utilization of knowledge in biomaterials among the UCLA community, as well as all members of SFB, especially those in the Southern California area. Our goals for the UCLA SFB student chapter are:

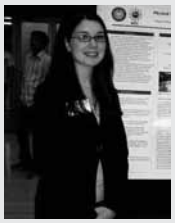
- Enhance student interest in biomaterials and related disciplines.
- Promote the advancement of biomaterials research and education.
- Promote industrial relations, innovations, and entrepreneurship.
- Further the aims and objectives of the SFB as they relate to student research and education.

We aim to achieve these goals by offering a venue for students, post-doctoral scholars and faculty members to network and present on their biomaterials-related research. Additionally, we are encouraging members from around the UCLA campus, including biological sciences and Schools of Engineering, Dentistry and Medicine, to participate so we can learn from one another and start new collaborations.

The formation of a new student chapter of SFB at UCLA coincides with merging of the Biomedical Engineering Interdepartmental graduate program into the Bioengineering Department at UCLA effective Fall 2012. The Biomedical Engineering Interdepartmental Program (BME IDP) was established in 1997 and admitted its first graduate students in the fall of 1998. Shortly after, in 2004, the undergraduate Bioengineering Department was established and has seen rapid growth in enrollment at UCLA. Over the years, both the BME IDP and Bioengineering Department have focused on interdisciplinary and translational research, which benefits from collaborations within the School of Engineering, as well as with the Schools of Dentistry and Medicine, and the College of Letters and Sciences. Currently on campus, there is a focus on entrepreneurship under the auspices of Bioengineering. This has led to new collaborations with the faculty of our David Geffen School of Medicine and Anderson School of Business. With the merger, there are more than 80 faculty members in the Bioengineering Department at UCLA, including members of the Schools of Engineering, Dentistry and Medicine, as well as the College of Letters and Sciences.

The UCLA SFB student chapter was founded by Helena Chia, Arnold Suwarnasarn, Abigail Corrin and Chase Linsley, graduate students in the Bioengineering Department at UCLA, with advisement from Prof. Howard Winet. As the only student chapter in California, we are interested in involving others in our area and would like to reach out to other SFB members who want to be involved in SFB at a local level. Additionally, we invite all SFB members who wish to be involved in activities happening at UCLA SFB or who want to just say 'Hello' to contact our student chapter (uclasfb@gmail.com). We look forward to a great year and meeting the other student chapters and SFB members at the national meeting.

Ashley Parker, the 2012-2013 President of the University of Memphis SFB chapter.



Ashley graduated from West Jones High School in Laurel, Miss., and went to the University of Southern Mississippi (USM) for her undergraduate degree. She graduated magna cum laude with a bachelor of science in Polymers and High Performance Materials from USM in 2009 and was awarded a National Science Foundation Graduate Research Fellowship to continue her studies in Biomedical Engineering in the Joint Program at the University of Memphis and University of Tennessee Health Science Center. She was awarded a master's degree in 2011 and is currently a PhD candidate hoping to graduate next year. Ashley is working with Dr. Warren Haggard on modifying chitosan sponges for the local delivery of both antibiotics and antifungals in traumatic wounds for polymicrobial infection prevention. Ashley hopes to work in the medical device or pharmaceutical industry and has interests in product development, regulatory affairs and clinical affairs.

Member News

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Springer e-books) and as a hardcover printed book. The book was written by internationally acclaimed researchers, some of them members and fellows of SFB. It consists of 18 chapters, 516 pages and 192 illustrations.

Hitesh Handa, Ph.D., Department of Surgery, University of Michigan, recently received funding from NHLBI for a K25 grant entitled, "Prevention of thrombosis by NO-Secreting Polymers."

Thomas J. Webster, Ph.D., has recently been selected as the Department Chair of Chemical Engineering at Northeastern University in Boston.

It was good to hear from "retired" members of the Society. **Edward W. Merrill, Ph.D.,** a recipient of our Founders Award, remembers a pleasant association with SFB and members over the years. He indicates that even though he has been retired for more than 10 years, he still feels strongly about the professional role of the Society For Biomaterials. Dr. Merrill writes "…As a member of another society, I note that from time to time, they touch upon biomaterials, but they do not replace SFB, so I urge SFB to stay in business." Dr. Merrill is Professor Emeritus at MIT, and as a prominent researcher in biomaterials in the 1960s and '70s, he and his colleagues showed polyethylene oxide was remarkably inert (as compared to other materials) when in contact with blood. At MIT, Dr. Merrill also used his expertise in polymer chemistry, especially the study of membranes, as well as his expertise in blood rheology, to make major contributions to the development of the artificial kidney and oxygenation of the blood during open-heart surgery.

Students in the News:

Mary Beth Browning, a Ph.D. candidate in the Department of Biomedical Engineering at Texas A&M University is one of 85 women doctoral candidates from across the United States and Canada to receive a 2012-2013 Philanthropic Educational Organization (PEO) International Scholar Award. She was given the additional distinction of being named the Presidential Endowed Scholar, one of eight endowed scholarships awarded each year. This organization provides financial aid to promote and celebrate women in education. Mary Beth is a fourth-year graduate student in the laboratory of **Dr. Elizabeth Cosgriff-Hernandez**, where she is working on developing a small-diameter vascular graft for bypass surgeries. Mary Beth was also selected as a National Science Foundation Graduate Research Fellow as a first year graduate student and her work on vascular grafts has resulted in three first-author refereed journal articles.

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faculty and other employees as part of their job is assigned to the University, though royalties and other benefits are shared with the inventors. Properties generated by students are owned by them, unless they have used significant university resources in developing the invention. The same guidelines apply for inventors external to the university. Most universities have similar rules, and the share of royalties returned to the inventors is often quite generous, relative to the situation in industry.

However, I have found there are three general scenarios in which IP issues in design classes can interfere with innovation, as well as with the educational goals of the class. The first is when external speakers or other participants are invited to be involved in class in a capacity in which new IP might be generated. Typically, these participants are asked to sign a standard non-disclosure form, which stipulates that they not discuss any new ideas that arise from class with others outside of class. This agreement is meant to protect the students. Any ideas that have previously been generated or disclosed, as well as existing IP, are of course exempted, and typically these forms are not controversial. However, a smaller set of people seem to automatically feel that that they are "signing something away" when asked to complete this form, even though I try to emphasize that the IP in question does not exist yet, and that if they are involved in its creation then they will be inventors according to standard practices.

The second situation where IP sometimes impacts a class is when financial sponsorship is provided by an external company or organization. The design class I currently teach has company sponsorship that pays for the invitation of external speakers, materials and supplies for the class, as well as prototyping and other costs incurred by the project teams. Importantly, inventorship in the class is assigned according to standard guidelines (to students, faculty, and other participants as appropriate), and the sponsoring companies do not share in the initial IP generated by the students. However, our sponsorship contract allows the funding company to have the first right to negotiate a license within a limited timeframe. The negotiation is handled by the university, but the rights of all the inventors are represented as in any other negotiation. If an agreeable license is not negotiated, then the IP rights return to the inventors. Again, in a small number of cases, potential participants in my class balk at sponsored projects because they are worried that they will lose control of their IP. From my perspective the agreement we have in place is mainly to protect the rights of students, to ensure that they are represented in any licensing. I would argue that is a good deal for all involved, since the initial development of the idea in class is paid for, while the inventors retain their ownership of the IP, but also have an inside track in present their concept to an interested party that could support further development.

Few would argue that IP is not necessary, since it is a key part of the foundation upon which our current business models are based.

The third situation where I have seen IP interfere with innovation is when inventors cannot agree on the direction to take a project after completion of a class. In some (though admittedly relatively rare) cases, the projects developed in class are shown to have real commercial potential. Usually the project team members are co-inventors on the IP, sometimes with other participants external to the class. If not all the inventors are interested in further pursuing product development, then agreements need to be reached to appropriately assign the IP, so that development can move forward. This is another situation in which I have seen people be unwilling to relinquish their IP, in spite of the fact that they are not interested in pursuing its development. In the case of students, this situation sometimes arises because some team members have jobs lined up and are therefore not willing to commit to being part of a start-up. This situation can be problematic, and often leads to abandoning the product. In my current class, students are asked to sign a document at the beginning of the year stating that they will either participate in the development of the IP, or will freely transfer their portion to the other team members. The intent of this document is to allow product development to progress, as long as there are interested team members.

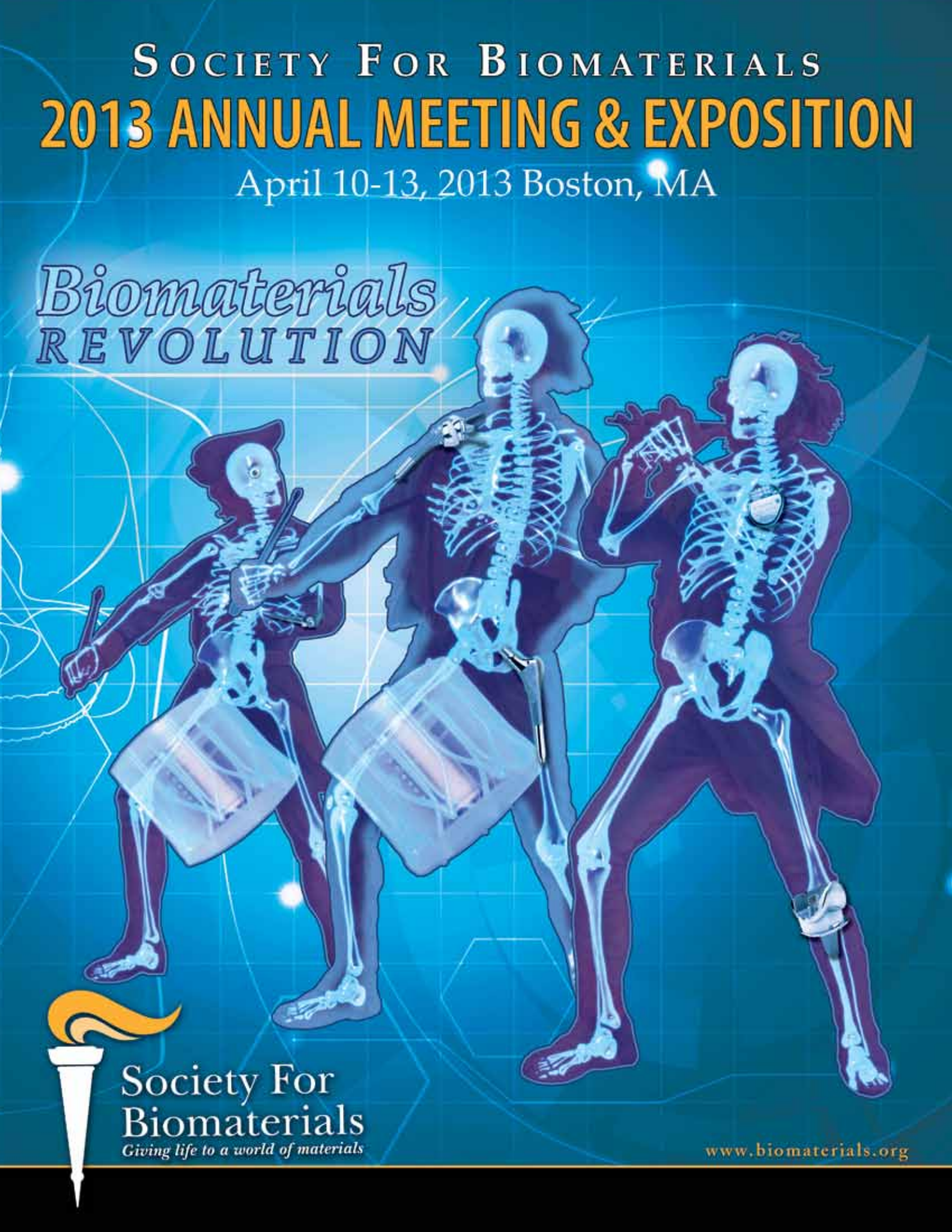
Few would argue that IP is not necessary, since it is a key part of the foundation upon which our current business models are based. However, I do sometimes feel frustrated that issues of potentially assigning IP can prevent people from fully participating in the innovative design experiences that are being implemented at many academic institutions. In particular, it is unfortunate that human nature sometimes sees the possible negative aspects of "losing" IP as more concrete than the potentially important advances that can be made by promoting unfettered innovation. Is there an alternative? I'm not sure, but as always I am interested to hear from the SFB membership about this topic. If you have had similar experiences, or have found ways to make IP "work" in your classes, please let me know. Fortunately, the instances of IP causing real problems in academic design classes are relatively rare. But it is somewhat ironic that a mechanism set up by our government to stimulate creativity and innovation in society can have a stifling effect in the classroom.

SOCIETY FOR BIOMATERIALS

2013 ANNUAL MEETING & EXPOSITION

April 10-13, 2013 Boston, MA

Biomaterials REVOLUTION



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