REMEMBERING GÜNTHER HEIMKE
UPDATE FROM THE BMPC SIG AND BTI SIG

BIOMATERIALS C

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

FOURTH QUARTER 2019 • VOLUME 41, ISSUE 4

ALSO INSIDE

AN INTERVIEW WITH CARL SIMON

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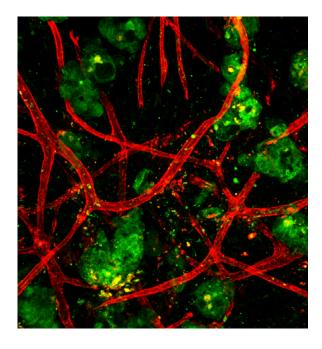
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ON THE COVER

The cover image, provided by Prof. Ram Annamalai of the F. Joseph Halcomb III, MD Department of Biomedical Engineering at the University of Kentucky, shows an immunofluorescence image of endothelial networks (red) from the vasculogenic microtissues encircling the osteogenic microtissues (green) containing mesenchymal stem cells. This combinatorial approach emulates the native coupling of vasculogenesis and osteogenesis and offers an enhanced therapeutic strategy for mature and vascularized bone regeneration. Applying this strategy, Prof. Annamalai's team aims to develop autologous cell therapy for nonunions.

From the Editor

A FEW WAYS TO BOLSTER HUMAN CAPITAL

By Guigen Zhang, Editor, SFB Forum



Human capital? No, I am not talking about the money we have or the stocks we possess; rather, I am referring to our intellectual capacity. The meaning of human capital has evolved over the years. It used to be regarded as knowledge, skills and work experience; then it expanded to

include the ability to learn, think creatively, respond to change and handle risk and adversity. Now, it includes the skills in comprehension of humanistic needs and aptitude for humancentered innovative endeavors.

Recently, I reread the article "The Business Case for Curiosity" by Prof. Francesca Gino in the *Harvard Business Review* (Sept–Oct, 2018) and noted that some of the suggestions Prof. Gino gave would be of great value to students and post-docs who are seeking ways to jumpstart their careers and make a difference to society, either in a scientific sense or a humanistic one. Here, I highlight three of the five ways Prof. Gino listed — I hope that SFB students and post-docs will take notes.

DEVELOPING INTELLECTUAL CURIOSITY

IDEO, the design and consulting company, seeks to hire "T-shaped" employees: people with deep skills that allow them to contribute to the creative process (the vertical stroke of the T) and a predisposition for collaboration across disciplines, a quality requiring empathy and curiosity (the horizontal stroke of the T). The firm understands that empathy and curiosity are related: Empathy allows employees to listen thoughtfully and see problems or decisions from another person's perspective, while curiosity extends to interest in other people's disciplines, so much so that one may start to practice them. And it recognizes that most people perform at their best not because they're specialists but because their deep skill is accompanied by an intellectual curiosity that leads them to ask questions, explore and collaborate.

To identify potential employees who are T-shaped, IDEO pays attention to how candidates talk about past projects. Someone who focuses only on his or her own contributions may lack the breadth to appreciate collaboration. T-shaped candidates are more likely to talk about how they succeeded with the help of others and to express interest in working collaboratively on future projects. To assess curiosity, employers can also ask candidates about their interests outside of work.

Reading books unrelated to one's own field and exploring questions just for the sake of knowing the answers are indications of curiosity. And companies can administer curiosity assessments, which have been validated in a myriad of studies. These generally measure whether people explore things they don't know, analyze data to uncover new ideas, read widely beyond their field, have diverse interests outside work and are excited by learning opportunities.

CULTIVATING INTELLECTUAL HUMILITY

Why do we refrain from asking questions? Because we fear we'll be judged incompetent, indecisive or unintelligent. When we demonstrate curiosity about others by asking questions, people like us more and view us as more competent, and the heightened trust makes our relationships more interesting and intimate. By asking questions, we promote more meaningful connections and more creative outcomes.

Higher levels of intellectual humility (the ability to acknowledge that what we know is sharply limited) are associated with a greater willingness to consider views other than our own. People with more intellectual humility also do better in school and at work. Why? When we accept that our own knowledge is finite, we are more apt to see that the world is always changing and that the future will diverge from the present.

FOCUSING ON LEARNING RATHER THAN RESULTS

It's natural to concentrate on results, especially in the face of tough challenges. But focusing on learning is generally more beneficial to us and our organizations, as some landmark studies show.

A body of research demonstrates that framing work around learning goals (developing competence, acquiring skills, mastering new situations and so on) rather than performance goals (hitting targets, proving our competence, impressing others) boosts motivation. And when motivated by learning goals, we acquire more diverse skills, do better at work, get higher grades in college, do better on problem-solving tasks and receive higher ratings after training.

To close, let me briefly tell you what we have prepared for you in this issue. You will read our Letter from the President, Members in the News, Staff Update and Student News columns, as well as updates from the Biomaterials & Medical Products Commercialization SIG and Biomaterials–Tissue Interaction SIG. In our regular columns, you will read Industry News, Government News and a Book Review. In Memoriam, you will read remarks by Paul Ducheyne on Günther Heimke, a pioneer in the field of biomaterials. In this issue, we also share with you the Code of Ethics recently approved by the SFB Council and highlights from the International Nanomedicine and Drug Delivery Symposium recently held in Cambridge, Massachusetts. We also feature an interview with Carl Simon on his unique career path. I encourage all SFB members to share with us similar reflections and highlights from biomaterials-related scientific gatherings and meetings you've had in your regional events.

All the best,

Guigen Zhang

From the President

By Horst von Recum, SFB President



Dear Friends and Colleagues,

It has been an honor to serve as your President of the Society for Biomaterials this past Quarter. Our wrap-up of the 2019 meeting in Seattle confirmed that it had strong financial and

societal performance and was an excellent point to be ending the 2019 year with, since in this coming year we will not be holding our National meeting in the US. Lack of a US meeting impacts both our income (national meetings are the single largest income item in a normal year), and the continuity of member participation. We expect the financial successes of the last couple years combined with some belt-tightening measures will see us through this next year, to emerge on the other side with hopefully another great US National meeting, to be held in Chicago in 2021.

Don't forget that we will not be idle this coming year. I still hope to see you all at the Biomaterials World Congress from 19-24 May 2020 in Glasgow Scotland, hosted by the European Society for Biomaterials. We expect to see an excellent program there as well, and encourage you to contribute as you would for one of our national meetings (wbc2020.org). It's not too late to help! (I think reviewers are still needed. Feel free to reach out).

Plans continue to progress for the Fall of 2020 when our Society will also hold a joint symposium with the Japanese Society for Biomaterials from December 11-13, 2020 in Hawaii.

"FOR THE FIRST TIME IN THE HISTORY OF OUR SOCIETY, OUR LEADERSHIP COUNCIL CONSISTS PREDOMINANTLY OF WOMEN.

AS I MENTIONED IN MY BEGINNING OF THE YEAR ADDRESS, WOMEN IN OUR SOCIETY REPRESENT ONE OF THE STRONGEST GROWING SEGMENTS.

WE CAN CERTAINLY ATTRIBUTE THE GROWTH AND SENSE OF COMMUNITY TO EXCELLENT PAST LEADERSHIP AND CURRENT LEADERSHIP."

Other aspects of the society, such as local Biomaterials Days, *Biomaterials Forum*, Council, committees, and local chapter activity are expected to continue as we would any other year.

If you had the luck/misfortune of hearing my address at the Business Meeting in Seattle, you will know that I further urge all of you to use this year as a period of self-reflection and renewal. Specifically, I would like each of you to ask yourself two questions: 1) "What is my Biomaterials Community?" and 2) "Have I passed on my legacy to others." I will explain in a little more detail. This quarter I wanted to approach my own observations on these two points, to indicate the data that I have uncovered, indicating a much more positive, growing community than I had expected to find.

BIOMATERIALS COMMUNITY: CONFIDENCE IN A CAPABLE LEADERSHIP TEAM

In July we had a teleconference for the leadership Council for our Society, planning the years activities. This was followed by an in-person meeting in October. You may not be aware, but for the first time in the history of our Society, our leadership Council consists predominantly of women. As I mentioned in my Beginning of the Year Address, women in our Society represent one of the strongest growing segments. We can certainly attribute the growth and sense of community to excellent past leadership (including past presidents Linda Lucas, Anne Meyer, Martine LaBerge, Lynne Jones, Karen Burg, and Liisa Kuhn), and current leadership, including Shelly Sakiyama-Elbert our President-Elect and Past Secretary-Treasurer; as well as Elizabeth Cosgriff-Hernandez, current Secretary-Treasurer. What I was impressed with at our council meeting was to see how much conversations changed as to what the Society meant to its individuals and where the Society was going. Conversation included different opinions and was very optimistic and hopeful; a clear demonstration of our emphasis on the value of diversity and inclusion. As an example, Cherie Stabler, your Memberat-Large, used her position on council to actively move new policies forward. She has also worked with our membership committee to develop an extensive survey that will be distributed in the coming months, determined to increase the value of our society to members from industry, and academia, and to better inform standards organizations. Please take the time to complete the surveys that will be coming out in the coming weeks as the results will help us shape the future of the Society! And thank you, Cherie! I look back at how much more I could have / should have done in my term as Member-at-Large all those years ago. So my take home message is that I feel confident in the rest of the leadership in our Society, and encourage you to reach out to your leaders. They have a voice and are using it.

BIOMATERIALS DAYS: PASSING ON OUR LEGACY

Two weeks ago, I had the opportunity to participate in a Biomaterials Day at Case Western Reserve University. CWRU is

in a consortium with three other schools (U. Michigan, CMU. and U. Pitt), where we rotate which location requests the Biomaterials Day in a given year. In addition to this being a good Biomaterials Day model that other regions have also adopted, it has helped build regional communities, including creation of new chapters, etc. Similar to my Council experience, I felt that our Biomaterials Day had a strong, vibrant dynamic, with many early career scientists participating and becoming involved in the Society. Also I think our Biomaterials Day has industry sponsors for the first time! I challenged the attendees to think about what they want out of the Society and how they can help to ensure the evolution of our Society to get us there. Many people came to me afterwards, energized and looking to participate further. There was some concern that the next meeting was out of the country and that they wouldn't be able to afford to attend, and would lose momentum in their SFB interests, and/or search for other meetings to go to that year. To keep up the momentum, I

challenge each of you to spend this year a) participating in your own local Biomaterials Day, engaging others; and b) planning your next Biomaterials Day for your school or your region. In closing, I think my initial, grim outlook as to the future of the Society might have been premature. New data from this quarter might indicate that the society is still thriving in the trenches. Throughout the rest of this year I will continue to reach out to all of you through a number of different means, and will be curious as to the results of your internal reflection. In the meantime, you should never hesitate to reach out to me. You can always reach me at horst@case.edu. I look forward to hearing from you and to serving you and your Society for the coming year.

Best Wishes, Horst von Recum

HAVE A LETTER TO
THE EDITOR,
REGIONAL BIOMATERIALS
EVENT HIGHLIGHTS
OR COVER ART
TO SHARE WITH
FORUM READERS?

PLEASE CONTACT
Guigen Zhang at
quigen.bme@uky.edu.



Dr. Günther Heimke, third from left

Remembering GÜNTHER HEIMKE

By Paul Ducheyne, University of Pennsylvania

Dr. Günther Heimke, the third president of the European Society For Biomaterials, passed away on Aug. 19, 2019, in Kiel, Germany, at the age of 97 years. He succeeded Dr. Jean Leray, who shortly before died in an avalanche in the Alps. Previously, Dr. Heimke had been treasurer from about the founding of the Society (1976) until his election as president.

Dr. Heimke was born in Berlin in 1922, survived the war and pursued studies of physics at the Martin Luther Universität, Halle-Wittenberg. This university was located in the former East Germany, close to Leipzig. Before the wall was built, he moved to West Germany and developed an outstanding career in the German industry that was being rebuilt in the post-war years. He worked in high-tech ceramics at Friedrichsfeld, and it is there that he developed his interest in biomaterials.

Dr. Sam Hulbert, one of the founders of SFB, worked on porous alumina in the early '60s. This work elicited the interest of three high-tech ceramics companies in Europe, one in France and two in Germany. It was at Friedrichsfeld, Mannheim, that Dr. Heimke directed the program to develop alumina as an artificial bearing material in total joint replacements (heads and acetabular components of total hip joint prostheses first). In this capacity, he was a colleague and collaborator of Prof. Peter Griss, who moved from Mannheim to the Philipps Universität,

Marburg, Germany, when appointed its professor and chairman of orthopaedic surgery.

Frialit, the separate division for oxide ceramics, was created within Friedrichsfeld in the '70s. Friedrichsfeld was renamed Friatec in 1992.

It wasn't long before Dr. Heimke also turned his attention to dental implants that incorporated alumina. Dr. Heimke was one of the pioneers involved in the development of the first dental implant systems in Germany and Europe in the '70s and '80s. He was closely associated with the Special Research Center for Dental Implantology at the Dental School of the University of Tübingen (a German Research Foundation–supported program). As such, Dr. Heimke contributed in a major way to the success of the Frialit I Tübingen alumina immediate implants for front teeth replacement. All Frialit products are part of the Dentsply catalogue nowadays.

When Dr. Heimke retired from Friedrichsfeld, he joined the bioengineering faculty at Clemson University and continued to inspire young minds. When he eventually really retired, he liked being in his beloved Casa Fascino Magnetico in Magadino, on the Swiss side of Lago Maggiore. His life was a life well lived.

Member News

By Cherie Stabler, Member-at-Large



I am so honored to serve as your 2019-2020 Member-at-Large representative! In this role, I will strive to provide your collective voice to the SFB Board and Council. I am actively working to support and expand our supportive and engaging community with broad and diverse

membership engagement. Please feel free to share your ideas and concerns with me directly at cstabler@bme.ufl.edu. Also, make sure you respond to our survey emails — your participation in these surveys help us capture the interests and needs of all of our members.

Some of this quarter's exciting member news and accomplishments:

The 2019 Young Innovator of Cellular and Molecular Bioengineering awardees were recently announced and include current Society for Biomaterials members **Ashish Kulkarni**, assistant professor of chemical engineering at the University of Massachusetts Amherst, **James Dahlman**, assistant professor of biomedical engineering at the Georgia Institute of Technology & Emory University, and **Stephanie Seidlits**, assistant professor of bioengineering at UCLA.

The selected participants of the National Academy of Engineering's (NAE) 25th annual U.S. Frontiers of Engineering (USFOE) symposium hosted by Boeing in September 2019 included current Society for Biomaterials members **Eun Ji Chung,** Gabilan assistant professor of biomedical engineering at the University of Southern California, **Emily Day**, assistant professor of biomedical engineering at the University of Delaware, **Cole A DeForest**, Dan Evans Career Development of chemical engineering at the University of Washington, and **Jamal Lewis**, assistant professor of biomedical engineering at the University of California Davis.

Josephine Allen, associate professor in material science and engineering at the University of Florida, sent a study into space for 30 days aboard the International Space Station in May of 2019. The study, which launched from NASA's Cape Canaveral aboard Space-X-17, involves assessing the effects of the space environment on vascular cells to better understand the mechanism behind zero-gravity induced cardiovascular deconditioning. The experimental samples were returned to UF in June 2019 and are currently undergoing post-flight transcriptomics analysis.

Danielle Benoit, professor of biomedical engineering at the University of Rochester, was recently promoted to the rank of full professor and Director of the Material Science program. In addition, her recent PhD graduate, Kenneth Simms, was awarded the International Association for Dental Research Colgate Research in Prevention Travel Award and the American Association of Dental Research Bloc Travel Award at the most recent International Association of Dental Research Conference. Another doctoral student, Marian Ackun-Farmmer, was the recipient of the Best Poster Award at the Gordon Research Conference on Cancer Nanotechnology (2019) and the Outstanding Contributions and Service for the University of Rochester in Biomedical Engineering Award (2019).

Joel Bumgardner, a professor of biomedical engineering at The University of Memphis, was recently named chair of the Department of Biomedical Engineering at the University of Memphis.

Jennifer Elisseeff, Morton Goldbert professor of biomedical engineer at Johns Hopkins University, was recently awarded a Director's Pioneer Award from the National Institutes of Health High-Risk, High-Reward Research Program. This Pioneer Award focuses on exploring the role of immune cells in healing.

Brendan Harley, Robert W. Schaefer Professor of chemical and biomolecular engineering at the University of Illinois, and Jennifer West, Fitzpatrick Family University Professor of Engineering of biomedical engineering at Duke University, co-chaired the Biomaterials and Tissue Engineering Gordon Research Conference held in Castelldefels, Spain (near Barcelona) from July 28-August 2, 2019. Brian Aguado, postdoctoral researcher at the University of Colorado, chaired the Gordon Research Symposium for trainees ahead of the conference, featuring Dr. Amar Sawhney as Keynote Speaker to discuss MedTech Entrepreneurship. The main conference featured sessions on Molecular Design of Materials, Biomimicry, Microfabricated Systems to Manipulate Cells and Mimic Organs, Stem Cells in Tissue Engineering, Commercialization and Clinical Translation, Engineered Tumor Models, and Realization of Engineered Tissues with invited speakers from academia, industry and clinical medicine presenting their latest research. Highlights of work presented at the conference included **Dr. Adam Feinberg** (Carnegie Mellon) discussing advanced biofabrication techniques that he has employed to build components of a heart, published in Science on August 2, and **Dr. Heather Prichard** (Humacyte) discussing

Member News (continued)

clinical translation of bioengineered blood vessels. The top poster presentations from Young Investigators (students, fellows and junior faculty) were recognized and invited for oral presentations. These included **Gillie Agmon** (Stanford), **Genesis Lopez-Cazares** (Michigan), **Maria Coronal** (Georgia Tech), **Anita Shukla** (Brown), **Jeroen Leijten** (Twente), and **Donny Hanjaya-Putra** (Notre Dame). The next Biomaterials and Tissue Engineering Gordon Research Conference will be held in 2021 and will be chaired by **Andrew Putnam** (Michigan) and **Tatiana Segura** (Duke).

Ryan K. Roeder, professor of aerospace and mechanical engineering at the University of Notre Dame, recently presented his new biomaterial technology at the Spine Surgery Think Tank in June 2019. His patented porous and bioactive PEEK interbody fusion cage is licensed to HAPPE Spine, LLC, which anticipates FDA approval of this technology for facilitating osteointegration in early 2020.

Cato Laurencin, Albert and Wilda Van Dusen Distinguished Professor of orthopaedic surgery and chemical, materials and biomedical engineering at the University of Connecticut School of Medicine, was recently awarded the 2019 National Academy of Medicine (NAM) Walsh McDermott Medal, the 2019 National Academy of Engineering (NAE) Simon Ramo Founders Award, and the United Nations Educational, Scientific and Cultural Organization (UNESCO)-Equatorial Guinea International Prize for Research in the Life Sciences. One of only 3 awardees, the 2019 NAM Walsh McDermott Medal recognized Dr. Laurencin for his devoted mentorship of early career and underrepresented minority scientists, as well as his substantial activity to NAM committees. Dr. Laurencin was awarded the 2019 NAE Simon Ramo Founders Award for his pioneering contributions in the engineering of tissues, his activity in scientific policy, and his promotion of diversity and excellence in science. Dr. Laurencin is the first to receive both of these prestigious awards. In addition,

Dr. Laurencin will be awarded the UNESCO-UNESCO-Equatorial Guinea International Prize for Research in the Life Sciences award in February 2020 during the Africa Union Heads of States Summit taking place in Addis Ababa, Ethiopia. This award serves to acknowledge leaders "who have made significant efforts through scientific research towards improving the quality of human life". Dr. Laurencin is one of only three 2019 laureates.

Jennifer West, Fitzpatrick Family University Professor of Engineering of biomedical engineering at Duke University, recently published a manuscript in the Proceedings of the National Academy of Sciences outlining clinical results from treating 16 prostate cancer patients at the Icahn School of Medicine at Mount Sinai in New York using nanoparticle-based, focal therapy. This photothermal cancer therapy approach uses illuminated nanoparticles developed by Dr. West and her collaborator Naomi Halas, Stanley C. Moore Professor of electrical and computer engineering at Rice University. Nanospectra Biosciences currently funds these clinical trials.

Advanced Medical Technologies Ltd Inc (AMT), a hi-tech medical device company founded by a group of long-time SFB members, successfully completed the First-in-Man (FIM) implantation of a poly(L-lactide) bioresorbable coronary stent (AMSorbTM) made by an additive manufacturing/3D printing technology in the 1st Hospital of Beijing University on July 23, 2019. As of Sept 12, a total of 13 patients received AMSorbTM. This FIM study was the first part of a large-scale Chinese regulatory agency approved clinical trial initiated by Beijing Advanced Medical Technologies Ltd Inc (AMT). This was the first time a 3D printed cardiovascular bioresorbable stent was used in a clinical setting. The six-month follow-up result is expected by mid-2020.

ATTENTION MEMBERS!

WE WOULD LOVE TO HEAR FROM YOU.

IF YOU HAVE NEWS TO SHARE WITH FORUM READERS, LET US KNOW.

EMAIL YOUR NEWS AND ANY PHOTOS TO INFO@BIOMATERIALS.ORG

AND YOU COULD BE FEATURED IN THE NEXT ISSUE.

Staff Updates

By Brittany Noll, Assistant Executive Director



Greetings from the Society For Biomaterials headquarters! The Society's Board of Directors and governing Council met on Oct. 15, 2019, at SFB headquarters in Mount Laurel, New Jersey. They reviewed the 2020 budget and continued their work implementing the strategic plan for the

Society. Following is a summary of the actions and plans for the Board, Council, committees and task forces.

BOARD/COUNCIL

President, Horst von Recum, PhD

The Board previously added the Diversity and Inclusion Task Force. Charges were reviewed at the board meeting. The current plan is to codify this task force as a permanent committee, with a bylaws amendment to be voted on at the 2021 Annual Meeting.

AWARDS, CEREMONIES AND NOMINATIONS COMMITTEE

Chair: Liisa Kuhn, PhD

The committee received a total of 63 award nominations, as well as a full slate of officers to stand for election in 2020. Officer candidate information and award announcements will be featured in the next issue of the *Forum*. Thank you to all who made nominations, and please start thinking about possible nominations for next year — especially those who may have interest in serving on the Society's Board of Directors as president-elect, secretary-treasurer-elect or member-at-large.

BYLAWS COMMITTEE

Chair: Ashley Carson Brown, PhD

The committee will be reviewing the bylaws and discussing amendments, including the addition of a Diversity and Inclusion Committee, as mentioned.

EDUCATION & PROFESSIONAL DEVELOPMENT COMMITTEE

Chair: Anirban Sen Gupta, PhD

The committee reviewed submissions for 2020 Biomaterials Days grants. All nine applications were approved for funding; however, some of the proposals will require some modification before funds can be awarded.

Biomaterials Days organizers will receive a package that includes retractable banners, swag items, flyers, promotional slides and a membership promotion code. Students and post-docs who register for a Biomaterials Day event can use the promotion code for a \$50 discount off their membership dues.

Anirban Sen Gupta worked with Special Interest Group (SIG) Representative Danielle Benoit to reach out to SIG chairs to solicit topics for webinars for their individual SIGs. Topics were submitted, and the SIG chair and Education & Professional

Development Committee will review the topics to create a webinar schedule for 2020.

FINANCE COMMITTEE

Chair: Sarah E. Stabenfeldt, PhD

After the success of the 2019 Annual Meeting in Seattle, projections indicate a healthy net income for 2019, and the retained earnings should stabilize resource requirements for the 2020 World Congress year. The SFB 2020 budget was approved with investments in Biomaterials Days, a new marketing initiative and a breakeven budget for the Fall Symposium being held in Hawaii in December 2019, which is jointly sponsored by the Japanese Society For Biomaterials.

INDUSTRIAL AFFAIRS COMMITTEE

Chair: SuPing Lyu, PhD

The committee will plan to organize a forum for device companies, suppliers and government agencies to harmonize regulatory efforts and stabilize supply chains. These efforts will include a panel discussion at the 2021 Annual Meeting.

LIAISON COMMITTEE

Chair: Tim Topeski, PhD

SFB is working with the Materials Research Society to organize a webinar on synthetic biology in 2020. In addition, SFB will pitch to host the 2028 World Congress.

MEMBERSHIP COMMITTEE

C. LaShan Simpson, PhD

Current membership stands at 1,377, with 678 active, 95 post-grad, 50 retired and 554 student members. The committee continues to develop strategies to increase membership, focusing on industry and clinical sectors. The committee has developed three member surveys to go out to SFB members. One was sent in October to verify member contact information. The next will be a member exit survey for those who chose to leave the Society, and the last will be a member needs survey to gauge satisfaction with SFB's benefits for current members and ask for ideas on improvement and added value.

PROGRAM COMMITTEE

Chairs: Elizabeth Cosgriff-Hernandez, PhD, and Nicholas P. Ziats, PhD

The 2020 Society For Biomaterials Fall Symposium will take place in Honolulu, Hawaii, from Dec. 11–13, 2020. The call for abstracts will be issued in the first guarter of 2020.

SPECIAL INTEREST GROUPS

Danielle Benoit, PhD

All SIGs submitted budget proposals for 2020, and we will be planning an All SIG Mixer at the World Biomaterials Congress

Staff Updates (continued)

in Glasgow in May 2020. Many SIGs will also sponsor student awards at the World Biomaterials Congress. In addition, the Protein and Cells at Interfaces SIG has been renamed the Biointerfaces SIG. The publication of the *SIGnal* newsletter continues on a monthly basis.

NATIONAL STUDENT CHAPTER/YOUNG INVESTIGATORS

Jason Guo, National Student Chapter President, and Brian Aguado, PhD

The SFB National Student Chapter and the Young Investigator Group will be co-sponsoring another mixer with the young investigator groups from the European and Canadian Societies at the World Congress.

If you have any questions,

need any information or have suggestions for improved services, please feel free to contact the Society's Headquarters office:

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Student Chapter News

STAYING ORGANIZED IN GRAD SCHOOL

By Jason Guo, National Student Chapter President



Greetings SFB student members! With the start of a new school year, we often find ourselves taking on new classes, new projects, new teaching assignments and more. Furthermore, it can often feel like your responsibilities are all competing individually for your time. So, how do you stay

organized and juggle all the responsibilities of graduate school? As a fifth-year graduate student, one thing that has become clear to me is that using your time efficiently can not only enable you to accomplish much more than you thought but also free up critical hours each day for self-care and fulfilling hobbies outside of your career. While I may not be a certified expert on time or project management, I can share a few key pieces of advice that have worked for me and others.

SCHEDULE, SCHEDULE, SCHEDULE

The greatest asset to productivity for my graduate career has been Google Calendar. While research may be unpredictable in its outcomes, the start times, durations and timepoints of many experiments can be planned ahead of time. Furthermore, as you gain sufficient experience with the common assays, reactions, etc. of your research projects, you can often predict and track the amount of time it takes to accomplish specific tasks. By plotting tasks in your experiments as calendar events with defined start and end times (whenever possible), you can strategically plan and move around your experiments/writing/etc. on your calendar in a way that packs the most tasks into any given day while minimizing downtime, which often lends itself

to procrastination. I've always found it most helpful to plan out a couple days, if not a week, in advance; this planning process typically only takes about 10 to 20 minutes. By planning in advance, I can make sure that tasks with earlier deadlines are accomplished earlier in the week and, additionally, that lower priority tasks are scheduled after higher priority tasks. If this sounds daunting, rest assured that it becomes second nature after just a little bit of practice, and that it gets even easier to plan and prioritize as you become more familiar with your own research projects.

One important caveat here is that you should always plan with some buffer time between events. Labwork can be highly variable in the time it takes to complete, so I've found that it helps me stay on track if I plan for 15 to 30 minutes of extra buffer time for any task. The quality of my labwork is also improved if I don't feel rushed and know that I have buffer time to spare. A related concept to keep in mind is that your daily schedule of experiments should never be considered rigid, with the exception of, say, meetings where you're professionally beholden to others' time. If an experiment takes 30 minutes longer than expected, then move the subsequent events on your calendar 30 minutes later! If your scheduled tasks then begin to run past a reasonable working hour, then move those tasks to empty spaces in the following days on your calendar. The goal is never to follow your calendar 100% to the original plan, but rather to adapt it to fit your needs as they progress that day or week.

TIME FOR SMALL TASKS

Feel inundated with emails and administrative tasks? Set aside dedicated time to working on them! A simple 20 to 30 minutes a day can sometimes be enough to hunker down and knock out all of these small tasks, so that they don't distract you during more focused work. I personally like to write all of my small tasks (as they come up) into a single 30-minute calendar event at the end of the day (essentially a checklist) so that I don't forget anything. Alternatively, I've synced my emails to my phone so that I can take care of lower priority emails while waiting in the elevator, standing in line at Chipotle, etc.

FOCUSED WORK

Many tasks such as writing and, of course, labwork are accomplished much more effectively and much more quickly when we're able to absolutely focus our mind on the task at hand. We're all guilty of procrastinating on social media instead of writing that manuscript, and there's definitely no argument being made here against social media. Consider, however — what if those needs could be compartmentalized in a way that they supplement rather than interrupt work? It turns out, there are actually straightforward ways to achieve just that! The Pomodoro technique is one commonly known method of time management that breaks work into cycles of 25 minutes of focused work

followed by 5 minutes of break, with longer 15-minute breaks every fourth cycle. Nowadays, there are plenty of free apps that can help you organize your work this way with user-defined intervals. The primary benefit of organizing break time is that rather than fall into the trap of ending up on social media for extended durations, you can fulfill the same needs within a defined, controlled pocket of time.

CONNECT WITH US!

Hopefully, you've enjoyed reading this and these pieces of advice can be helpful as you develop your own ideas on how to best manage your time. Personally, I've found that concretely organizing my time with Google Calendar and other tools mentioned in this article has granted me more free time and less anxiety about unfinished tasks at the end of the day.

Have any ideas for the National Student Chapter? Interested in participating or taking on a leadership position? Contact me at JLG19@rice.edu. You can also find SFB and its members on social media, including Facebook, LinkedIn and Twitter. More information on these social media outlets can be found here: https://www.biomaterials.org/about-about-society/sfb-social-media. Have an enjoyable and productive year!

Code of Ethics for the Society for Biomaterials

The collective activities of biomaterials scientists (i.e., those involved in the research, development of and clinical implementation of medical products using biomaterials), as represented by the members of the Society For Biomaterials, comprise a multidisciplinary and learned profession that has a direct and vital impact on public health. This role carries immense ethical responsibility. Stakeholders include (but are not limited to) patients and the public at large, scientists, engineers, clinicians, lawyers, insurers, hospitals, universities, regulators, educators, and professional societies (including SFB) and foundations. Involved in a field dedicated to the protection of the public health, safety and welfare, those practicing biomaterials science are obligated to adhere to the highest principles of ethical conduct, honesty, integrity, fairness and equity.

Thus, each biomaterials scientist shall:

- Act in such a manner as to uphold and enhance the honor, integrity and dignity of the profession.
- Hold paramount the safety, health and welfare of the public in the performance of their professional duties.

- Hold paramount a responsibility to all stakeholders, including patients, clinicians, the U.S. Food and Drug Administration, developers and manufacturers, and payors.
- Maintain a commitment to practice biomaterials research, development, commercialization and clinical implementation, following the highest standards of professional integrity at all times.
- Follow the highest standards of collaboration, authorship, peer review, education and mentoring.
- Maintain the highest standards for responsible conduct of research and development.
- Adhere to the need for evidence-based claims of biomaterials and medical device outcomes.
- Respect all forms of intellectual property.
- Avoid financial and other conflicts of interest related to the profession.

Highlights from the International Nanomedicine and Drug Delivery Symposium

The 17th International Nanomedicine and Drug Delivery Symposium was held from Sept. 22–24, 2019, in Cambridge, Massachusetts. The conference was organized by Dr. Daniel Anderson of MIT and Dr. Qiaobing Xu of Tufts University. The three-day conference featured talks from the top academics in the field of nanomedicine, as well as from C-suite executives from industry, ranging from new startups to heavy hitters such as Novartis and even venture capital firm Flagship Pioneering.

From the academic side, much of the research was focused on CRISPR-Cas9, CAR-T and immunomodulatory therapies. As the conference focused on nanomedicine, the use of novel nanocarriers to implement these and other techniques was heavily emphasized. From the industrial side, there was a particular focus on the challenges of scale-up and material consistency, particularly when working with challenging materials such as mRNA and nanoscale carriers. Overall, from both industry and academia representatives, there was a sustained discussion of the translational potential of the research being presented and

the process of clinical approval. Much of the CRISPR- and CAR-T-based therapeutics are just now reaching Stage I and II clinical trials, and so the symposium was an exciting opportunity to learn the very latest in clinical results, in some cases mere days after the results had been publicly disclosed. Furthermore, it was a unique opportunity to hear from industry leaders themselves about how clinical trial designs are adapting in response to early phase data and continued technological improvements.

In addition to the podium talks, 100 posters were presented in the poster session, showcasing the work of graduate and post-doctoral researchers in the field. Representatives from both leading peer-reviewed journals and sponsor companies judged the posters and awarded prizes to the best work. The conference was a tremendous success, and the 18th edition of the symposium will be held in the fall of 2020 at Rice University in Texas.



Poster award winner Shiran Ferber with conference chairs Prof. Daniel Anderson and Prof. Qiaobing Xu.

Biomaterials & Medical Products Commercialization SIG Update

The Biomaterials & Medical Products Commercialization Special Interest Group and its members exchange ideas and experiences regarding the translation, and subsequent commercialization, of medical products dependent upon biomaterials for utility and/or efficacy. Members include students, faculty, and industry representatives spanning numerous academic institutions, corporations, and regulatory entities.

The BMPC SIG had an exciting and successful Annual Meeting and Exposition in Seattle, Washington earlier this year. In addition to hosting and co-hosting 6 sessions, including two panel discussions on technology translation and commercialization, the BMPC hosted the annual Business Plan Competition. Moderated by Elaine Duncan (President, Paladin Medical, Inc.) and Jim Curtis (DuPont), this competition featured 4 international teams (2 USA, 1 Portugal, 1 Canada) who presented their business plans for a technology concept related to biomaterials:

- Evoke Medical, LLC: PiezoNail Stimulating a Pathway to Better Fracture Healing. Zachary R. Pessia, Craig A. Cunningham, Ember D. Krech, and E.A. Friis. University of Kansas.
- **SAPHTx:** Injectable Hydrogel for Treating Neovascular Ocular Diseases. Biplab Sarkar, Peter K. Nguyen, Zain Siddiqui, Vivek A. Kumar. *New Jersey Institute of Technology*.
- **B-CULTURE**. Raphaël F. Canadas, Joaquim M. Oliveira, Alexandra P. Marques, and Rui L. Reis. *University of Minho*.
- HumeurVitrée: Revolutionizing Retinal Detachment Surgery.
 Frances Lasowski, Ben Muirhead, and Heather Sheardown.
 McMaster University.

The teams were evaluated by a panel of industry judges: Sachin Mamidwar (Orthogen), Lihua Zheng (Zheng & Karg), Carl McMillin (Synthetic Body Parts, Inc.), Stephanie Steichen (DuPont), and Bob Hastings (DePuy Synthes Joint Reconstruction).

Congratulations to the first and second place winners – Evoke Medical, LLC and HumeurVitrée, who won \$1000 and \$500, respectively. The event was kindly sponsored by Tepha Medical Devices.

This event would not have been possible without the participation of our moderators, judges, corporate sponsor and, of course, the project teams. Thank you to everyone who was involved in making the BMPC Business Plan Competition a success!

The competition will be put on hold for the 2020 World Biomaterials Congress meeting, but will be re-initiated for the 2021 Annual Meeting and Exposition in Chicago, IL. Please reach out to Stephanie Steichen (BMPC SIG Chair, stephanie.steichen@dupont.com) or Bob Hastings (BMPC SIG Program Chair, bhastin2@its.jnj.com) if you have any interest in participating as a judge, mentor, or sponsor. We will also be soliciting abstracts from project teams interested in sharing their biomaterials innovations and business plans (official call for abstracts to follow).

2019 SIG UPDATES

The BMPC SIG, along with SFB Headquarters, has sent out a call for webinar topics for 2020. This webinar series is intended to leverage the deep biomaterials knowledge both in the BMPC SIG and in SFB at large to support continued education, SIG engagement, and society participation.

Some of the topics being considered by the BMPC SIG are (in no particular order):

Topic 1: Materials selection and evaluation considerations in medical product commercialization.

Topic 2: Regulations that help, hinder, or otherwise must be navigated for product commercialization.

Topic 3: Reimbursement: You've invented and developed a fantastic new medical product that can help humankind, cleared it through FDA, but without reimbursement through CMS and other payers, your success will be limited.

Topic 4: Understanding patents and other intellectual property protections.

Topic 5: Liability considerations, real and perceived risks in medical product commercialization.

Webinars are anticipated to begin in 2020. The initial solicitation for ideas and presenters concluded on November 1, 2019. However, as we work to develop this series, we ask that members continue to brainstorm topics that are related to our SIG's experience and expertise. If there is any interest in a particular webinar topic not listed above, or if you are interested in presenting a specific topic, please reach out to the BMPC SIG leadership.

Update from the Biomaterial-Tissue Interaction SIG

By Antonio Merolli

An incredibly worthwhile and successful Annual Meeting took place in Seattle! The beauty of the venue, the delicious food and the perfect organization contributed to a memorable meeting. However, our BTI SIG contributed, too.

The meeting started with a very interesting and crowded tour of the University of Washington. Our exceptional guide, BTI SIG Chair Floyd Karp, showed us the campus's famous cherry trees and facilities showcasing the decades-long work of Prof. Buddy Ratner and his coworkers.

Next, we enjoyed a high-quality BTI SIG technical presentation session. Certainly, we should mention the recipient of a certificate of commendation and a cash prize of \$100 for the best student oral presentation: Alisa Isaac from Texas A&M University, College Station, Texas, for her exceptional oral presentation, "The Anti-PEG Immune Response: Fact, Fiction or a Legitimate Concern for Biomaterials?"

The location of the poster session and its "eat while you read" setup made it very enjoyable. The quality of the posters submitted to our BTI SIG made it very difficult to select award winners. In the end, the two student posters selected were "Engineering Autoclavable and Injectable Hyaluronic Acid-Based Cryogel Scafflolds" by Mahboobeh Rezaeeyazdi from Northeastern University, Boston, Massachusetts, and "Increased Nanoparticle Uptake Under Disturbed Flow-Induced Degraded Glycocalyx Conditions" by Nandita Bal from Northeastern University, Boston, Massachusetts. We would have loved to recognize more of the many outstanding presenters!

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VERY ENJOYABLE."

The Bash event in the beautiful Seattle Art Museum was a highlight of the meeting. Our BTI SIG saved the best for last, as during the closing day we held our longtime planned tutorial on "Best Practices for Immunohistochemistry — Foreign Body and Other Responses to Medical Devices." Last year, the BTI SIG Board unanimously agreed that it was worthwhile for our group

to provide such an opportunity to all SFB members. The common approaches, such as immunohistochemistry, to characterizing the host response can be experimentally tricky to apply, resulting in artifacts that can be highly misleading. So, it was time for a refresher on concepts in the field. Talks included:

- Nicholas Ziats, Case Western Reserve University:
 "Immunohistochemistry to Aid Assessment of Devices —
 Foreign Body Giant Cell and Other Responses"
- Peggy Lalor, Histion, LLC: "Immunohistochemistry for Preclinical Studies: Techniques, Strategies and Pitfalls"
- Antonio Merolli, Rutgers University: "Application of Immunohistochemistry in the Study of Devices for Peripheral Nerve Guidance" (I am just noticing that I may have a conflict of interest in speaking so highly of this tutorial ... no, it was really good!)

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RESPONSES TO MEDICAL DEVICES.'"

Shall we provide this tutorial as a webinar? We'll discuss that soon for the SFB Annual Meeting in 2021.

Now, we are awaiting abstracts for the World Biomaterials Congress in Glasgow, UK. We should also highlight the SFB 2020 Annual Meeting in Hawaii; BTI SIG representatives will be there. Upon request from the World Biomaterials Congress and SFB organizing committees, we will contribute to the All SIG event that will take place in a fun location in Glasgow.

We look forward to meeting you in Hawaii and Scotland! (Wow! It is going to be an expensive year — but it's worth it.)

Industry News

By Steve Lin, Industry News Editor



Siemens Medical Solutions is acquiring **Corindus Vascular Robotics** for approximately \$1.1 billion. The deal is expected to close in the fourth quarter of 2019. Corindus, which manufactures the CorPath robotic platform aimed at assisting coronary and

vascular procedures, posted a \$9.7 million loss during the first quarter of 2019 and only had \$37.8 million of cash and cash equivalents on hand March 31. It appears Siemens Healthineers, the parent company, believes the addition of its imaging and artificial intelligence tools to Corindus' robotics platform will help it garner a stronger foothold into the vascular robotics sector.

Cleveland, Ohio-based medical device maker **Checkpoint Surgical** received breakthrough device designation from the U.S. Food and Drug Administration (FDA) for its brief electrostimulation therapy system intended for use in patients being treated for nerve injury. The technology, called the Checkpoint BEST system, is designed to improve outcomes after surgical intervention by providing electrical stimulation of peripheral nerves to bolster nerve regeneration. Checkpoint Surgical said it is actively enrolling patients in a clinical study of the technology at Washington University in St. Louis and is interested in adding more study sites, building on a recent study in animals.

The FDA is focused on improving efficiency of its 510(k) review process, through which the majority of premarket device authorizations are made. Recently, the agency issued four finalized or updated guidance documents key to its effort to streamline the 510(k) marketing authorization pathway to promote faster access to new medical technologies. The group of documents covers the special 510(k) program, the refuse to accept policy for 510(k)s and the format for traditional and abbreviated 510(k)s. The FDA said that the combined documents may conserve resources for both the agency and industry without altering the statutory criteria for substantial equivalence.

Baxter International agreed to acquire **Cheetah Medical**, the developer of a noninvasive fluid management monitoring system called the Starling SV, for up to \$230 million. The device's sensor pads are applied to the chest, enabling clinicians to assess heart function and fluid responsiveness to determine the amount of fluid needed for the individual patient to maintain optimal organ and tissue perfusion. The technology is designed for use in critical care, operating room and emergency department settings. Baxter agreed to pay \$190 million in cash for Cheetah, plus an additional \$40 million to be paid upon achievement of clinical and commercial milestones.

Notified body **BSI** has issued a conformity certificate to a **Novartis** inhaler under the incoming EU Medical Device Regulation, the first of its kind under the new regulations set to take effect next year. Under the older EU Medical Device Directive, the product was regulated as a Class I device and didn't require notified body review. Under the incoming regulations with more stringent rules, the product is classified as a Class IIa device and necessitates review.

Created in 2007, the **Medicare Fraud Strike Force** has units operating in 23 districts and has charged nearly 4,000 defendants who have collectively billed the Medicare program for more than \$14 billion. According to the most recent statistics from January, the strike force has brought 2,117 criminal actions, secured 2,754 indictments and recovered \$3.3 billion in connection with its investigations. Lester Stockett, owner and CEO of telemedicine company Medellin, pleaded guilty to taking part in one of the largest schemes to defraud Medicare ever investigated by the FBI and the Health and Human Services Office of the Inspector General and prosecuted by the Department of Justice.

Stryker plans to acquire sister companies **Mobius Imaging** and **Cardan Robotics** for \$370 million in upfront cash. An additional \$130 million is on the table based on completion of certain development and commercial milestones. Stryker will gain Mobius' Airo CT scanner, a mobile diagnostic imaging system. The FDA first granted 510(k) clearance to an earlier version of the system in 2013, adding a pediatric indication for the product last year. Cardan Robotics was founded in 2015 and is working to develop robotics and navigation systems for surgical and interventional radiology procedures.

Conformis has sued **Zimmer Biomet**, accusing the orthopaedic device giant of infringing four of its patents by making and selling certain knee, shoulder and hip replacement products. A complaint filed in the U.S. District Court for the District of Delaware alleges that Zimmer Biomet systems infringe on patient-specific instrument systems and techniques for joint replacement surgery that result in a more precisely placed implant. Conformis said it has suffered economic harm as a result of the alleged patent infringement and is seeking triple damages for lost profits and a "reasonable" royalty for its claim of willful infringement, as well as attorneys' fees and related costs.

Government News

NATIONAL ACADEMIES' FORUM ON REGENERATIVE MEDICINE

By Carl Simon, Government News Editor



ASTM STANDARDS BEING DEVELOPED FOR BIOINKS

Two new work items on bioinks have been initiated in ASTM. One is ASTM WK65681, "New Guide for Bioinks and Biomaterial Inks Used in Bioprinting." This standard will be an

umbrella document to define terminology and address important issues that may impact performance, reproducibility and quality control of bioinks. The second is ASTM WK65680, "New Test Methods for Printability of Bioinks and Biomaterial Inks." This document will describe two tests using an extrusion-based bioprinter to "extrude multiple lines or to build up a wall as a means of assessing printability of bioinks." Please see the links below for more information or to join the working group.

ASTM STANDARD ON DECELLULARIZED EXTRACELLULAR MATRIX IS IN PRESS

A new ASTM standard entitled "New Guide for Evaluating Extracellular Matrix Decellularization Processes" has recently gone to press and will soon be available for purchase online.³ The document summarizes methods used to assess decellularization processes and provides guidance to assist developers in deciding how to characterize their products.

U.S. FOOD AND DRUG ADMINISTRATION'S NEW BREAKTHROUGH DEVICES PROGRAM

The U.S. Food and Drug Administration (FDA) has a new

Breakthrough Devices Program for devices "that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions." ^{4,5} The goal of the program is to accelerate review by providing greater interaction with FDA staff, including senior management. The FDA may assist with an efficient study design that could use surrogate endpoints and adaptive study designs. The review will receive priority status by being placed at the top of the appropriate queue and may receive additional review resources as needed. The FDA may assist in composing the Data Development Plan and a Clinical Protocol Agreement. Please see the link below for more information and to determine eligibility for the program.

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WE WANT TO FEATURE YOUR EXCITING BIOMATERIALS ARTWORK ON THE COVER OF BIOMATERIALS FORUM.

Deadline: Accepted on a rolling basis.

Instructions: Please email artwork (digital images, artistic creations, etc.) to the Executive Editor of the *Biomaterials Forum*, Guigen Zhang, guigen.bme@uky.edu. All artwork with biomaterials relevance that have not appeared as a *Forum* cover are welcome. Multiple submission are permissible.

Description: Selected artwork will appear as the cover of a future issue of *Biomaterials Forum* along with a brief "On the Cover" description of the subject and name/affiliation of the creator.

Format: High-resolution electronic version in .gif, .tiff, or .jpeg file format.

An Interview with Carl Simon



Editor's note: Dr. Carl Simon is a longtime contributor of the Forum as the government news editor. He has done basic and applied research in the field of biomaterials for 20 years, working for the U.S. government at the National Institute of Standards and Technology (NIST)

within the Department of Commerce. If you are regular readers of the Government News column he composes, you may have benefited from his unique perspective from within the government on how to facilitate biomaterials research and development. Carl attended his first SFB Annual Meeting in 2002 in Tampa. In this interview, I intend to give you a closer view of his career path and thoughts on the Society.

Guigen Zhang (GZ): In what subject area did you get your undergraduate and graduate degrees?

Carl Simon (CS): I have a BS in biology from Bucknell University and a PhD in biochemistry from the University of Virginia (UVA).

GZ: What made you choose those subjects and universities? **CS:** When I was in high school, the mother of my good friend was my biology teacher. She paid extra attention to me during class since I was friends with her son and she had known me since I was a kid. She called me out in class, expected me to do well and talked to me about biology outside of class. She gave me disappointed looks if I did not live up to her expectations. This personal interaction from someone I knew and trusted made me love biology. Sitting at the foot of my bed filling out college applications, I had to select a major. Biology was the natural choice. I didn't know much about biology careers, only that biology felt right.

I chose to attend Bucknell because my friend's older sister, Julia, whom I looked up to, went there. It also felt right. At Bucknell, I had an inspiring biochemistry teacher named Prof. Clapp. The sense of awe in his voice during the lecture when he taught us about the catalytic triad in the active site of an enzyme, the reaction intermediate ... it blew my mind. I could hardly believe that was how living systems operated. Another key experience was in a physiology class when we learned about second messengers, cyclic AMP, membrane signaling and how human physiology was controlled by these biochemical events. I remember thinking that I would be good at figuring that stuff out. I didn't realize it at the time, but that was the instant when I decided to go to graduate school.

As college ended, I did not want to work. I liked school; graduate school was an easy decision, and biochemistry would be the major. At my first graduate school interview, the program director told me that I was not fit for graduate school. That really shook me, since this first interview was at my "backup" school. Fortunately, I was accepted to other programs. I was excited

to start and showed up at UVA one week after graduating from Bucknell in June 1992. I had no money; the stipend of \$11,000/ year seemed like a fortune, and school was better than working.

My first semester at UVA, I had another inspiring biochemistry teacher, Prof. Ching-hsien Huang, who gave me the catalytic triad lecture for the second time. Again, the amazement at the enzymatic mechanism, stabilizing the reaction intermediate and lowering the activation energy. When he finished his delivery, the class erupted in applause. It sounds corny, but this really happened.

GZ: What was your most important lesson from graduate school?

CS: Probably the failures. After a year or more of hard work, I had no useful results. It forced me to step back and think things through more carefully. I learned to plan, to work more efficiently, to do sufficient replicates to know that the results were reliable and to take ownership of my work. When I first started, I would do an experiment one time and use the results to make a decision. This practice led me in circles. After I started repeating experiments to figure out what was reliable, I began to accumulate useful data. Also, I figured, "My advisor is a smart guy; I'll just do what he says." But when things failed, the onus was on me, not on my advisor. I didn't understand — how could it be my fault? I just did what I was told. At that point, I started using my mentor as a source of advice and guidance instead of seeing him as the decision-maker. I took ownership. I was also lazy about documenting my work. It is important to write up each experiment with all key experimental details, make all the plots, think about the data and write down conclusions. Early on, I plowed ahead as fast as possible, several weeks at a time. When I would finally pause to organize my results and figure out my next steps, I had forgotten much of what I had done. Once I learned to do replicates, document my work and take ownership, things went much better.

GZ: What did you do after graduation?

CS: My PhD thesis was in the field of second messengers and signaling, and I was ready for a change. One of my thesis committee members had been contacted by a NIST scientist looking for a post-doctoral fellow to set up a cell culture lab in the NIST Polymers Division. The division wanted to expand its biomaterials program into tissue engineering. I'd heard of "tissue engineering," and it sounded exciting. Moving from a biochemistry department to the Polymers Division was great. I was immersed in a totally new culture (government instead of academia) and a totally new discipline (materials science instead of biochemistry). There were no lectures about phosphofructokinase, lipid membrane biophysics or DNA replication, but many lectures about phase separation in polymer blends, polymer mechanics and dieletric materials. I enjoyed this

steep learning curve. Also, I unknowingly became the resident expert in bio-stuff. As a young scientist, my ego appreciated it when senior materials science staff came to ask me questions about cell biology.

GZ: Can you give examples of the kinds of things you learned after your formal education ended?

CS: I had no interaction with industry during graduate school. I had no understanding of manufacturing, standards, the role of government in research and how industry approaches research. Industry wants to do things as efficiently, inexpensively and simply as possible. If a manufacturing process has 10 steps, then there are 10 things that can go wrong. Nine steps would be better. Can you remove a step? This will save time and money and make the process more robust. Assay validation is also important and harder than it appears. A lot of people in industry work to validate bioassays, to develop strategies to determine that the results can be trusted. Better assays mean better tissueengineered medical products.

GZ: What particular research directions are of high priority at your place of work?

CS: Placed in the Department of Commerce, the NIST mission is on quality of life and economic security. NIST is a measurement lab, so the focus is on measurement science, standards and technology. For biomaterials and tissue engineering, this translates to product characterization, test methods, ASTM and ISO. The perfect project for a NISTer is to develop an improved measurement method that becomes widely adopted by an industry for characterizing a manufactured product. Another common activity is to organize key stakeholders in an industry to write a white paper or an ASTM standard that becomes a definitive source of information for a particular topic. This could be a discussion of the measurement needs for an industry, a guide for conducting a particular measurement or an interlaboratory study to assess the reproducibility of a test method.

GZ: What do you do in a typical week? How do you divide your time between those activities?

CS: Well, like most people, I do too much email. I do a lot of planning, calling people, meeting people and reading literature. Analyzing data from post-doctoral fellows or collaborators, making plots, doing statistical tests. Writing papers, standards, abstracts and recommendation letters. Organizing sessions, symposia and workshops; I try to organize something every other year. Reviewing papers and grants. Lab maintenance; I maintain several labs, and equipment is always breaking. Something always needs to be repaired or cleaned or replaced.

GZ: Do you set your own priorities and deadlines? If so, how do you do that?

CS: Somewhat. For the most part, I set my own priorities, but within boundaries. There is a lot to consider. There are my

management team's goals (the group leader, division chief and lab director), U.S. public opinion, the president's agenda, U.S. Food and Drug Administration (FDA) priorities and my own perceptions. NIST identifies strategic focus areas, and I strive to align with them. So far, this has not been an issue, since biology has been steadily growing in the 20 years since I joined NIST. Current NIST focus areas include engineering biology, biomanufacturing, precision medicine, and artificial intelligence and healthcare. These inputs must be balanced with impact of the project, cost, time, my skills and the skills of my collaborators. Also, don't forget personal interests ... you have to like what you are doing! The management team frequently discusses focus areas with staff and has a hand in shaping research programs. We must consistently interact with stakeholders to stay apprised of current needs. Each week, I try to do at least one phone call or meeting with somebody new to discuss needs, collaborations and new ideas.

GZ: Any advice for young biomaterials scientists about time management?

CS: It's hard! I don't think that I do it that well, so it's hard to give advice. Try to control the email. I try to say no to the things that are not advancing my main goals. I set one or two main priorities for any given week and make sure they get done, even if I have to drop other commitments. I spend a couple hours every three weeks reviewing my goals to make sure that I am not getting off track.

GZ: How did your education prepare you for the job you do today? **CS:** The best thing I learned in my PhD program was problemsolving. You must overcome a lot of obstacles to do useful research. Asking for help from others is important. One thing I neglected was developing leadership and people skills. You need both people skills and technical skills to succeed. I'm introverted, so it is easier for me to work on the technical things than on the people things. Science is a very interactive activity, though; you have to be able to get along with all types of people, in terms of personalities, scientific backgrounds and cultural backgrounds. SFB helped me with this by providing leadership opportunities through the Special Interest Groups (SIGs).

GZ: What are some of your favorite aspects about working at NIST? **CS:** I like working with industry and doing research that aims to support industry. There is a big, eager, growing tissue engineering industry that craves more interaction with basic research scientists to solve industrial research problems. It feels like a wide-open arena of possibilities with many research niches waiting for willing scientists to fill them.

GZ: What courses or activities would you recommend that college students take to be prepared for a job like yours? **CS:** Statistics and learning a programming language: These are key for doing research nowadays. Also, take up a leadership activity. When I was a post-doc, I was a captain in my Tuesday

An Interview with Carl Simon (continued)

night dart league, which had some wild personalities. This was great experience for working with research teams, which also tend to have wild personalities!

GZ: What is some of the best career advice you've been given? **CS:** You need to learn to say these two words frequently: "I'm sorry." I heard that from Mike Yaszemski, and it is so true. You can fix a lot of problems with those words, but they are hard to say.

Another is, "Focus on the people." I've heard that from several sources. Science is technical and competitive, which leads our attention away from people. People considerations have to be central to all decision-making. Focusing on people takes time and effort, and it can be tempting to overlook people when your schedule is busy.

One more: "Be yourself." When I compare myself to others, it can cause self-doubt. Sometimes when I attend a great talk, I find myself thinking, "If only I could do what they do," or, "If only I could do this or that; then I would be a better scientist." When I focus on how the resources currently at my disposal can be used in an impactful way, things always seem to work out well. Usually, everything I need for success is already available to me.

GZ: What influence has the Society For Biomaterials had on your life and career?

CS: The Society For Biomaterials has been the most important professional society in my career. SFB has about 1,000 people, which is a great size for a society. It's small enough that you can get to know people and don't feel lost in the crowd, but large enough that you get to meet lots of new people at each meeting. Most of my network, contacts and collaborators are people I met at SFB. It is valuable to have a home society that you attend frequently. By seeing the same group of people consistently, year after year, you get to know them, and they get to know you. You develop friends and relationships, work together on committees and collaborate on research.

Also, organizing symposia, sessions and workshops at SFB has been a great opportunity. You can select another scientist you would like to meet to co-chair the session with you. You can invite other scientists you'd like to interact with to give presentations in your session. For young scientists, this leadership role is especially important for others to see you as an authority, since you will organize the session, invite the speakers and lead the discussion. This can be an intimidating process, but it is worth the stress. I find it useful to build the sessions around research areas that I want to learn more about, in areas

where I am active, so that I can ask the questions that I have been struggling with. I can see if others are thinking along the same lines, or if they have insight to share.

GZ: Have you participated in the SFB SIGs?

CS: I was active in SIGs for many years and met a lot of great scientists through them. SIGs provide lots of leadership roles: 14 SIGs times eight positions per SIG = 112 leadership positions. I was active in the Protein and Cells at Interfaces SIG, where I wrote articles for the *Biomaterials Forum*, served as program chair and twice as SIG chair, designed the SIG website and wrote SIG newsletters. SIGs are an easy way to get tuned in to SFB and engage like-minded colleagues.

GZ: Please share where you think the future of biomaterials/ tissue regeneration is going.

CS: Biomanufacturing is important. A lot is being invested: Production Assistance for Cellular Therapies (\$100 million), the Advanced Regenerative Manufacturing Institute (\$80 million), the National Institute for Innovation in Manufacturing Biopharmaceuticals (\$70 million), the Medical Technology Enterprise Consortium (\$60 million) and the National Cell Manufacturing Consortium (\$20 million).

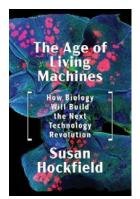
The goal of these investments is to help businesses overcome the "valley of death" between the discovery research phase and the profitable business phase. It includes things such as bioreactors, biomaterials characterization, defined and animal-free culture mediums, tissue preservation, transportation, label-free methods for product characterization, packaging and data management.

Small-molecule drugs are typically composed of a single molecule whose identity can be definitively established by analytical methods. In a cell-containing device, the cells are composed of thousands of molecules, and they are responsive to their environment, which makes them more difficult to manufacture reproducibly and to characterize following their manufacture. Methods for measuring cell quality attributes have high variability, which makes it difficult to assess manufacturing quality. If you improve the test methods for assessing product consistency, then you can improve the manufacturing process. Tighter specifications on a manufactured product will improve the odds of detecting a positive outcome in a clinical trial. Malcolm Moos from the FDA pointed this out to me, and it is an important concept for tissue engineering and regenerative medicine, which are becoming successful industries.

Book Review

THE AGE OF LIVING MACHINES: HOW BIOLOGY WILL BUILD THE NEXT TECHNOLOGY REVOLUTION

By Lynne Jones, Book Review Editor



The Age of Living Machines: How Biology Will Build the Next Technology Revolution Susan Hockfield W.W. Norton & Company, New York 2019 248 pp ISBN 978-0393634747

Bioengineering is defined as "a discipline that applies engineering principles of design and analysis to

biological systems and biomedical technologies." This is often how education programs in engineering are framed — but bioengineering can be so much more. That is what this book is about. Dr. Susan Hockfield argues that biology and engineering are converging in a transformative process.

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AND DEVELOPMENT AND THE

TRANSLATION OF NOVEL IDEAS

TO PRODUCTS."

The book contains the following chapters:

Where the Future Comes From

This chapter sets the stage for the rest of this book. While it is somewhat autobiographical, it also introduces us to Dr. Hockfield's interests in molecular biology and genomics. She

introduces us to some of the leaders of science and engineering, including James Watson, Karl Taylor Compton, J. J. Thomson and others. This chapter stimulated me to want to read further.

Can Biology Build a Better Battery?

The discovery of DNA and RNA was transformative in and of itself. We learned how nucleic acids arranged in specific patterns carried the information for biologic functions. Dr. Hockfield introduces us to Angela Belcher, PhD, who suggested that we could engineer viruses to "grow electronic circuits and, ultimately, batteries." This approach could serve as an alternative to our current dependence on fossil fuels by creating renewable energy. This chapter slowly leads us through the processes involved in the development of this project from understanding DNA and RNA to how viruses are unique to manipulating these features to create a virus "coin cell" battery.

Water, Water Everywhere

There is increasing concern that the supply of potable water will not be able to meet demand in the relatively near future. The World Health Organization reports that, by 2025, half of the world's population will be living in water-stressed areas. ² This chapter describes how a protein called aquaporin can be incorporated into a sheet of membrane to filter contaminants in water and how this resulted in a commercially available product. One of the things that I found interesting is how aquaporin was serendipitously discovered — not uncommon to many inventions.

Cancer-Fighting Nanoparticles

This chapter follows the research pathway of Sangeeta Bhatia, MD, PhD, of MIT. Using nanotechnology, novel approaches can be developed to locate cancer cells and for early diagnosis of small masses throughout the body. I found the approach of using PEG "shields" on nanoparticles to prevent agglutination until they reach the region of interest to be particularly interesting. Dr. Bhatia's work shows the advantage of a multidisciplinary approach to address challenges in medical research.

Amplifying the Brain

Perhaps you saw the CBS "60 Minutes" episode showing a woman feeding herself with a robotic arm.³ I remember thinking about how amazing this was and wondering how far we have come. This chapter discusses the biology and engineering approaches used to conceive and implement the intracortical brain–computer interface to accomplish the goal of computerized limbs. There is also an interesting backstory to the practicalities of developing prosthetic technology.

Book Review (continued)

Feeding the World

I was first introduced to the world of plant science in a conversation held at an SFB meeting. I found it interesting that biomechanical engineers, individuals that I usually worked with to study human kinematics, also studied the movement of plants. Who knew? This chapter starts with a snapshot of a "growth house" at the Donald Danforth Plant Science Center in Olivette, Missouri. We are introduced to the utility of big data regarding phenotypic screening obtained from the camera imaging of large numbers of plants — hundreds of plants per day. Danforth researchers can then genetically modify the plants to produce high yields and disease- and insect-resistant crops.

Cheating Malthus, Once Again: Making Convergence Happen Faster

This chapter returns to the ponderings of Dr. Hockfield. The title of the chapter is based on the claims of Reverend Thomas Robert Malthus, who in 1798 warned of "widespread outbreaks of famine, war and disease that would keep population growth in check." Dr. Hockfield describes the benefit of speeding up the process of convergence of biology and engineering to address many of our medical and societal needs. She also presents a strong argument for the need for government funding of research to maximize this potential.

This book was like reading a novel that you cannot put down. It is not just about the examples of how biology and engineering have converged but also the process of research and development and the translation of novel ideas to products. I enjoyed reading the pathway that was followed to accomplish the goal, the specific contributions of innovative scientists and engineers, and how collaboration and teamwork accelerated this process. I remember how I felt when in fifth grade I learned about the atom. This excited me and led me on my way to a career in science. This book brought back that feeling. It was exciting to see the possibilities. My recommendation: Read this book for the fun of it, and leave stimulated to learn more.

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- What is bioengineering? Berkeley Bioengineering website. https://bioeng. berkeley.edu/about-us/what-is-bioengineering. Accessed November 7, 2019.
- Drinking-water. World Health Organization website.https://www.who.int/en/ news-room/fact-sheets/detail/drinking-water. Accessed November 7, 2019.
- 3. Breakthrough: Robotic Limbs Moved by the Mind [Video] 60 Minutes. CBS. December 30, 2012.

Call For Applications

The Society For Biomaterials would like to thank Guigen Zhang, PhD, University of Kentucky (*Biomaterials Forum* Editor) and Adam Ekenseair, PhD, Northeastern University (Web editor) for their contributions as editors over the past five years. As their terms at the editor post come to an end in the coming year, the Society seeks volunteers to fill the editor roles for the next five-year term. The responsibilities of these positions are detailed in the attached Request For Proposals (RFPs). The RFPs for Web Editor and *Biomaterials Forum* Editor are also posted on the SFB website (visible on the homepage only to members who have logged in.) Both Editor positions are non-voting ex-officio members of SFB's Governing Council.

If you are interested in either position, please contact Dan Lemyre at <u>dlemyre@biomaterials.org</u> by February 1, 2020. Please be sure to include a resume, vision statement, and letter(s) of recommendation as outlined in the RFP.

If you know of a potential candidate who might be interested or particularly well suited to either of these positions, we encourage you to recruit them!

Thank you in advance for your consideration!



BIOMATERIALS FORUM EDITOR

Objective

Organize, develop and upgrade the quarterly Society For Biomaterials newsletter, *Biomaterials Forum* with the support of Association Headquarters and other members of the Society For Biomaterials as available. The Society's management office provides hands on design service and publication.

Terms:

The term of office shall be for 5 years, with continuation at the consent of the Editor, Council of the Society, and Board of Directors. Detailed terms of editor agreement will be made available to candidate editors upon submission of a proposal. Candidates must be an Active or Senior member in good standing of the US Society For Biomaterials and must remain so for the term of service. Candidates must provide at their own expense, computers, telephone access and Internet access. No hardware or contract services shall be provided, although reasonable expenses shall be reimbursed.

Format of the Proposal:

- Resume including biomaterials and publications experience
- Vision statement for *Biomaterials Forum* (not more than one page)
- 1-3 Letters of Reference stating qualifications and experience appropriate for Editorship

All of the above information should be forwarded in one package to the Executive Director (Dan Lemyre: dlemyre@biomaterials.org) by February 1, 2020. Service will begin at a time agreed upon by the Editor and the Council of the Society. Candidates will be contacted on a rolling basis beginning immediately.

Skills and requirements of proposed editor:

The Editor should have experience with scientific publications and newsletter design, content, and editing. Experience or familiarity with digital social media would be desirable. The candidate must be a biomaterial scientist from any recognized professional discipline and should describe relevant experience in the proposal. (Note: Because the Editor shall be expected to make judgment on appropriate content in the website that could be of a technical nature, a biomaterials related technical or clinical education is considered a minimum level of experience.) Additional publication or graphic design experience will also be considered to demonstrate talent of the candidate. All "hands-on" work will be provided by Association Headquarters or as directed by the Editor.

Responsibilities of Editor of Biomaterials Forum:

- Establish an editorial schedule with help and guidance of the Managing Editor at Association Headquarters
- Solicit content from regular contributors, a.k.a. reporters
- Solicit related feature articles and top stories
- Author content based upon current press releases, key news items, and public domain information
- Edit and approve content from members, officers, SIGs, and committees
- Author "compiled from reports" as needed for "Top Stories"
- Identify potential advertisers

In the proposal discuss how the candidate may provide the above stated services and offer other suggestions that may be relevant to *Biomaterials Forum*.



WEBSITE EDITOR FOR SOCIETY FOR BIOMATERIALS

Objectives

- Organize, develop and upgrade the Society For Biomaterials website with the support of Association Headquarters and other members of the Society For Biomaterials as available. The Society's management office will provide "hands on" design service and website hosting.
- Continue oversight of content and quality of website for the Society For Biomaterials for the term of office.

Terms:

The term of office shall be for 5 years, with continuation at the consent of the Editor, Council of the Society, and Board of Directors. Candidates must be an Active or Senior member in good standing of the US Society For Biomaterials and must remain so for the term of service. Candidates must provide at their own expense, computers, telephone access and Internet access. No hardware or contract services shall be provided, although reasonable expenses shall be reimbursed.

Format of the Proposal:

- Resume including biomaterials and website experience
- Vision statement for the website (please, less than 3 pages)
- 1-3 Letters of Reference stating qualifications and experience appropriate for Editorship

All of the above information should be forwarded in one package to the Executive Director (Dan Lemyre: dlemyre@biomaterials.org) by February 1, 2020.

Service will begin at a time agreed upon by the Editor and the Council of the Society. Candidates will be contacted on a rolling basis beginning immediately.

Skills and requirements of proposed editor:

The Editor should have experience with website design, content, and editing. The candidate must be a biomaterial scientist from any recognized professional discipline and should describe relevant educational experience in the proposal. Experience or familiarity with digital social media would be desirable. (Note: Because the Editor shall be expected to make judgment on appropriate content in the website that could be of a technical nature, a biomaterials related technical or clinical education is considered a minimum level of experience.) Additional publication or graphic design experience will also be considered to demonstrate talent of the candidate. All "hands-on" work will be provided by Association Headquarters or as directed by the Editor.

Responsibilities of Editor:

- Oversee that AH has made updates as required throughout the year
- Assure the web content is accessible to the members and the public
- Update news and member postings
- Assure navigation of features and links for optimum performance
- Assure the website is a fresh resource for biomaterials information
- Assure the site offers appropriate methods for purchase of texts, biomaterial publications and other items including, of course, registration to upcoming meetings, etc.
- Oversee any request by a member or association group to post information/notices, news, articles regarding biomaterial events, policies, regulatory issues
- Encourage contact/response information for posting/ mailing opinions or providing input on policies and regulatory issues under development
- Work with advertisers, exhibitors and biomaterials resource companies to develop appropriate advertising access and exhibition information. Consider the potential for a biomaterials resource guide on-line that would provide a method of locating biomaterials for development or industrial applications

In the proposal discuss how the candidate may provide the above stated services and offer other suggestions that may be relevant to the Society For Biomaterials website.

DECEMBER 11–13, 2020

ON WAIKIKI BEACH • HONOLULU, HAWAII

www.Biomaterials.org

The Society For Biomaterials (US) and the Japanese Society for Biomaterials are hosting a joint symposium that will highlight the seminal work of four pioneers in the biomaterials field! The three-day program will feature addresses by our honorees and other sessions of interest in their respective areas of expertise:



James M. Anderson, MD, PhD *Case Western Reserve University*Implant Pathology and the Foreign Body Reaction



Art Coury, PhD

Northeastern University

Biomaterials Evolution: Commercial
to "Designer" Polymers — A 50 Year
Perspective



Tadashi Kokubo, PhD *Kyoto University and Chubu University*Driving Force for Promoting Innovation of Biomaterials: from Bioglass to Bioactive Metals



Teruo Okano, PhD Tokyo Women's Medical Universityand the **University of Utah**Design of Intelligent Surfaces for
Cell Sheet Tissue Engineering

