2022 AWARD RECIPIENTS

A MESSAGE FROM THE NEW PRESIDENT

BIOMATERIALS FORUM

OFFICIAL NEWSLETTER OF THE SOCIETY FOR BIOMATERIALS

SECOND QUARTER 2022 • VOLUME 44, ISSUE 2

ALSO INSIDE

A NIIMBL PERSPECTIVE ON MATERIALS CHALLENGES AND OPPORTUNITIES FOR THE FUTURE OF BIOPHARMACEUTICAL MANUFACTURING

Q&A WITH BUDDY RATNER, THE UNIVERSITY OF WASHINGTON

AN OVERVIEW OF THE UNIVERSITY OF WASHINGTON'S CENTER FOR DIALYSIS INNOVATION

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Scientific photos may be submitted for cover consideration in future issues. Submit color photo, no larger than 4" x 6", along with credit information and scientific description, to the Executive Editor.

BIOMATERIALS FORUM

The official news magazine of the **SOCIETY FOR BIOMATERIALS** • Volume 44, Issue 2

SPECIAL INTEREST GROUP REPORTERS

BioInterfaces	TBD
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Biomaterials Education	Sarah Rowlinson • sarcorow@gmail.com
Biomaterial-Tissue Interaction	Antonio Merolli • antonio.merolli@rutgers.edu
Cardiovascular Biomaterials	Astha Khanna • akhanna@gravertech.com
Dental/Craniofacial Biomaterials	TBD
Drug Delivery	Eun Ji Chung • eunchung@usc.edu
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Orthopaedic Biomaterials	Roche C. de Guzman • roche.c.deguzman@hosftra.edu
Surface Characterization & Modifications	TBD
Tissue Engineering	Jessica M. Gluck • jmgluck@ncsu.edu

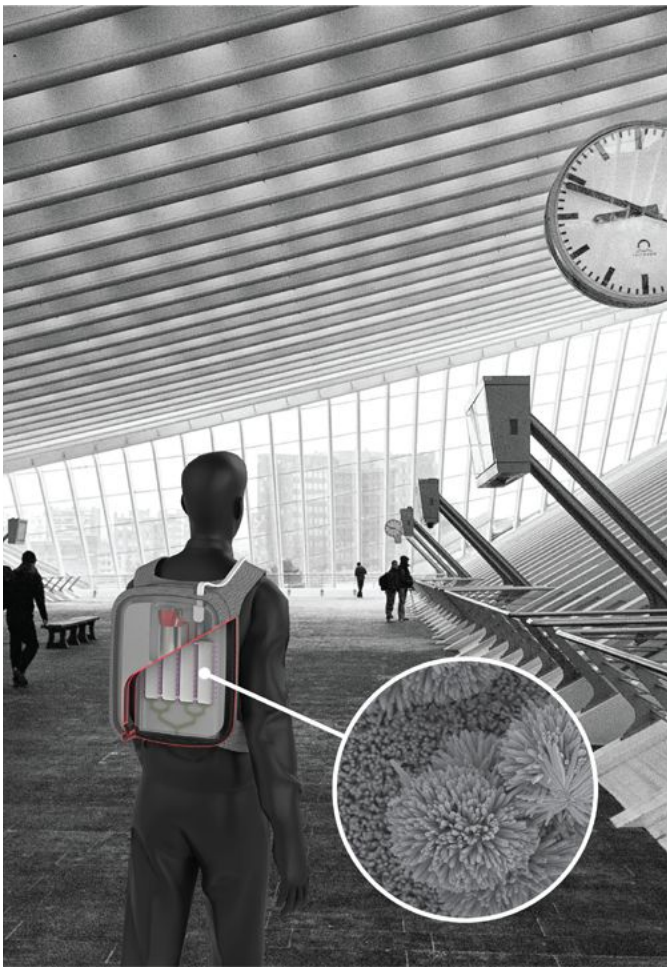
If interested in filling a vacancy above, please reach out to your SIG Chair.
Contact information can be found on individual SIG pages as found **here**.

Contents

THE TORCH

NEWS & UPDATES

FEATURES



ON THE COVER

A wearable kidney hemodialyzer such as the one under development by the University of Washington Center for Dialysis Innovation (CDI) will allow dialysis patients to travel and enjoy a more normal life, not tethered to a heavy machine in a dialysis center. A micrograph of the nanowire TiO_2 surface that catalyzes the conversion of urea to N_2 and CO_2 is shown in the blow-up. (Artistic rendering by Jeremy Barribeau)

From the Editor

By Roger Narayan, Biomaterials Forum Executive Editor

I hope that all of you enjoyed the Annual Meeting as much as I did. I am glad to share this second quarter issue of *Biomaterials Forum* with you. After highlighting several universities on the east coast, this issue focuses on pioneering biomaterials activities on the west coast, specifically at the University of Washington. We are fortunate to share a question and answer feature with Buddy Ratner, a leader in our field for several decades. We are also glad to share his history with the University of Washington's Center for Dialysis Innovation. This issue also includes a feature by Ruben G. Carbonell, Sandeep Kedia and Christopher J. Roberts on materials challenges and opportunities for biopharmaceutical manufacturing. In addition, the article considers the National Institute for Innovation in Manufacturing Biopharmaceuticals' efforts to support technical advances in the biopharmaceutical field. The issue also includes reflections from Elaine Duncan on her service to the society over the years. Carl Simon, our government news editor, provides useful information related to the National Institute of Health's data management and sharing policy. Subramanian Gunasekaran shares his thoughts about how to revitalize the society and technical contributions of our colleagues. Other highlights of this issue include a letter from our president, this year's award recipients, staff updates, member news, industry news, student travel achievement recognitions and student news.

This fall will bring the Society For Biomaterials's co-sponsorship of the Materials Science & Technology Annual Meeting. This meeting, which also serves as the annual meeting for the American Ceramic Society and the fall meeting of The Minerals, Metals & Materials Society (TMS), has been held since 2003. This year, the meeting will be held October 9-13 at the David L. Lawrence Convention Center in Pittsburgh. The Society For Biomaterials is sponsoring three symposia at the meeting, including "Biological Responses to Materials and Biomaterial Responses to Tissues," "Biomaterial Applications in Today's Industry: Development , Translation & Commercialization," and "Biomaterial Applications (Wound Healing, Orthopedics, Dental, etc.)." The MS&T biomaterials symposia have received over 100 abstracts for oral presentations to this point — we anticipate a strong and lively biomaterials focus at the meeting. The meeting will also include an Undergraduate Student Poster Contest and a Graduate Student Poster Contest; both contests will include poster presentations and oral rapid-fire sessions. I hope that all of you will encourage the students you mentor to consider these opportunities.

Yours truly,
Roger Narayan

CALL FOR COVER ART

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 info@biomaterials.org, to the attention of the Executive Editor of the *Biomaterials Forum*. All artwork with biomaterials relevance that have not appeared as a *Forum* cover are welcome. Multiple submissions 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.

From the President

By Elizabeth Cosgriff-Hernandez, SFB President

Dear Friends and Colleagues,

I am truly honored to serve you as president of the society over the next year (2022-2023). SFB is the first scientific meeting that I attended as a student and it has been an incredible support community throughout my career. I have always valued the training and opportunities that I received here, and I look forward to working with the Board and Council to continue to build our society so that every member can thrive. I want to thank Guigen Zhang as well as the Board and Council for their dedicated service to our Society over the past year. I also want to recognize the staff of Association Headquarters (AH), in particular Dan Lemyre, for their tireless efforts on behalf of the Society. The ever-changing dynamics of the pandemic have created countless challenges that the AH staff have met with grit and creativity. As a result of this leadership and dedication, SFB has weathered the last two years better than many other scientific societies. In the coming year, I want to continue to adapt to meet our changing member needs, expand accessibility by embracing technology advances, and build an inclusive community to support the success of all of our members.

First, I believe that any scientific society rises and falls by the participation of its members. In order to ensure the longevity of our society, we must be able to pivot and adapt to meet the changing needs of our members while balancing our long-term financial viability. The society serves many roles for its membership: a venue for scientific discourse, a training ground for students, network and support at all stages, and a common ground for scientists from academia, industry and the clinic to interact. I will continue to work to make sure that the value proposition for SFB membership is strong for each sector of the biomaterials community and each level, from undergrad to senior scientist. As part of that effort, I will be holding a series of listening sessions throughout the year to hear from you about how the Society can better serve your needs. I also encourage you to share your ideas and suggestions with me directly at cosgriff.hernandez@utexas.edu.

One of the positive outcomes that emerged from the challenges of the past two years is the reduced barriers and increased participation in webinars and virtual networking. Although I greatly enjoyed seeing many of you in-person in Baltimore, I believe that we should continue to take advantage of virtual programming and networking to expand our reach and enhance accessibility. We are piloting a virtual option to our Annual Meeting this year where we stream a portion of our meeting (e.g., plenaries). I believe that this provides an opportunity to connect with more members that may not be able to attend in-person. We have also used virtual platforms throughout the year to increase the number of networking and mentoring events that support our members (e.g., Joint Picture-a-Scientist event, Art of ECTM, student-led panel discussions and webinars). I would love to hear your feedback on these virtual events and new ideas for engaging our membership all year long.

IN ADDITION TO IMPROVING MEMBERSHIP VALUE AND INCREASING ACCESS, I PLAN TO CONTINUE TO WORK TO MAKE THE SOCIETY AN INCLUSIVE COMMUNITY WHERE ALL OF OUR MEMBERS CAN THRIVE.

In addition to improving membership value and increasing access, I plan to continue to work to make the Society an inclusive community where all of our members can thrive. Diverse teams are needed to enhance human health; however, systemic racism and historical barriers continue to marginalize communities and individuals in our society. We need to actively work to dismantle these barriers and directly address discrimination to build a community that respects and embraces the differences in identity among our members, profession, and the communities we serve. I look forward to continuing partnering with the newly formed DEI Committee to cultivate and promote a diverse and inclusive Society. Based on committee recommendations, we have implemented new family-friendly policies, pronouns on badges, and name pronunciation guides at our meeting this year. We are also continuing our networking mixers and lunches to provide opportunities for our members to connect with people of shared identities. This year we also had more programs focused on highlighting our members (3MT, PRA, Black and Latinx Voices) and sessions focused on underserved communities (Healthcare Disparities, Women's Health). Many of these events were initiated by our members and I would be more than happy to help you implement your ideas in next year's meeting. As we begin planning for the 2023 SFB Meeting, please be sure to share your ideas with the Program Committee when the call for ideas and proposals comes out.

Thank you for your dedication and contributions to our Society and I look forward to hearing from you!

Left to right, top to bottom are: Kam Leong, PhD; Elaine Duncan; Guillermo Ameer, ScD; Allen Y. Wang, PhD; Michael J. Mitchell, PhD; David Kohn, PhD; Julia Babensee, PhD; Laura Suggs, PhD; Ankur Singh, PhD; Ashley Brown, PhD; Henry Beaman; Anujan Ramesh; Natalie Petryk; Savan Patel; Briana Cristal Martin-Villa; and Andres J. Miramontes

The following professionals are recognized for their outstanding achievements in and contributions to the biomaterials field. Each award recipient was honored during the Opening Ceremony at this year's Society for Biomaterials 2022 Annual Meeting and Exposition on Wednesday, April 27, 2022. View the full press release here.

Founders Award: *Kam Leong, PhD, Columbia University*

Society For Biomaterials Award for Service: *Elaine Duncan, Paladin Medical, Inc.*

Technology Innovation and Development Award:

- *Guillermo Ameer, ScD, Northwestern University*
- *Allen Y. Wang, Ph.D. and ETHICON SURGICEL® Powder Cross-functional Team*

Clemson Award for Applied Research: *David Kohn, PhD, University of Michigan*

Clemson Award for Basic Research: *Julia Babensee, PhD, Georgia Institute of Technology and Emory University*

Clemson Award for Contributions to the Literature: *Laura Suggs, PhD, The University of Texas at Austin*

Mid-Career Award:

- *Ashley Brown, PhD, North Carolina State University and the University of North Carolina at Chapel Hill*
- *Ankur Singh, PhD, Georgia Institute of Technology*

Young Investigators Award: *Michael J. Mitchell, PhD, University of Pennsylvania*

Student Awards for Outstanding Research

- *Henry Beaman, Syracuse University*
- *Anujan Ramesh, University of Massachusetts Amherst*

Recipient in the Masters Candidate Category:

- *Natalie Petryk, Syracuse University*

C. William Hall Scholarship: *Savan Patel, University of Pennsylvania*

Cato T. Laurencin Travel Fellowship:

- *Andres J. Miramontes, The University of Texas at Dallas*
- *Briana Cristal Martin-Villa, Stanford University*

Society For Biomaterials 2022 Award for Service

AWARDEE ELAINE DUNCAN'S REFLECTIONS ON SERVICE TO THE SOCIETY FOR BIOMATERIALS

The Society For Biomaterials is the premier professional organization formed to address a ubiquitous and challenging problem in healthcare technology: what material in contact with the body will serve its needed purpose Founded almost fifty years ago, by those who recognized that innovative medical therapies were limited by the suitable materials, the Society sought to advance the development of biomaterials in whatever ways possible. Members challenged the frontiers of material science and practical engineering test methods to press forward the understanding and improvement of biological and mechanical responses — within ethical, financial, legal and regulatory constraints. The formation of the Society For Biomaterials joined together a group of people for the particular purpose of providing timely biomaterials solutions that maximized patient benefits and minimized risk. People from industry, academia, hospitals, law firms, regulatory agencies, for example, gave their time, energy and inspiration.

Considerable progress has been made since the founding, but stumbles have occurred as well. I have been an eyewitness to these in my various responsibilities in the biomaterials industry and physically benefitted from a few of the successes. Since 1979 I have served the Society in many roles, such as launching the first adjunct "workshop" on histology in 1981, chairing the first meeting outside the university setting in 1986 and third editor of *Biomaterials Forum*-- to name a few. Not one minute of my time in service to the Society For Biomaterials has been a waste. Some efforts were a dead end, like the time we thought we could organize biocompatibility data about specific materials onto CDs and have the Society sell the CDs. Naïve yes, but the point was to try to make the selection of well characterized biomaterials easier for the medical industry and thus devices safer. Service to the Society gave me reason to travel. We were in Berlin soon after the Wall came down giving me an opportunity to take an antique train across what had been East Germany to Hanover and then to Frankfort on a high-speed train.

And who could forget taking the Shinkansen across Japan between Tokyo and Kyoto with Mount Fuji out the window. The quest for better biomaterials is global and it has never been more necessary that we continue our mission.

We have not sustained the level of participation of clinical practitioners that was envisioned by the founders. Directors of medical device corporations and angel investors are not packing the seats at our meetings to find the best resources for the newest therapies, like they once did. Regulations and standards are being published by the mile with very little contribution from the Society committees who might share a more balanced perspective on what it means to be "biocompatible." We have lost the status as an influencer in these domains. The overburden of expensive repetitive testing of well characterized materials in common applications shackles all of us and diverts resources from innovative research, while examples abound of products which passed all the "standardized" tests but were not fit for service in their intended use.

While diversity, equity and inclusion are currently prominent issues in professional organizations, Society members understand the Society was formed for the welfare of humanity. *It's not about you*. The Society is FOR biomaterials. It is not a social club. Your voice will be heard when you have something to say. If somehow after all these years there is insufficient inclusion, speak up, but then get back to the business of the Society FOR Biomaterials. Your reward for sticking it out and serving the Society will come to you: that's for sure. Perhaps in the future the ladies who lunch might use their forum to discuss ways to make biomaterials better purposed for the female body rather than equity-fretting. The "special interest" groups might become FOCUS GROUPS for common critical topics: not dividing and diverting resources.

For the next half century let's build on what the Society has accomplished and redouble our efforts to keep that darn Torch lit! To all the wonderful friends I have made in service to the Society, let's keep on keeping on.

Staff Updates

By Shena Seppanen, Assistant Executive Director

Hello from Society For Biomaterials (SFB) Headquarters! Our thanks and appreciation to all those who joined us for the 2022 Annual Meeting & Exposition! With the beginning of a new program year, the Society's Board of Directors, Governing Council, Committees, and Special Interest Groups (SIGs) will continue the work of advancing the Society's mission. We also extend a warm welcome to our new leadership volunteers, as listed below.

ANNUAL BUSINESS MEETING

The Society's Annual Business Meeting took place on Friday, April 29, 2022 in Baltimore, Maryland at the Baltimore Marriott Waterfront. Results of the spring election were announced, and the following people have been elected as officers for the SFB Board of Directors:

2022-2023 President-Elect: William R. Wagner, PhD, University of Pittsburgh, McGowan Institute for Regenerative Medicine

2022-2023 Member At-Large: Stephanie Seidlits, PhD, University of Texas at Austin

In addition, the Bylaws Amendments presented to the membership for approval passed, and the following members were elected to the 2022-2023 Awards, Ceremonies and Nominations Committee: The following were elected by the members present — Lesley Chow, PhD; Ankur Singh, PhD; Elizabeth Lipke, PhD; Jamal Lewis, PhD.

New Council — The following members will comprise the 2022-2023 Council, serving alongside the elected Board as Committee Chairs:

Awards, Ceremonies, and Nominations	Horst von Recum, PhD
Bylaws	C. LaShan Simpson, PhD
Diversity, Equity, and Inclusion	Edward A. Botchwey, PhD
Education and Professional Development	Brendan Harley, PhD
Finance	Danielle Benoit, PhD
Industrial Affairs (f/k/a - Devices and Materials)	Gopinath Mani, PhD
Liaison	Bingyun Li, PhD
Membership	Gulden Camci-Unal, PhD
Presidents Advisory	Guigen Zhang, PhD
Program	Jennifer Woodell-May, PhD and Karen Christman, PhD
Publications	Jan Stegemann, PhD
Student Chapter President	David Eduardo Flores Prieto

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

Society For Biomaterials
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Phone: 856-439-0826
Fax: 856-439-0525
Email: info@biomaterials.org

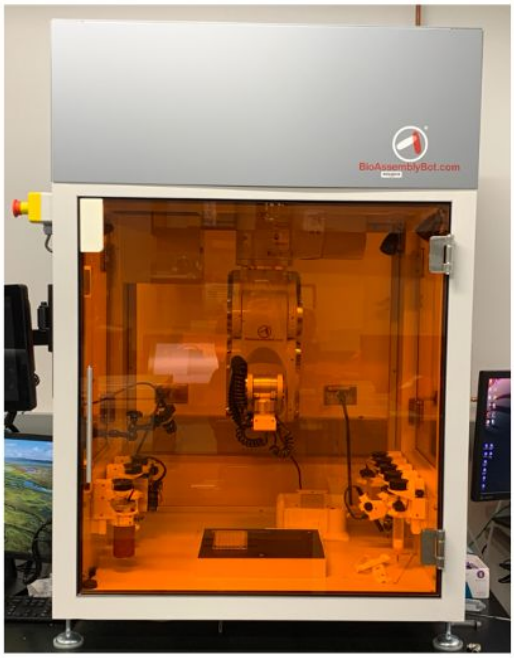
Member News

By John P. Fisher, PhD, Member-at-Large

Joyce Wong, Boston University, has been elected President of AIMBE for 2022-2024.

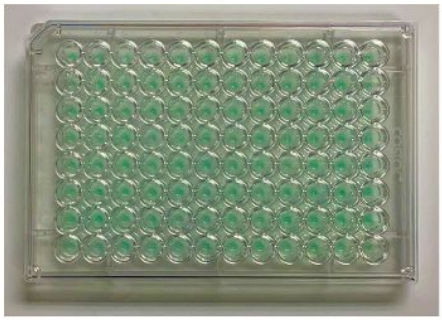
Raven Khoury, University of Texas El Paso, shares about a unique, versatile, 3D bioprinted, high-throughput cardiac model which has been developed for drug toxicity studies and various tissue engineering applications.

Since conventional human cardiac two-dimensional (2D) cell culture and multilayered three-dimensional (3D) models fail in recapitulating cellular complexity and possess inferior translational capacity, we designed and developed a high-throughput scalable 3D bioprinted cardiac spheroidal droplet-organoid model with cardiomyocytes and cardiac fibroblasts that can be used for drug screening or regenerative engineering applications. A 3D bioprinted spheroidal cell model is expected to provide an enhanced habitat for tissue formation as it enables sufficient distribution of oxygen, media, growth factors, nutrients and ions into the scaffold maintaining cell growth and proliferation. The key objective was to create a 3D cardiac tissue

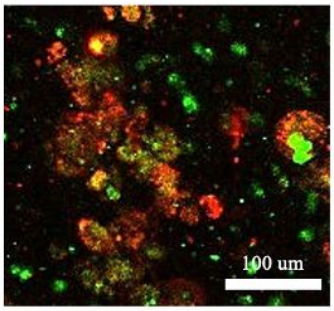


The BioAssemblyBot (BAB) 3D Printer

3D bioprinted cardiac spheroidal droplet



96- well array as a high-throughput screening platform



CM (PKH-67) - CF (PKH26)

Member News (Continued)

model which is capable of mimicking in-vivo conditions allowing for a better understanding of cardiac biology and facilitate the study of cardiac biomarkers as targeted therapeutic strategies.

Nicholas Peppas, University of Texas, was profiled as a pioneer of advanced healthcare materials in an April 7 article in Advanced Science News.

Cheryl Gomillion, University of Georgia, was recently awarded an NSF CAREER Award for the work entitled "CAREER: In Vitro Model Approaches Leveraging Quantitative Cancer Cell Properties as Determinants of Metastatic Potential."

Jessica Gluck, North Carolina State University, is planning a fall 2022 tissue engineering seminar series and is looking for speakers, including student speakers.

C. LaShan Simpson, Mississippi State University, was recently awarded an NSF CAREER Award for the work entitled "BRITE Relaunch: Examining the Role of Mechanotransduction in Smooth Muscle Cell Phenotype Modulation."

Lawrence Gettleman, University of Louisville, was recently named the recipient of the Ryge-Mahler Award in Clinical Research by the Dental Materials Group of the International Association for Dental Research.

Scott Wood, South Dakota School of Mines & Technology, was recently awarded an NSF CAREER Award to study integrin-mediated mechanotransduction in chondrocytes using an engineered biomaterial-based microphysiological system.

The *Journal of Functional Biomaterials* recognized publications from **David K. Mills, Louisiana Tech University,** and colleagues; **Francesco Baino, Politecnico di Torino** and colleagues; and **Carla Emiliani, University of Perugia**, and colleagues, as winners of the JFB 2021 Highly Cited Paper Awards.

NASA awarded **David K. Mills, Louisiana Tech University**, a research grant entitled "Nano-Based Ceramic-Metal Composites to Support Planetary Agrosystems."

CALLING ALL BOOKWORMS!

If you'd like to contribute a review of your recent favorite read to the ***Biomaterials Forum***, send it for consideration to the Editor at ***Roger_narayan@ncsu.edu***. If it's approved, it will be published in a future Forum Book Review column!

A NIIMBL Perspective on Materials Challenges and Opportunities for the Future of Biopharmaceutical Manufacturing

By Ruben G. Carbonell, Sandeep Kedia, Christopher J. Roberts



The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is a public-private partnership to accelerate innovation in the biopharmaceutical industry, and to educate and train a world-leading workforce to advance U.S. competitiveness in this critical sector.

NIIMBL's membership includes most of the major biopharmaceutical manufacturing companies and their suppliers, and numerous small companies, academic institutions, and nonprofits. NIIMBL programs aim to increase the biomanufacturing readiness levels of new technologies and foster adoption by the broader biopharmaceutical industry, to increase productivity, reduce costs, and enhance patients' accessibility to new drugs.[1]

In this report we highlight some important materials' issues that would greatly benefit the future of biopharmaceutical manufacturing, and invite engagement of the biomaterials community to help address these crucial needs.

MATERIALS FOR SINGLE-USE TECHNOLOGIES (SUT): PERFORMANCE AND SUSTAINABILITY

Biopharmaceutical manufacturing practice is rapidly evolving from traditional, reusable stainless-steel (SS) equipment to polymer-based single-use disposable devices (SUD) for a wide range of operations. These include cell culture bioreactors, depth filtration, product concentration, diafiltration, ion exchange, and more recently, affinity-based product capture. The use of SUD for fill-finish operations has not been as extensive due to concerns about sterility, product quality and stability requirements of products that could be in vial storage for years.[2]

Stainless-steel equipment requires sterilization, utilizing substantial amounts of chemicals, water, and energy, and need to be tested for contamination. Single-use polymer bioreactors come pre-sterilized by the manufacturer and are discarded after production of a single batch.[3] These systems reduce capital and operating costs and are now available with volumes up to 6,000 L for large scale operations.[4]

Single-use polymer-based membranes and monoliths used in purification have lower dynamic binding capacities than chromatographic resins due to their lower surface areas per unit volume and are therefore particularly well-suited for flowthrough removal of impurities such as host cell proteins, DNA. However, membranes and monoliths exhibit much higher flow permeabilities than packed beds and can be operated at shorter residence times in a cyclic fashion to enhance overall productivity.

Recent developments using nonwoven fabric membranes grafted with hydrogels have resulted in significantly enhanced binding capacities,[5] but there is room for further improvements with the development of new structures with larger surface areas and high flow permeabilities.

All SUD in contact with biologics are considered biohazards and need to be autoclaved before disposal in a landfill or incinerated

A NIIMBL Perspective on Materials Challenges and Opportunities for the Future of Biopharmaceutical Manufacturing (Continued)

to generate energy. A Biopharma Recycling Program has been developed to enable reuse of these materials as industrial-grade construction materials[6]. The Bioprocess Systems Alliance (BPSA) has published life-cycle assessment, engineering practices, and post-use management considerations for SUTs for bioprocessing.[7-9] There is a strong need for novel approaches to recycle and reuse polymeric materials used in SUTs for upstream and downstream, including the use of biodegradable polymers.

MATERIALS FOR SENSORS FOR IN-LINE MONITORING AND REAL-TIME RELEASE

The BioPhorum Biomanufacturing Roadmap on In-Line Monitoring and Release, published in 2017, listed the major priorities for in-line sensors to enable process monitoring and control, as well as the real time release of drug products. The last few years have seen great advancement in the introduction of multiplexed approaches to process monitoring that rely on at-line Raman and Far-IR spectroscopy, and there is great interest in other in-line and at-line technologies for measuring quantities such titers, charge variants, glycosylation patterns and adventitious agents (viruses, bioburden).

Most of these new sensor technologies will rely on microfluidic interfaces to facilitate multiplexing, and fluid handling. Others, like SPR, may rely on 2D and 3D printed ligands or biological molecules to help identify and separate samples according to their chemical and/or structural specificity.[1] These selective separations will require new ligands that can be based on mammalian antibodies (human, camelid, etc.) as well as a wide variety of available small protein platforms, aptamers and peptides.[11] Significant work needs to be done to develop new, more precise coupling chemistries to control the activity, orientation and ligand density on polymers, inorganics, glasses, metals or other surfaces to be used for sensor development.

MATERIALS FOR NEW VACCINE AND DRUG MODALITIES

Vaccines play a key role in disease prevention and are the main weapon in our fight against pandemics. Effective and broadly used vaccines are made from a variety of technology platforms, including live-attenuated or inactivated viruses, protein antigens from the surface of the virus, purified polysaccharides, saccharides conjugated to a protein, mRNA and viral vector delivery. The common goal is to elicit a protective immune response in the patient. Rapid analytical characterization of these vaccines remains a challenge as well as the development of rapid and meaningful *in-vitro* potency assays. This is an area where NIIMBL can make a major contribution.

There is also a strong motivation to produce vaccine powders that are stable during storage, particularly if they can be transported in formats ready for delivery to the patient.[12] These approaches could alleviate the significant current cold chain supply chain issues encountered in worldwide distribution of vaccines.

Gene and cell therapies are rapidly gaining ground for the prevention, treatment, and cure of chronic and deadly diseases worldwide. The COVID-19 mRNA vaccines introduced us to a clear example of the ability of mRNA to induce the patient's own cells to transiently produce the relevant spike protein of the COVID-19 virus and promote an immune response in the body to ameliorate the effects of the disease.

The mRNA based COVID-19 vaccines are currently delivered intramuscularly using lipid nanoparticle (LNP) packages that promote their uptake into the patient's cells. The use of LNPs is an important and challenging area in materials science that plays a crucial role in gene therapy more broadly. LNPs are also being considered for delivery of CRISPR-Cas9 therapies which rely on Cas9/sgRNA ribonucleoprotein complexes to target and edit the DNA of a patient.[13]

A NIIMBL Perspective on Materials Challenges and Opportunities for the Future of Biopharmaceutical Manufacturing (Continued)

In addition to these liposome-based structures, other nanocarriers are being studied for nucleic acid delivery, including inorganics (calcium phosphate), cationic polymers such polyethyleneimine, dendrimers, and cell penetrating peptides (CPP). Hydrophobic core nanoparticles made of gold, silica or other materials can be decorated with hydrophilic oligonucleotides via thiol linkages and DNA nanostructures on the surface can be used to produce "DNA origami" to capture oligonucleotide during delivery.[14]

CONCLUSIONS

Materials science has played in a key role in biopharmaceutical manufacturing and is well poised to play an even more important role in the future. There is an important need for more efficient process and analytical equipment in the manufacturing floor, as well as in product development and drug delivery applications for these new modalities. The examples provided here are not all inclusive, but they are representative of the important role of biomaterials in biologics manufacturing.

ACKNOWLEDGEMENTS

This article was supported by an award from the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) and financial assistance from the U.S. Department of Commerce, National Institute of Standards and Technology (70NANB17H002). The authors would like to thank Barry Buckland, Maria X. Chacon, Kelvin H. Lee and John Schiel for their contributions to this article.

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Q&A with Buddy Ratner, The University Of Washington

LONG-TIME SOCIETY FOR BIOMATERIALS (SFB) MEMBER BUDDY RATNER DISCUSSES HIS TIME AT THE UNIVERISTY OF WASHINGTON AND WITHIN THE SOCIETY

By Buddy Ratner

The Engineered Biomaterials (UWEB) program has been one of the most successful projects on biomaterials that has been funded by the National Science Foundation. What features have led to its success?

University of Washington Engineered Biomaterials (UWEB) was a success and I'm proud of the outcomes from 11 years of generous NSF and industry funding (1996-2007). The starting point for this success is the excellent platform the NSF provides for the principal investigator to build upon. They have much experience with structuring and guiding engineering research centers (ERCs). Some key features of NSF ERCs were (are) a multidisciplinary investigator group, a strong interaction with companies that are relevant to the center, empowering key staff people with meaningful leadership positions, creating opportunities to bring diverse leaders and researchers to the ERC and a focus on education/training of students to carry the excitement forward.

The NSF set the stage for the UWEB ERC to succeed. Next, a strong research/development theme was needed. In 1995, I had already been researching biomaterials for 28 years. When I started in biomaterials research, cell-surface receptors were just barely discovered. Cytokines had not yet been defined. The cell was thought of as a "bag of jelly" and its importance to biomaterials was not clear. The interesting exception was blood platelets. From the earliest days of biomaterials, platelets were recognized as key to blood interactions. In the interim between my start in biomaterials research in 1967 and 1995 when we wrote the UWEB application to the NSF, the molecular biology revolution took place. There was a mechanistic appreciation that a soluble (or insoluble) signaling molecule could bind to a receptor on a cell, induce a conformational change in that receptor that would send signals into the cell telling it how to behave. This signaling could trigger the ribosome to make new proteins that might be released from the cell instructing other cells in the body. This appeared so mechanistic —straightforward chemical reactions generating complex events. It seemed that an engineer could harness this recognition and specificity to direct how cells behaved — i.e., put us in control of the biological reaction to biomaterials rather than "sticking the material in and seeing what happens." Also, about that time, I began to appreciate the nature of the foreign body reaction and how this generally accepted outcome from the implantation of biocompatible biomaterials had many negative consequences for implanted electrodes, drug delivery systems, breast implants, pacemaker leads, etc. So, we coupled the ideas of engineering molecular biology and its potential for improving biocompatibility to yield the key research theme for UWEB.

At the University of Washington at that time we had world leaders in biocompatibility and world leaders in molecular biology (particularly associated with inflammation). I had a Department Chair, Lee Huntsman, who was supportive and enthusiastic. The exciting research theme with relevance to the medical device industry, the world-class researcher group and administrative support from the University of Washington allowed us to score one of four ERCs funded that year (179 proposals were submitted for that ERC round).

What suggestions do you have for biomaterials researchers who seek to develop large-scale biomaterials efforts at their institutions?

I'll just reiterate some of my description of the origins of UWEB, above. Components needed to launch large-scale biomaterials efforts include 1) a novel (but scientifically defensible) research theme, a theme that can differentiate you from the other 33,800 papers on biomaterials published in 2021; 2) collaboration and partnership with thought leaders and key researchers relevant to your theme; 3) a supportive administration at your institution; 4) motivated students; 5) a strong infrastructure and (6) importantly, cash to fuel the collaborations and pay for the research and students.

You are currently co-leading a Center for Dialysis Innovation with Dr. Johnathan Himmelfarb, a UW School of Medicine professor. What sorts of interactions with clinicians do you feel provide the highest impact for biomaterials researchers?

Throughout my career I have been fortunate to have close MD collaborators. The medical disciplines have included laboratory medicine, hematology, vascular surgery, ophthalmology, orthopedics, pelvic surgery, cancer, nutrition, diabetes, pancreatic surgery and nephrology. Physicians with a passion to drive advances for their patients make ideal collaborators — their patient-focus, deep knowledge of the disease or injury, surgical skill, access to patients and access to facilities propel the projects.

Q&A: The Engineered Biomaterials Program and More (Continued)

The story of our Center for Dialysis Innovation (CDI) is a sterling example of such a collaboration. And there's a wonderful historical precedent to our CDI. At the University of Washington, in 1960, the first human was chronically dialyzed. This was possible because of collaboration between a nephrologist, Belding Scribner, with a chemical engineer, Les Babb and a bioengineer, Wayne Quinton. That collaboration, launched in the late 1950s and brought to fruition with the demonstration that a patient, Clyde Shields, could be kept alive for years with insufficient natural biological kidney function, has led to a therapy that now sustains the lives of some 4 million people worldwide.

The development of hemodialysis was obviously a huge advance. But, when Dr. Himmelfarb arrived at the University of Washington, he sought me out to discuss the shortcomings of 21st century hemodialysis. For a patient on kidney dialysis today, their expected lifespan averages four years. Quality of life is poor for these patients with compulsory visits to dialysis centers three times a week, painful, disfiguring needle sticks to access blood and a debilitating feeling described as "washed out" after dialysis. And this life-supporting treatment is very expensive to the healthcare system and the patient. Dr. Himmelfarb noted that there have been no game-changing innovations in kidney dialysis since that 1960. We envisioned new approaches to the problem, brought in teams of investigators from fve engineering departments and, with a generous gift from the non-profit Northwest Kidney Centers, set out to rethink hemodialysis for the 21st century. For example, dialysis today requires about 120 liters of high-quality water. We can now remove uremic toxins from the patient's blood using only 1-2 liters of water by photo-catalytically decomposing the urea to CO2 and N2. We are also making advances in blood compatibility and needleless blood access that will lead to portable and wearable forms of dialysis within six years. To get back to the original question, I believe the CDI nicely illustrates the power of strong scientist/engineer/physician collaboration.

You have seen the growth of the Society over many years. What do you see as greatest benefit of a biomaterials researcher through being a member of the Society?

I started with the Society For Biomaterials (SFB) in 1975, the year the society was first conceived, at a meeting at Clemson University. I have indeed seen (and appreciated) the growth of our society. I consider my professional involvement with SFB over the past 47 years to be one of the key factors that led to success in my career. At SFB, as a young scientist, I met the pioneers in our field. They educated me, inspired me, mentored me. At our annual meeting (and other smaller gatherings) there are opportunities to rub shoulders with the biomaterials thought leaders and movers, something that will never happen from reading papers.

There is one particular piece of advice I give to all the students I mentor: get significantly involved with a professional society that mirrors your interests. SFB is a fabulous forum for career advancement. Join a SIG, volunteer for a committee or show up at functions and introduce yourself to people you admire. Significant society involvement is a superb path to expanding opportunities, learning new things and meeting individuals who will become mentors and friends.

An Overview of the University of Washington's Center for Dialysis Innovation

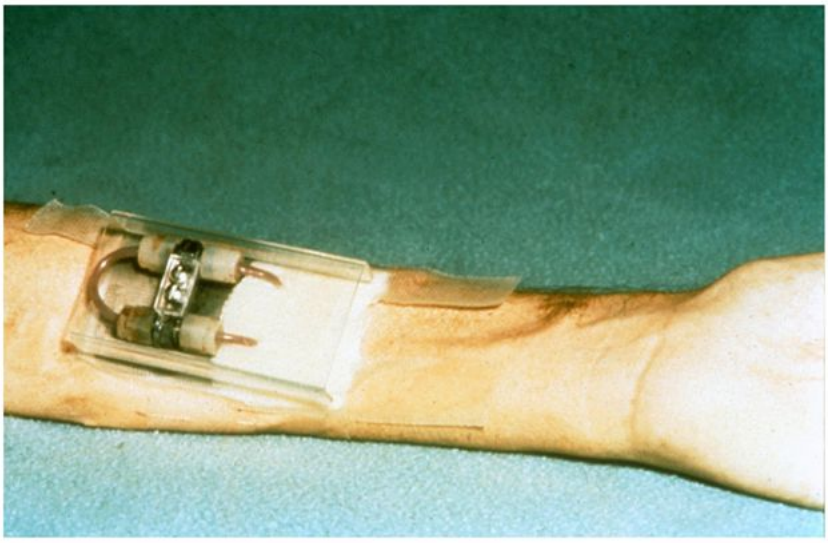
By Buddy Ratner

Kidney dialysis and biomaterials have been closely associated since the 1950s. Willem Kolff, MD, who demonstrated in 1943 that a human could emerge from a uremic coma after dialysis treatment, had access to only common materials (cellulose, for example). But, in Volume 1 Issue 1 of *Journal of the American Society For Artificial Internal Organs* (1955; note: 20 years before SFB was formed), there were many articles discussing synthetic materials for artificial kidneys. A major innovation that opened the door to the chronic hemodialysis was made by MD nephrologist Belding Scribner at the University of Washington working with bioengineering Wayne Quinton. In 1960, they used Teflon, silicone rubber, stainless steel and polyester fabric (Dacron) to create a blood access device that allowed them to chronically dialyze Clyde Shields, the first patient in the history of this planet who survived irreversible kidney failure and was sustained by dialysis (for 11 years).

Fast forward to 2022 and we find 400,000 people in the US and perhaps 4 million worldwide, whose lives are dependent upon kidney dialysis. People are alive with dialysis, but largely, they are not happy or healthy. The average lifespan of a patient starting hemodialysis in 4-5 years. They must travel to dialysis centers and spend four hours in a chair three times per week. With travel and prep time, half their week is involved with their hemodialysis treatment. They are typically penetrated with two large-bore needles three times per week, a painful procedure and disfiguring to limbs. After dialysis, they feel "wiped out" — nausea, cramps, headaches, lethargy, etc. And this sub-standard therapy is expensive. One percent of the entire US budget goes to addressing the needs of patients with end stage renal disease. It is also environmentally unsound. Some 400 liters of water goes down the drain with each dialysis session (multiply 400 l/session x 4 million people x 150 sessions per year and you get a huge volume of water) and also massive amounts of PVC tubing, hollow-fiber dialyzers and other disposables are tossed with each session. Over some 60 years, there has been little change or innovation in how we do hemodialysis. Clyde Shields, if he were alive today, would recognize all the general aspects of the therapy — the apparatus is fancier, but basically the same.

In 1972, I completed a PhD thesis titled, "The Interaction of Urea with Poly(2-hydroxyethyl methacrylate) Hydrogels." I pointed out, then, that 1,000 people in the US each year were on hemodialysis (in contrast to maybe 350,000 people on hemodialysis today). After my PhD research, at the University of Washington, my efforts shifted to blood compatibility (incidentally, important for hemodialysis) and vascular prostheses (important for blood access in hemodialysis) but I was not directly working on hemodialysis. Perhaps I thought of it as an old-fashioned theme?

In about 2015, Professor Jonathan Himmelfarb (MD nephrologist), recently arrived at the University of Washington, approached me proposing that we collaborate, nephrologist and engineer, to rethink this old and far-from-ideal technology,



Belding Scribner, MD, Wayne Quinton and the Quinton-Scribner Shunt (Images courtesy of the Northwest kidney Centers)

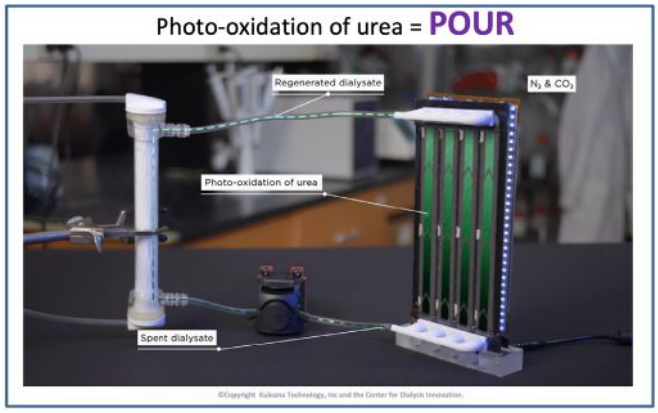
Kidney Dialysis, Biomaterials and the University of Washington Center for Dialysis Innovation (CDI) (Continued)

bringing to it 21st century ideas. Frankly, I had not appreciated how, in all those years since my PhD thesis, little had changed. I also came to the realization that, with my central research focus of biomaterials, perhaps the major consumer of biomaterials today is kidney dialysis. Dr. Himmelfarb and I conceived of the Center for Dialysis Innovation (CDI). The CDI was formally launched in the University of Washington in 2017. Our launch was "jet-propelled" with a generous five-year research grant from the Northwest Kidney Centers, a non-profit dialysis provider (and, in fact, the world's first dialysis center). CDI is a partnership with ten collaborating faculty members (from five engineering departments), some 30 students, postdocs and technicians and a closely integrated patient advisory board (if patients won't embrace our developments, the developments will have little impact). With this motivated, visionary group, we set out to re-envision how we do dialysis today.

The CDI is now approaching five years. Our vision is that hemodialysis in the near future will be portable or wearable, in contrast to today's in-center dialysis that uses large, expensive, stationary machines. Portable and wearable hemodialysis requires:

- Dialysis with 1-2 liters of water, in contrast to 400 l.
- Dialysis that removes approximately 15 g of urea/day + other toxins
- Dialysis that addresses electrolyte balance and water homeostasis
- Blood-compatible materials superior to those we have today
- Painless, safe blood access
- Infection resistance

The CDI has made ground-breaking strides in each of these points. We now photo-catalytically convert urea to CO2 and N2 permitting us to dialyze against small volumes of water. We developed biomaterial surface modifications based on carboxybetaine zwitterionic polymers and plasma deposited fluoropolymers that show superior blood compatibility. A new vascular access graft that heals without a fibrous capsule should permit longer, safer blood access. Blood access is being further advanced with a revolutionary, automated catheter connect/disconnect system. Many other advances that, due to space limitations, cannot be described in this short article, have been made, all with a tight engineering focus on safe, effective, economically sound hemodialysis. A few articles cited below elaborate on some of the CDI developments. A short video presents our vision for the future of hemodialysis.



To speed CDI developments to patients, the CDI has spun out from the University of Washington Kuleana Technology, Inc. Kuleana is a Hawaiian word suggesting care and responsibility. We think this well-describes the intent of Kuleana Technology — to bring 21st century technologies to patients in need of kidney dialysis.

The CDI has been one of the most exciting projects in my career. It is interesting and gratifying to appreciate this 50-year bridge between my PhD thesis research and my most recent research efforts. Importantly, I see the CDI output positively impacting an underserved patient group with developments that can reach those patients in just a few years.

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Industry News

By Gopinath Mani, Industry News Editor

Artio Medical, Inc., a medical device company developing peripheral vascular and neurovascular products, recently announced that it received US Food and Drug Administration (FDA) clearance for its Solus Gold **Embolization Device**, a next-generation product for **peripheral vascular occlusion**.[1] Continued blood flow through damaged or diseased blood vessels can result in life-threatening bleeding and other serious medical conditions.[1] Peripheral vascular embolization is a minimally invasive procedure that blocks or reduces blood flow in blood vessels.[1] The Solus Gold Embolization Device combines a flexible catheter assembly and a non-porous, balloon-like gold implant for easy delivery, precise placement, and immediate vessel occlusion.[1] The device is indicated to obstruct or reduce the rate of blood flow in the peripheral vasculature.[1] The delivery system balances flexibility and pushability, enabling physicians to navigate tortuous vasculature.[1] Following a controlled expansion and simple mechanical detachment, the non-porous and balloon-like gold implant provides 360° vessel apposition for immediate and complete occlusion, and resists migration and recanalization, providing physicians with a "one-and-done" solution for peripheral vascular occlusion.[1]

Heidelberg-based Precisis GmbH has received Breakthrough Device Designation from the U.S. Food and Drug Administration (FDA) for its EASEE **brain stimulator**.[2] FDA's breakthrough devices program classifies medical devices that have the potential to enable more effective treatment of life-threatening or irreversibly debilitating diseases or conditions.[2] The goal is to make them available to patients faster.[2] Globally, **epilepsy** is one of the most common chronic neurological disorders and has an immense impact on the lives of those who suffer from it.[2] Moreover, one in three patients is considered drug-refractory and requires additional technical or surgical therapies.[2] In this context, EASEE (an acronym for "Epicranial Application of Stimulation Electrodes for Epilepsy") could offer these patients the potential to receive a more effective, minimally invasive epilepsy therapy and to improve their quality of life.[2] EASEE is a system for individualized brain stimulation, which is precisely placed above the origin of the epileptic seizure in the brain, but is surgically inserted only underneath the scalp.[2] This means that the skull bone is not opened, and the brain itself remains untouched.[2] The thin electrodes are not visible from the outside and ensure unrestricted freedom of movement for patients.[2] The therapeutic impulses can be individually customized for each patient, and regular modifications can be made throughout the duration of the treatment.[2]

atHeart Medical, a medical device company dedicated to establishing the new standard of care for **closure of atrial septal defects** (ASD), today announced it has received approval for the start of the second phase of its ASCENT ASD U.S. Investigational Device Exemption (IDE) pivotal trial.[3] Commonly described as a "hole in the heart," an ASD is an opening in the septum between the left and right atria.[3] Most ASDs are **congenital defects**, affecting six in 10,000 births.[3] They can also be the result of a procedure that requires transseptal crossing.[3] A large atrial septal defect can cause extra blood to overfill the lungs and overwork the right side of the heart.[3] If not treated, the right side of the heart eventually enlarges and weakens.[3] The blood pressure in the lungs can also increase, leading to pulmonary hypertension.[3] When ASDs require closure, the current standard of care is to implant a septal occluder with a metallic frame through a minimally invasive procedure.[3] This prospective, single-arm study is evaluating the safety and efficacy of the reSept™ ASD **Occluder**, the first occluder with a metal-free, bioresorbable frame, for the treatment of patients with clinically significant, isolated ASDs.[3] Primary endpoints will be compared with established performance goals for previously FDA-approved transcatheter ASD occluders.[3] The reSept ASD Occluder aims to address the limitations of current occluders which have metallic frames that can place patients at risk of complications associated with long-term presence of metal in the heart and may limit future transseptal interventions, such as mitral valve interventions.[3] Initial clinical experience demonstrates positive safety and performance in the closure of the ASDs treated with the company's device.[3]

The U.S. Food and Drug Administration's **Oncologic Drugs Advisory Committee** is holding a meeting on April 21, 2022, to discuss safety findings across the entire class of **PI3K inhibitors for hematological cancers**.[4] Dysregulated PI3K signaling helps malignant lymphocytes survive and proliferate.[4] The FDA is essentially asking the advisory committee to make a recommendation on whether future approvals for this class of drug should be based on randomized data instead of single-arm clinical trials.[4] Currently, there are four PI3K inhibitors approved by the FDA under this context.[4] They are Gilead Sciences' Zydelig (idelalisib), Bayer's copanlisib, Secura Bio's develisib, and TG Therapeutics' umbralisib.[4] A fifth drug, alpelisib, a PI3K alpha-specific inhibitor approved for breast cancer and PIK3CA-related overgrowth spectrum, will not be included in the discussion.[4] All of the drugs have shown durable overall response rates or improvements in progression-free survival.[4] However, the side effects are serious and potentially deadly.[4] The FDA is proposing three changes for the advisory committee to consider.[4] First, they push for careful dose selection by way of thorough dose exploration through early randomized trials.[4] Secondly, they advise companies to avoid single-arm trials as regulatory strategies.[4] And third, fully collect and analyze

Industry News (continued)

overall survival data to evaluate how the drug affects the "ultimate safety endpoint."[4]

Keymed Biosciences announced that the U.S. Food and Drug Administration (FDA) granted CMG901 Fast Track Designation as monotherapy for the treatment of unresectable or metastatic **gastric and gastroesophageal junction cancer** which have relapsed and/or are refractory to approved therapies.[5] This is another milestone after CMG901 received Orphan-drug Designation from the FDA.[5] Among all the **Claudin 18.2-targeted drugs**, CMG901 is the first and only one which received this FDA designation so far.[5] This designation was granted based on the phase 1 studies that assessed the safety, tolerability, pharmacokinetic (PK), and preliminary efficacy of CMG901.[5] CMG901 consists of three components: a monoclonal antibody targeting Claudin 18.2, a cleavable linker and a potent cytotoxic payload (MMAE).[5] Claudin 18.2 has been identified as a highly selective molecule that is widely expressed in multiple solid tumors, including gastric cancer and pancreatic cancer, suggesting that Claudin 18.2 is an ideal target for tumor therapeutic development.[5] CMG901 can cause tumor cell death by several mechanism:[5] (a) CMG901 binds to Claudin 18.2 positive cell via its monoclonal antibody portion. After binding, CMG901 will be internalized into lysosome by tumor cells and release the cytotoxic payload, leading to cell cycle arrest and apoptosis of the tumor cells; (b) CMG901 can stimulate cellular and soluble immune effectors that activate antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) to destroy the Claudin 18.2 positive cells. Preclinical studies suggest that CMG901 can effectively kill gastric cancer cells with much stronger antitumor potency than zolbetuximab analog or the unconjugated antibody of CMG901.[5] Meanwhile, CMG901 also shown good tolerance and favorable safety profile in preclinical studies.[5]

TOOsonix A/S, a pioneer in **high intensity focused ultrasound** (HIFU) for dermatology recently announced that the first patients with basal cell carcinoma have been treated in a new clinical study using its System ONE-M device.[6] **Basal Cell Carcinoma** (BCC) is the most common cancer in the world.[6] It is sun-induced and is expected to increase in incidence along with the increase of the elderly population.[6] Adding safe, effective, and cost-efficient treatments will therefore be important for both patients and healthcare providers around the world.[6] The clinical study will include 40 patients diagnosed with superficial BCC.[6] The HIFU treatment will be administered as a single dosing of approximately 1-2 minutes of active focused ultrasound.[6] The treatment does not require any local anesthetics and no special after-care.[6] Study participants are monitored with regular follow-up visits over 12 months after treatment.[6] An interim report with evaluation of cure rate and safety profile three months after treatment is planned.[6] The TOOsonix high intensity focused ultrasound system used in the study delivers highly accurate doses of energy to focal points in a chosen depth.[6] It can therefore directly and selectively treat areas affected by basal cell carcinoma, typically invading the outer layer of the human skin.[6] System ONE-M is a focused ultrasound device operating at 20 MHz, which creates thermal focal zones in the epidermis and dermis of the human skin.[6] Within the focal zone, the temperature rapidly increases to 50-60 °C, which causes local cell death.[6] The body's own healing processes will subsequently remove and replace the treated field with new and healthy tissue.[6] The system provides an innovative and easy-to-use image-guided treatment modality, that enables physicians and other qualified practitioners to offer convenient, safe and effective therapy to their patients.[6]

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Government News

DATA SHARING

By Carl Simon, Government News Editor

In 2013, President Obama issued an executive order requiring the government to make its data accessible to the public. Recently, U.S. National Institutes of Health (NIH) released a new Data Management and Sharing Policy. As stated on the site, "Sharing scientific data accelerates biomedical research discovery, enhances research rigor and reproducibility, provides accessibility to high-value datasets, and promotes data reuse for future research studies." Further, it is stated that "the sharing of scientific data expedites the translation of research results into knowledge, products, and procedures to improve human health." The policy requires that research proposals include a plan for how research data will be shared.

When undertaking a large, multiyear project, with several team members, it can be an overwhelming task to figure out how to disseminate the data. Often, many different types of data are collected, from many different sources, in different formats, using different nomenclature, including different types of replicates. The data often come in different processing states, including the two most obvious which are raw data and final aggregated data. Aggregated data are the fully processed and analyzed data that are combined from many replicates to make plots in papers. However, there are often many intermediate types of data in various states of processing. Analytical pipelines often undergo sequential processing steps such as cropping, trimming, removing bad data, smoothing, averaging, filtering, etc. Each of these steps may produce intermediate data. Which of these data ought to be shared?

At a minimum, the aggregated data that are used to make the figures in the paper should be made available. If the manuscript has x-y plots, then the x- and y-coordinates, including the error bars, should be available. This can be achieved with an Excel spreadsheet, or a .csv file, where each tab in the spreadsheet can address a figure from the paper. These files must be annotated and have notes to help the user understand the data. A README tab may be included that describes the overall layout of how the data are arranged. A spreadsheet of this nature will be relatively small in size and can be published as a supplemental information file with the primary manuscript on the journal website.

Next, authors should consider if their raw data has value to others. This may vary by the project. If a terabyte (TB) of data has been collected for a project, then it would be a massive task to share it. It may take several months to annotate and organize a TB in a manner that can be understood by users. A careful decision must be made to determine if it would be of value to share large data sets.

Databases exist for sharing certain types of data, such as protein structural data, microarray data and sequencing data and X-ray powder diffraction, and these should be utilized.

Data that is collected for developing new measurement methods or new data analysis methods may be of particularly high value. Others may use the data to verify that they are performing the new measurement correctly, or they could use the data to develop improved methods for data analysis. Data used for training artificial intelligence algorithms could be of high value, since others may use the data to train their algorithms to increase algorithm reliability.

DATA USED FOR TRAINING ARTIFICIAL INTELLIGENCE ALGORITHMS COULD BE OF HIGH VALUE, SINCE OTHERS MAY USE THE DATA TO TRAIN THEIR ALGORITHMS TO INCREASE ALGORITHM RELIABILITY.

For sharing data beyond the journal website, such as raw and processed data, many options exist that depend on factors such as the amount of data, budget, audience, data transfer speeds, how much explanation the data may need and accessibility. A key point is to find a solution that provides you with a digital object identifier (DOI). A DOI "is a unique alphanumeric string assigned by a registration agency (the International DOI Foundation) to identify content and provide a persistent link to its location on the internet." If possible, the data DOI should be obtained prior to publishing your primary research article, so that the data DOI can be provided in the publication. Another key point is knowing your audience. It is critical to share your data in a way that can best reach the appropriate audience.

One option is to use a website, such as Zenodo or Figshare, which can host your data and make it publicly findable and downloadable. Another option is a journal called Data in Brief, that can host your data and provide a DOI, as well as publish a short article describing your data.[10] Also, some institutions host data from their staff. NIST has a web service to host data from staff which provides a minimalistic text interface and a DOI.

Prior to publishing data, the data need to be organized in a simple, clean manner so that users can easily understand the data.

Government News (continued)

Data can be organized in a variety of ways, such as by figure number (from the primary research article), by experimental treatment, or by date. A detailed README file that explains how the data are organized should be provided with the data to assist the user.

As you embark on your next research campaign, keep data sharing in mind so that you can take early steps to make things easier when it comes time to publish. A key bottleneck to data sharing is file and folder naming. Since the final data structure is unknown at the time when the data are collected, the file naming scheme that is selected at collection may no longer make sense when the project is completed a year or two later. File names should not be too long since many systems have a path limit of 256 characters. The path limit is the number of characters in the folder path including the file name. Possibly the best method for folder naming is to use the date with a short text string to describe the experiment, such as this: "2022.05.31_RPE_4wks_aphidocolin." Then place the relevant files in the folder including a README file that summarizes the experiment. The date should be formatted as shown (year then month then day) so that the folders can be sorted by date. After the project is complete, there may be thousands of files, making it too cumbersome to rename the files in a way which makes it easier for someone to navigate.

When I first realize that a discussion is starting to become a long-term project, I create what I call my "first contact" file. The first contact file gives an overview of the treatments to be tested and is invaluable in keeping the data organized.

This is an example of information that went into a cell imaging experiment first contact file:

- 18-cell lines expressing different proteins
- 2 treatments: inhibit differentiation & induce differentiation
- 6 time Points: weeks 1 to 6
- 5 replicates (five wells)
- 6 volumes of interest from each well
- 4 channels:
  - Nucleus: Hoechst
  - Actin: AlexaFluor 555-phalloidin
  - Cell Membrane: Cell Mask Deep Red Plasma Membrane
  - GFP
- Each Z-stack has 27 tifs
  - Each image is 16 bit
  - X = 1278 pixels, Y = 1078 pixels, 2.6 MB/image
  - Voxel dimensions: X = 217 nm, Y = 217 nm, Z = 500 nm
  - Volume dimensions: X = 276 µm, Y = 276 µm, Z = 13.5 µm
- 18 cell lines X 2 treatments X 6 time points X 5 replicates X 6 VOI = 6,480 Image sets
- 6,480 image sets X 4 channels X 27 slices = 699,840 images
- 699,840 images X 2.6 MB/image = 1.82 TB of data

Data sharing is an important aspect of research that is rapidly evolving. There are many factors to consider and the effort can be significant (months). *Isn't this a waste of time?* It could be. As discussed above, you ought to do the minimum of making the aggregate data used to make the figures in the paper available. Beyond that you have to decide how much additional data should be made available. Is there value in making the raw data, the intermediate data or the processed data available? There are a lot of data scientists, software developers and scientists using data to train artificial intelligence algorithms; this field may place a high value on your data and use it in unforeseen ways.

Contacts: Carl Simon, carl.simon@nist.gov

Student Travel Achievement Recognitions

Ashley Brown, PhD, Special Interest Group Representative

The Student Travel Achievement Recognitions (STARs) recognize research excellence and develop future leaders within our Society. The STAR recipients are selected according to the following procedures:

Special Interest Group (SIG) Officers review a list of the STAR applicants who applied for the STAR Awards when submitting their meeting abstracts, along with their abstract titles and scores. Each SIG then nominates several students for consideration. The SIG Chair Committee then reviews the nominations and selects the STAR recipients who each receive a monetary award of $250 and a certificate of recognition. Those abstracts recommended by the SIGs, but not selected by the SIG Chair Committee receive honorable mentions.

2022 STAR AWARD RECIPIENTS

Nilabh Kajave, Florida Institute of Technology
BioInterfaces SIG: #8 ORAL

Atip Lawanprasert, Penn State University
BioInterfaces SIG: #10 ORAL

Victoria Muir, University of Pennsylvania
Biomaterials Education SIG: #568 POSTER

Hannah Durr, University of Akron
Biomaterials & Medical Products Commercialization SIG: #328 ORAL

Maryam Ramezani, Syracuse University
Biomaterials & Medical Products Commercialization SIG: #326 ORAL

Derek Avery, Virginia Commonwealth University
Biomaterial-Tissue Interaction SIG: #307 ORAL

Daniel Song, University of Maryland
Biomaterial-Tissue Interaction SIG: #147 ORAL

Ana Sheridan, North Carolina State University
Cardiovascular Biomaterials SIG: #269 ORAL

Alexandra Rindone, Johns Hopkins University
Dental/Craniofacial Biomaterials SIG: #191 ORAL

Madeline Fuchs, University of Florida
Drug Delivery SIG: #140 ORAL

Kelsey Swingle, University of Pennsylvania
Drug Delivery SIG: #31 ORAL

Mohammadjafar Hashemi, Auburn University
Engineering Cells & Their Microenvironments SIG: ORAL #186

Sauradeep Sinha, Stanford University
Engineering Cells & Their Microenvironments SIG: ORAL #68

Sahil Inamdar, Arizona State University
Immune Engineering SIG: POSTER #636
Karen Martin, Georgia Institute of Technology
Immune Engineering SIG: POSTER #305

Subhadeep Dutta, Arizona State University
Nanomaterials SIG: ORAL #248

Nhu Truong, University of Maryland, Baltimore
Nanomaterials SIG: ORAL #35

Carlisle DeJulius, Vanderbilt University
Ophthalmic Biomaterials SIG: ORAL #276

Lucas Olson, Virginia Commonwealth University
Orthopaedic Biomaterials SIG: ORAL #265

Karen Xu, University of Pennsylvania
Orthopaedic Biomaterials SIG: ORAL #338

Michael Berger, Virginia Commonwealth University
Surface Characterization & Modification SIG: ORAL #195

Anne Katherine Brooks, Virginia Commonwealth University
Surface Characterization & Modification SIG: ORAL #291

Abhishek Dhand, University of Pennsylvania
Tissue Engineering SIG: ORAL #290

Joshua McCune, Vanderbilt University
Tissue Engineering SIG: ORAL #125

Samantha Zambuto, University of Illinois at Urbana-Champaign
Tissue Engineering SIG: ORAL #160

2022 STAR AWARD HONORABLE MENTIONS

Leah Borden, University of Maryland, College Park
BioInterfaces SIG: #44 ORAL

Sabrina Macias, University of Florida
BioInterfaces SIG: #303 ORAL

Clyde Overby, University of Rochester
BioInterfaces SIG: #141 ORAL

Student Travel Achievement Recognitions (continued)

Mona Mansouri, The University of Akron
Co-sponsored Biomaterial-Tissue Interaction SIG/Engineering Cells and Their Microenvironments SIG: #239 ORAL

Tran Ngo, National Institutes of Health
Biomaterial-Tissue Interaction: #764 POSTER

Sweta Roy, Syracuse University
Biomaterial-Tissue Interaction: #506 POSTER

Mohammadjafar Hashemi, Auburn University
Cardiovascular Biomaterials SIG: #187 ORAL

Junlang Li, North Carolina State University
Cardiovascular Biomaterials SIG: #862 POSTER

Emily Margolis, University of Michigan
Cardiovascular Biomaterials SIG: #188 ORAL

Nicholas Fischer, University of Minnesota
Dental/Craniofacial Biomaterials SIG: #193 ORAL

Jennifer Patten, Temple University
Drug Delivery SIG: #357 ORAL

Selen Uman, University of Pennsylvania
Drug Delivery SIG: #271 ORAL

Tracy Chung, Johns Hopkins University
Engineering Cells & Their Microenvironments SIG: #168 ORAL

Liana Kramer, Emory University
Engineering Cells & Their Microenvironments SIG: #241 ORAL

Elizabeth Curvino, Duke University
Immune Engineering SIG: #38 ORAL

Alexander Kwiatkowski, University of Florida
Immune Engineering SIG: #37 ORAL

Margaret Manspeaker, Georgia Institute of Technology
Immune Engineering SIG: #62 ORAL

Damion Dixon, University of Georgia
Orthopaedic Biomaterials SIG: #839 POSTER

Kenneth Alexander, University of Kentucky
Surface Characterization & Modification SIG: #844 POSTER

Aya Ali, University of Mississippi Medical Center
Surface Characterization & Modification SIG: #845 POSTER

Matthew Aronson, Children's Hospital of Philadelphia
Surface Characterization & Modification SIG: #327 ORAL

Caitlyn Greene, Syracuse University
Surface Characterization & Modification SIG: #113 ORAL

Narges Yazdani, Northeastern University
Surface Characterization & Modification SIG: #847 POSTER

Sophia Letcher, Tufts University
Tissue Engineering: #625 POSTER

Yining Liu, Duke University
Tissue Engineering: #264 ORAL

Fan Zhang, North Carolina State University
Tissue Engineering: #278 ORAL

Revitalizing Our Society For Biomaterials

By Subramanian Gunasekaran, PhD, Biomaterials & Medical Products Commercialization SIG Forum Reporter

As an active member of the Society For Biomaterials (SFB) since 1984, I have been witnessing the flow of our Society. The growth & development of SFB has been good; however, our Society has not touched the pinnacle. What do we lack? Proper recognition from the Medical Clinical System. What do I mean by that? The immense Research & Development (R&D) contributions to the Healthcare Community by our Society Members are not adequately addressed to the regulators and the payors of medical devices towards commercialization.

In my opinion, the significance of the Special Interest Group (SIG), Biomaterials & Medical Products Commercialization (BMPC), is probably to fill in the gap between SFB and Food and Drug Administration (FDA)/Medicare. For example, currently, the commercial valuation of a medical device is performed thrice annually by the RelativeValue Update Committee (RUC) comprised of 31 physicians from the societies affiliated with the American Medical Association (AMA). There is no place to impart the biomaterial science information to the valuation committee by the SFB members. On that note, a consortium must be formed to bridge the existing gap between the Clinical Associations and Basic Scientific Societies (like our SFB) for assisting FDA to Evaluate the Safety & Efficacy and Centers for Medicare & Medicaid Services (CMS) to provide a more justifiable Commercial Valuation of the Tissue Regenerative Medical Devices. It is high time we bring authoritative emphasis on the need for Basic Science Education.

Following are a few examples to document the technical contributions of our Society members:

- Establishment of American Society for Testing and Materials (ASTM) Standards for the Characterization of Type-I Collagen for use in Surgical Applications (ASTM-F2212-2009) - through the efforts of Dr. David Kaplan, FDA with the involvement of SFB members.
- Exposure of inappropriate claims of recombinant methods to produce Type-I collagen molecule that is coded by two separate genes and hence not feasible.
- Brought out the fallacy in the current wound care protocol advocating improper frequency of dressing changes every 48 hours irrespective of whether the granulation happens or not.
- Objected to the irrelevant usage of the term "activated collagen" for the broken-down peptides of approximately 3000 MW (Molecular Weight)
- Disclosure of the scientific fact recently published that the biodegraded elastin molecule is carcinogenic and thereby usage of matrices containing Elastin can pose a safety threat that has to be enforced by FDA and to make CMS re-evaluate the commercial value of such devices.

Student News

David Flores, SFB Student Chapter President

Welcome our newly elected board members for the 2022-2023 cycle!

Grant Scull, a PhD student from UNC-Chapel Hill and North Carolina State University, will serve as President-Elect. Arian Veyssi, a PhD student from University of Texas at Austin, will serve as Secretary/Treasurer-Elect. Amberlyn Simmons, a PhD student from Arizona State University, will serve as Bylaws Chair. All of the new members have ample experience as board members of their local student organizations, and we are excited for the future events by the National Student Chapter.

In February, we held a seminar on "Creating impactful figures for papers, websites, and beyond" where the speakers gave their insight and tips on the important skill of making figures for scientific publications. Most recently, we held a joint panel with the Tissue Engineering and Regenerative Medicine International Society (TERMIS) Student and Young Investigator Section where the panelists discussed the differences in academic training and careers between Europe and North America. The recording from that panel will be available for SFB members in the near future. Please stay tuned for our upcoming events!

Follow us on our new Instagram @sfbstudents and expanded Twitter @sfb_students – or contact us through our Gmail address: sfbstudents@gmail.com

Society For Biomaterials

2023 ANNUAL MEETING AND EXPOSITION

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