Workshop on Measurement Needs for Biofabrication of Tissue Engineered Medical Products

Thursday December 1, 2022

11:00 AM – 5:00 PM ET

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

Goal: discuss and identify measurement needs for characterizing biofabricated, tissue engineered medical products for clinical applications.

Scope: Biofabricated tissue-engineered constructs have the potential to transform personalized medicine. However, characterizing these constructs post-fabrication and throughout preclinical use remains challenging. We will hold a one-day workshop on measurement needs for biofabricated constructs that contain cells, focusing on metrology for the structure of the constructs, cell viability in the constructs, and functional capacity of the constructs. This workshop will enable future research directions, standards development, and the adoption of these constructs for clinical use.

https://www.nist.gov/news-events/events/2022/12/workshop-measurement-needs-biofabrication-tissue-engineered-medical

Technical Program

Discussion leader: Greta Babakhanova, *National Institute of Standards and Technology (NIST)*

10:00 AM – 11:00 AM	Login to BlueJeans and Test System
11:00 AM – 11:10 AM	Welcome Address: Sheng Lin-Gibson, *NIST*
11:10 AM – 11:45 AM	Plenary: Jennifer H. Elisseeff, *Johns Hopkins University* Manufacturing complex biologics for regenerative medicine

Session 1: Cell Viability

Discussion leader: Alicia Henn, *BioSpherix*

11:55 AM – 12:05 PM	Naresh Menon, *ChromoLogic* Non-invasive non-contact real-time monitoring of cells within bio-reactors by direct imaging with optical coherence tomography
12:05 PM – 12:15 PM	Mrignayani Kotecha, *O2M Technologies* Nondestructive Cell Viability Assessment Using Oxygen Imaging
12:15 PM – 12:25 PM	Carl G. Simon, Jr., *NIST* Optical coherence tomography imaging for label-free measurement of cell viability in scaffolds
12:25 PM – 12:55 PM	Panel discussion
12:55 PM – 1:25 PM	Lunch

Session 2: Cell Phenotype

Discussion leader: Jeff Halpern, *University of New Hampshire*

1:25 PM – 1:35 PM	Marc Ferrer, *National Center for Advancing Translational Sciences* Advancing Drug Discovery with Biofabricated 3D Tissue Models
1:35 PM – 1:45 PM	Marcie Black, *Advanced Silicon Group* Protein sensing
1:45 PM – 1:55 PM	Kersti Alm, *Phase Holographic Imaging* Non-invasive quantitative live cell imaging
1:55 PM – 2:25 PM	Panel discussion
2:25 PM – 2:35 PM	Break

Session 3: Tissue Characterization

Discussion leader: Nathan Castro, *Nanochon Inc.*

2:35 PM – 2:45 PM	Rohan Shirwaiker, *North Carolina State University* Dielectric spectroscopy for in line monitoring of engineered tissue constructs
2:45 PM – 2:55 PM	Adam Feinberg, *FluidForm* In situ volumetric imaging and analysis of 3D bioprinted constructs using optical coherence tomography
2:55 PM – 3:05 PM	Bao-Ngoc Nguyen, *U.S. Food and Drug Administration* Characterization of Tissue Engineered Medical Products
3:05 PM – 3:35 PM	Panel Discussion
3:35 PM – 3:45 PM	Break
3:45 PM – 3:55 PM	Workshop Survey Review, Carl Simon, *NIST*

Technical Program

Breakout Session

Topics:
1. Potency & phenotype measurements
2. Cell viability measurements
3. Measurements of construct structure
4. pH, O_2 & metabolite measurements
5. Mechanical property measurements
6. Sterility measurements
7. Measurements of cell distribution in constructs
8. Measurements of raw materials
9. Scaffold reference material
10. Tissue mimics
11. Tissue reference data

Moderators:
Richard McFarland, *ARMI**
Mary Clare McCorry, *ARMI**
Kimberlee Potter, *VA§*
Leanne Friedrich, *NIST#*
Zeeshan Ahmed, *NIST#*
Billyde Brown, *GTMI^*
Callie Higgins, *NIST#*
Kirsten Parratt, *NIST#*
Taneka Jones, *Vericel*
Rohan Shirwaiker, *NC State University*
Dawn Henke, *Standards Coordinating Body*
Lexi Garcia, *ARMI**
Kaiming Ye, *Binghamton University*

3:55 PM – 4:35 Breakout session

Closing Session

4:35 PM – 4:55 Report back

4:55 PM – 5:00 PM Closing remarks
Greta Babakhanova, *NIST*

*ARMI – Advanced Regenerative Manufacturing Institute
§VA – United States Department of Veterans Affairs
#NIST – National Institute of Standards and Technology
^GTMI – Georgia Tech Manufacturing Institute

Workshop Steering Committee

Guillermo Ameer	Northwestern University
Greta Babakhanova	National Institute of Standards and Technology
Leanne Friedrich	National Institute of Standards and Technology
Dawn Henke	Standards Coordinating Body
Callie Higgins	National Institute of Standards and Technology
Jay Hoying	Advanced Solutions Life Sciences
John Huang	TheWell Bioscience, Inc.
Taneka Jones	Vericel Corporation
Mary Clare McCorry	Advanced Regenerative Manufacturing Institute
Marian Piekarczyk	Thermo Fisher Scientific
Laura Pierce	National Institute of Standards and Technology
Kimberlee Potter	U.S. Department of Veterans Affairs
Itedale Namro Redwan	CELLINK
Jane Romantseva	National Institute of Standards and Technology
Jonathan Seppala	National Institute of Standards and Technology
Rohan Shirwaiker	North Carolina State University
Carl G. Simon, Jr.	National Institute of Standards and Technology

Workshop Participants

(Alphabetical Order)

Zeeshan Ahmed, Ph.D.
Chemist, Project Leader
National Institute of Standards and Technology
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Dr, Zeeshan Ahmed is currently a project leader in the Sensor Science Division at NIST where his research activities focus on the development of novel, disruptive technologies that aim to replace legacy-based measurement platforms. Specifically, his current research is focused on the development of physics constrained machine learning models for photonic and quantum sensors. This line of inquiry seeks to enable a cost-effective, integrated multi-functional sensor package with intelligent-calibration capabilities. He currently serves as Chairman of Task group on Emerging Technologies under Contact Thermometry at the Bureau International des Poids et Mesures (BIPM). In addition, he holds an Affiliate Faculty position with George Mason University's Chemistry department and the Quantum Science and Engineering Center (QSEC). His background includes work in data analytics, nanophotonics, Terahertz spectroscopy of biomaterials and pharmaceuticals, surface enhanced deep UV resonance Raman spectroscopy, and time-resolved vibrational spectroscopy of proteins. He received his PhD from University of Pittsburgh and BSc from George Mason University.

Kersti Alm, Ph.D.
Chef Scientific Officer
Phase Holographic Imaging (PHI)
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Dr. Alm has cooperated with PHI since 2005 and is a vital part of the PHI team since 2009. All insights gained through her PhD studies at Lund University, Sweden, her postdoc time at Roswell Park, Buffalo, NY, and the years after that working as a researcher and lecturer at Lund University, have been applied in the development of a genuinely novel cell analysis system. Her focus has been to develop a method that will neither cause cell stress nor harm while also providing accurate kinetic data. This goal has been reached both through in-house studies and collaborations as well as joint publications with researchers around the world, e.g., at Malmö and Lund universities, Northeastern University in Boston, UCSF in California, and many more.
Digital holographic imaging has existed as a brainchild since the '70s. Now, it is a reality since computers became powerful enough to handle the algorithms required to reconstruct the hologram of an imaged object – or even living cell cultures. PHI has proudly been part of this development and today advances cutting-edge research by applying digital holography to cell-based science.

Non-invasive quantitative live cell imaging

Abstract: Cells that will be used for clinical applications need to go through rigorous quality controls before being administered to patients. Many analyses require sacrificing parts of the precious sample and removing the sample from the production line. Label-free cell phenotype measurements can contribute to a wide scope of cell health and quality controls without losing any part of the sample and removing the sample from the product line. Digital holography is a label-free, robust, minimally destructive imaging method for cell analysis. The cells can stay in their preferred cell carriers in their preferred environment while being monitored continuously. The resulting quantitative data can be used for cell health controls, proliferation and viability measurements, differentiation monitoring, and even release criteria. My talk will briefly describe digital holography and how relevant cell phenotype data can be extracted.

Guillermo A. Ameer, Ph.D.
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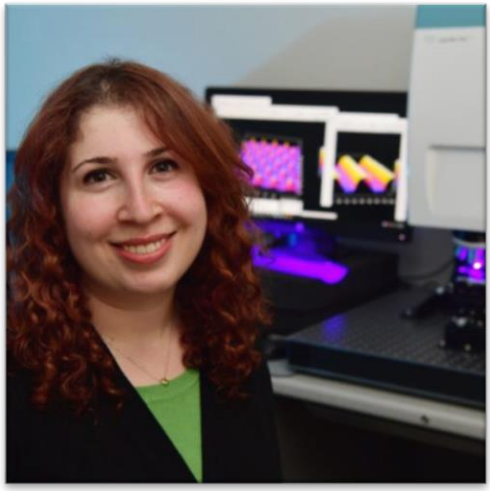
Dr. Ameer is the Daniel Hale Williams professor of Biomedical Engineering and Surgery in the Biomedical Engineering Department at the McCormick School of Engineering and the Department of Surgery at the Feinberg School of Medicine, Northwestern University. He is the founding director of the Center for Advanced Regenerative Engineering (CARE). His research interests include regenerative engineering, biomaterials, additive manufacturing for biomedical devices, controlled drug delivery and bio/nanotechnology for therapeutics and diagnostics.

Dr. Ameer's laboratory pioneered the development and tissue regeneration applications of citrate-based biomaterials (CBB), the core technology behind the innovative bioresorbable orthopaedic tissue fixation devices CITREFIXTM, CITRESPLINETM, and CITRELOCKTM, which were recently cleared by the FDA for clinical use and marketed worldwide. CBBs are the first thermoset synthetic polymers used for implantable biodegradable medical devices. The co-founder of several companies, Dr. Ameer has over 300 publications and conference abstracts and 65 patents issued and pending in 9 countries.

His awards include the Key to the City of Panama, the Society for Biomaterials (SFB) Clemson Award for Contributions to the Literature, the SFB Technology Innovation and Development Award, the Chinese Association for Biomaterials Global Biomaterials Leadership Award, the Tissue Engineering and Regenerative Medicine Society Innovation and Commercialization Award, and the Bioactive Materials Lifetime Achievement Award. Dr. Ameer is a member of the National Academy of Medicine, and a Fellow of the American Institute of Medical and Biological Engineering (AIMBE), Fellow of the Biomedical Engineering Society, Fellow of the AIChE, Fellow of the American Association for the Advancement of Science (AAAS), Fellow of the Materials Research Society, and Fellow of the National Academy of Inventors. Dr. Ameer is a Deputy Editor for the AAAS journal Science Advances, Associate Editor for the Regenerative Engineering and Translational Medicine journal, a member of the board of directors of the Regenerative Engineering Society and AIMBE, and chair of the AIMBE College of Fellows.



Greta Babakhanova, Ph.D.
Physicist
National Institute of Standards and Technology
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Dr. Greta Babakhanova is a Physicist in the Biomaterials Group at the National Institute of Standards and Technology (NIST). She completed her Ph.D. in Chemical Physics from the Advanced Materials and Liquid Crystal Institute, Kent State University in 2019. She is a recipient of the 2020 Glenn H. Brown Prize awarded by The International Liquid Crystal Society for her outstanding contribution to the science of liquid crystals. After graduation, she was awarded the NIST-NRC Postdoctoral Research Fellowship (2019-2021) which enabled her to work on cell viability projects at NIST. Her current primary technical objective is to develop robust non-destructive methods for characterization of tissue engineered medical products. Since April 2022 Dr. Babakhanova is also working in the Program Operations Division at the Office of Advanced Manufacturing, where she assists with the program management of NIST-funded initiatives.

Marcie Black, Ph.D.
Co-founder & CEO,
Advanced Silicon Group
marcie@advancedsilicongroup.com

Dr. Marcie Black is the co-inventor of the silicon nanowire array biosensor. Dr. Black brings expertise in building strong teams, managing development projects, patents, IP strategy, encouraging a healthy company culture, cost modeling, and running a startup. Prior to founding ASG, Marcie was the co-founder of Bandgap Engineering, which focused on lowering the cost of solar electricity through black silicon or silicon nanowire solar cells. Bandgap raised over $10 million of investment from VCs, angels, state, and national grants. In 2009, she was awarded an R&D 100 award for her contributions to work at LANL. Marcie also was honored as one of the ten "Women-to-Watch in 2010" by Mass High Tech.

Protein Sensing

Abstract: Dr. Black will discuss basic methods for measuring cell phenotype – especially proteins – and review some of the advantages and challenges for these. Then she will present the photoelectric ELISA biosensor, LightSense. LightSense will be able to detect a wide range of protein concentrations, monitor multiple proteins simultaneously, and measure proteins at low-concentrations even when submerged in a high-concentration of another protein and do so at a low-cost. Lastly, Dr. Black will point out a few other technologies that she finds promising to meet the market need for sensing.

Billyde Brown, Ph.D.
Senior Research Faculty, EWD Director
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Dr. Billyde Brown is a Senior Research Faculty and Education and Workforce Development (EWD) Director at the Georgia Tech Manufacturing Institute (GTMI), one of eleven interdisciplinary research institutes at the Georgia Institute of Technology. Dr. Brown's overall role is to create strong partnerships among industry, government, and academia in the area of manufacturing research, development, and deployment, while acquiring and managing sponsored research programs.

Dr. Brown is currently the PI of an Advanced Regenerative Manufacturing Institute (ARMI BioFabUSA) funded project to develop a wireless sensor system for real-time in-situ monitoring of critical quality attributes including pH, glucose, lactate, and protein biomarkers in human mesenchymal stem cell expansion bioreactors. Dr. Brown manages a Manufacturing Certificate program and proctors a Manufacturing Seminar Course for the Georgia Tech College of Engineering while hosting a 10-week GTMI Lunch and Learn Lecture Series each semester with high profile industry, government, and academic speakers to share advanced manufacturing knowledge within a global community. Dr. Brown also coordinates an annual 10-week Research Experience for Undergraduates (REU) summer program called REVAMP (Research Experiences for student Veterans in Advanced Manufacturing and entrePreneurship) sponsored by the National Science Foundation that maintains target demographics of 50% student veterans and 40% underrepresented minorities with STEM majors. Dr. Brown has strong expertise in several technical areas including electrochemical biosensors, nanomaterial synthesis and characterization, thin-film additive manufacturing, and electrochemical energy storage. Dr. Brown has over 20 peer-reviewed publications and is a regular reviewer of high impact factor peer reviewed journals. He earned his B.S. and Ph.D. degrees in Electrical Engineering from NC State University and Duke University, respectively.

Nathan J. Castro, Ph.D.
Co-founder
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Dr. Nathan J. Castro is an experienced biomedical researcher and entrepreneur. He has assisted in the design, testing, regulatory approval and clinical translation of 3D printed medical devices, as well as co-founded Nanochon, Inc. He is skilled in policy analysis, life sciences, data analysis, and quantitative research with particular interest in clinical translational (bench-to-bedside).

Jennifer H. Elisseeff, Ph.D.
Morton Goldberg Professor
Director of the Translational Tissue Engineering Center
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Dr. Elisseeff is the Morton Goldberg Professor and Director of the Translational Tissue Engineering Center at Johns Hopkins Department of Biomedical Engineering and the Wilmer Eye Institute with appointments in Chemical and Biological Engineering, Materials Science and Orthopedic Surgery. She was elected a Fellow of the American Institute of Medical and Biological Engineering, the National Academy of Inventors, a Young Global Leader by World Economic Forum. In 2018, she was elected to the National Academy of Engineering and National Academy of Medicine and in 2019 she received the NIH Directors Pioneer Award. In 2022, she was elected a fellow of the American Association of Arts and Sciences.

Jennifer received a bachelor's degree in chemistry from Carnegie Mellon University and a PhD in Medical Engineering from the Harvard–MIT Division of Health Sciences and Technology. Later she was a Fellow at the National Institute of General Medical Sciences, Pharmacology Research Associate Program, where she worked in the National Institute of Dental and Craniofacial Research. She is committed to the translation of regenerative biomaterials and has founded several companies and participates in several industry advisory boards including appointment by the governor to the State of Maryland's Technology Development Corporation. Dr. Elisseeff's laboratory has developed technologies licensed to startups, small and large companies. Lab-grown products have reached clinical testing as drugs, biologics, and devices in orthopedics, plastic and reconstructive surgery and lab is now running a Phase 2 clinical trial. She has served on an FDA panel and presented products to the FDA.

Jennifer's initial research efforts focused on the development of biomaterials for studying stem cells and designing regenerative medicine technologies for application in orthopedics, plastic and reconstructive surgery, and ophthalmology. Clinical results revealed the importance of the immune response in the biomaterial and regenerative medicine responses. This led to a significant shift in research efforts to biomaterials-directed regenerative immunology and leveraging the adaptive immune system to promote tissue repair. The group is now characterizing the immune and stromal environments of healing versus non-healing wounds and tumors. Biomaterials are now being applied to model and manipulate tissue environments and studying the impact of systemic and environmental factors such as aging and senescent cells, sex differences, and infection/microbiome changes on tissue homeostasis and repair. She has extensively published and lectured nationally and internationally on these topics.

Manufacturing complex biologics for regenerative medicine

Abstract: Tissue repair is a coordinated process that includes multiple immune and stromal cells working in concert to remove damage and rebuild matrix. Therapies that target multiple cell types and pathways in the repair process, and combination therapies, will likely be most effective in rebuilding tissue. Complex products such as biological scaffolds derived from the extracellular matrix (ECM) of tissues contain many components that can more broadly target the network of cells that promote wound healing. New regenerative immunotherapies derived from helminth soluble egg antigens contain a multitude of proteins and lipids that together stimulate tissue repair. Without a single agent mechanism of action, these complex products can be difficult to characterize with
respect to variability in batch-to-batch composition and biological activity. This presentation will discuss regenerative immunotherapies with complex composition and methods for screening efficacy and product development.

Adam Feinberg, Ph.D.
Co-Founder and Chief Technology Officer
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Dr. Adam Feinberg is Co-Founder and CTO of FluidForm Inc, a start-up company commercializing FRESH 3D bioprinting technology, and a Professor at Carnegie Mellon University in the departments of Biomedical Engineering and Materials Science & Engineering. He earned his BS in Materials Science & Engineering from Cornell University in 1999 with Co-op experience at Abiomed, Inc., working on total artificial hearts. He then earned his PhD in Biomedical Engineering from the University of Florida, focused on engineering cell-material interactions to prevent and enhance adhesion. This was followed by postdoctoral training at Harvard University, developing new biomaterials and stem cell-based cardiac tissue engineering strategies.
Dr. Feinberg has co-authored over 50 peer-reviewed publications, holds over 20 US patents and patent applications, and has received multiple honors including the NSF CAREER Award, the NIH Director's New Innovator Award, and Fellow of the American Institute for Medical and Biological Engineering. A primary research focus is engineering extracellular matrix (ECM) protein scaffolds using advanced biomanufacturing and 3D bioprinting approaches for multiple applications including cancer models, regenerative scaffolds, skeletal muscle, and cardiac muscle tissue engineering. At FluidForm, he is driving the commercialization of the FRESH 3D bioprinting platform for a wide range of applications in the pharma, medical device, and regenerative medicine industries.

In situ volumetric imaging and analysis of 3D bioprinted constructs using optical coherence tomography

Abstract: As 3D bioprinting has grown as a fabrication technology, so too has the need for improved analytical methods to characterize engineered constructs. This is especially challenging for engineered tissues composed of hydrogels and cells, as these materials readily deform when trying to assess print fidelity and other properties non-destructively. Establishing that the 3D architecture of the bioprinted construct matches its intended anatomic design is critical given the importance of structure-function relationships in most tissue types. I will present the development of a multimaterial bioprinting platform with integrated optical coherence tomography for in situ volumetric imaging, error detection, and 3D reconstruction. This enables quantitative 3D volumetric imaging with micron resolution over centimeter length scales, the ability to detect a range of print defect types within a 3D volume, and real-time imaging of the printing process at each print layer. These advances provide a comprehensive methodology for print quality assessment, paving the way toward the production and process control required for achieving regulatory approval and ultimately clinical translation of engineered tissues.

Marc Ferrer, Ph.D.
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Dr. Ferrer is the Director of the National Center for Advancing Translational Sciences (NCATS) 3D Tissue Bioprinting Laboratory, a multidisciplinary group with the goal of creating, validating, and using 3D bioengineered tissues for disease modeling and drug discovery and development. Previously, Marc was a Team Lead at the NIH Chemical Genomics Center working on the discovery of small molecule probes to study protein function. Before joining NIH, he was Director of Assay Development and High Throughput Screening at the Department of Automated Biotechnology at the Merck Research Laboratories. Marc received a BSc degree in Organic Chemistry from the University of Barcelona, and a Ph.D. degree in Biological Chemistry from the University of Minnesota.

Advancing Drug Discovery with Biofabricated 3D Tissue Models

Abstract: The NCATS 3D Tissue Bioprinting Laboratory (3DTBL) is a multidisciplinary laboratory with experts in bioengineering, assay development, HTS, automated biology and cell microscopy with the goal of creating a versatile and robust platform of biofabricated 3D tissue models for drug screening. We are assembling a portfolio of biofabricated normal and disease 3D tissue models that recapitulate faithfully the morphology, physiology and pathology of human tissues. These biofabricated 3D tissue models are produced in a multiwell-plate format with disease relevant phenotypic assays to quantitatively assess drug efficacy and toxicity. The expectation is that these physiologically relevant 3D tissue models will be clinically predictive cellular assays for drug discovery and development.

Leanne Friedrich, Ph.D.
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Dr. Leanne Friedrich (she/her) is a materials scientist at the National Institute of Standards and Technology working on embedded 3D printing of soft materials. Leanne earned a B.S. in materials science and engineering from Northwestern University in 2015. She earned a Ph.D. in materials from University of California Santa Barbara in 2020, developing methods to 3D print polymer matrix composites with controlled property gradients using direct ink writing with acoustophoresis. She joined NIST in 2020 as an NRC postdoc. Leanne's work focuses on developing guidelines for material selection and printing parameter selection in embedded 3D printing. By examining how the rheology of the ink, rheology of the support, and interfacial tension influence defects in printed structures, we can achieve more reliable prints with better shape fidelity, mechanical integrity, and functional properties. Leanne uses computational fluid dynamics simulations in OpenFOAM to study the underlying physics of the printing process, and she uses in-situ imaging experiments to measure defects in printed structures.

Lexi Garcia, M.S.
Director of Strategic Projects
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Lexi Garcia is the Director of Strategic Projects at the Advanced Regenerative Manufacturing Institute (ARMI) | BioFabUSA. As such she is responsible for coordinating and leading cross-functional teams to drive key project activities to help shape the long-term vision of the company. She leads ARMI | BioFabUSA's strategic standards initiatives, which includes guiding both ARMI members and other tissue engineered medical product (TEMP) subject matter experts through the standards development process, particularly those related to bioprinting. Lexi has a wide TEMP network and works to facilitate connections between key stakeholders throughout the tissue engineering community to enable partnerships that will propel the field forward. With degrees in Neuroscience from Middlebury College, and Conservation Biology and Sustainable Development from the University of Maryland, College Park (UMD) she has a unique systems perspective and approach to nurturing the tissue engineering ecosystem to garner consensus and improve collaborative efforts.

Jeffrey Halpern, Ph.D.
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Prof. Jeffrey M. Halpern (he/him) earned his PhD in Chemical Engineering in 2010 at Case Western Reserve University in Chemical Engineering. Halpern pursued a first postdoc (2011-2012) funded through an NIH NRSA fellowship at Case Western Reserve University in Biomedical Engineering and a second postdoc through Fulbright and Lady Davis Fellowships (2013-2014) in Israel at the Technion in the Department of Chemical Engineering. He joined the Department of Chemical Engineering at the University of New Hampshire. Recently, Halpern leads an NSF EPSCoR Track II (#2119237) team the development of "universal" biotechnology sensing platforms to enable the use of advanced manufacturing principles in biomanufacturing. As a collaboration across four states, NH, AL, ME, and WY, we aim to develop engineering principles to guide on-demand biosensor design covering the full assortment of sensor components: the recognition elements that bind analytes; the stimuli-responsive linkers that amplify the binding signal; the form factor of the sensor; and the final transduction of the signal. You can read more about our team here.

Dawn Henke, Ph.D.
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Dr. Dawn Henke has extensive experience in the advanced biological sciences and has played an active role in the regenerative medicine community throughout her career. Prior to joining SCB, she worked as a post-doctoral fellow at the National Institutes of Health, National Eye Institute performing stem cell research focused on developing retinal organoids from stem cells for testing and therapeutic purposes. She holds a PhD in Genetics and Genomic Sciences from the University of Alabama at Birmingham. As Senior Technical Program Manager, Dawn is the supervisor of the program manager team and acts as a liaison between the program managers and the executive director.

Alicia Henn, Ph.D., MBA
Chief Scientific Officer
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Alicia D. Henn PhD MBA is Chief Scientific Officer for BioSpherix, Ltd. Previously, Dr. Henn was an academic researcher in the cancer and immunology fields. Dr. Henn owns the In Vitro Reproducibility and Physiologic Cell Manufacturing groups on LinkedIn, promoting clonable, physiologically relevant cell environments for better scientific reproducibility and translatability.

Callie Higgins, Ph.D.
Materials Engineer, Co-Project Leader
National Institute of Standards and Technology
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Dr. Callie Higgins is the Co-Project Leader of the Photopolymer Additive Manufacturing (PAM) Project at the National Institute of Standards and Technology (NIST) in Boulder, CO and is an adjunct faculty at the Colorado School of Mines. Her work with Co-Project Leader, Jason Killgore, studying the fundamental properties of PAM systems was recently the sole awardee of one of the Federal Government's highest honors, the Samuel J. Heyman Service to America Medal (SAMMIES) for Emerging Leaders. She graduated with her PhD from CU Boulder's Department of Electrical Engineering with specialties in optics and material science where she characterized the fundamental properties of photopatterned hydrogels for use in regenerative medicine. Outside of the lab, she loves to adventure around the mountains; skiing, hiking, and picnicking the whole way up with her husband, friends, and family.

James (Jay) Hoying, Ph.D.
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Dr. James (Jay) Hoying is a Partner and Chief Scientist at Advanced Solutions Life Sciences with more than 30 years of experience in basic and applied biological sciences with a focus in tissue biology, tissue vascularization, and tissue fabrication. Prior to joining ASLS, he was Professor and Chief of the Division of Cardiovascular Therapeutics at the Cardiovascular Innovation Institute (CII) where he developed a broad background in tissue fabrication, cell therapeutics, and translation of discoveries to industry and the clinic. Dr. Hoying is an inventor of the AngiomicsTM microvessel technology and holds numerous patents related to vascularizing tissues and related cell-based therapies. Dr. Hoying received his BA and MS degrees in Biology and Molecular Biology from Case Western Reserve University and his PhD in Cardiovascular Physiology, with an emphasis on the microcirculation, from the University of Arizona. Following degree work, Dr. Hoying served as a New Investigator in the National Institutes of Health Program of Excellence in Molecular Biology of the Heart and Lung (POEMB). He currently serves on the Editorial staff of national scientific journals and reviews for individual and program grant proposals for the National Institutes of Health, the Veterans Affairs, the American Heart Association, and international funding agencies. Dr. Hoying is also a Fellow of the American Heart Association.

John Huang, Ph.D.
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Dr. John Huang is an inventor and entrepreneur in advanced biomedicine and bioengineering with a number of patented technologies. He is actively involved in product development and commercialization with great enthusiasm for novel biotechnologies and their influences on the life science industry. John is the founder and CEO of TheWell Bioscience, Inc., a pioneer in the 3D biomimicking platform for precision medicine, cell therapy, and biomanufacturing. The company uses its state-of-art biomatrix system to closely mimic the natural extracellular matrix of the human microenvironment and establish a robust 3D cell culture platform and smart delivery system to advance drug discovery, tissue engineering, cell therapy, and personalized medicine. The company received multiple awards, including Most Innovative 3D Hydrogel System in 2020 Healthcare & Pharmaceutical Awards, Listed as #1 of 8 Top 3D Bioprinting Startups Impacting The Biotechnology Industry, and Leading Innovators in Cell Therapy Research 2021 Healthcare & Pharmaceutical Awards. John served as an editorial board member and ad-hoc reviewer of 11 academic journals. He is the recipient of the Anheuser-Bush fellowship, the research foundation award, and 22 new ingenuity awards.

Taneka Jones, Ph.D.
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Dr. Taneka Jones is a visionary and inventor. Inspired by her ancestors, education is highly valued. She received a Ph.D. and a Master of Science Degree in Bioengineering from the University of Illinois-Chicago. Additionally, she holds a M.A in Teaching and earned a B.S. in Biological Sciences with a minor in Chemistry.

Dr. Jones served as a licensed professional educator with Chicago Public Schools while completing her graduate studies, and credits her continued success to her faith, which is her guidepost. In her current role as a Medical Science Liaison, she interfaces between academia and industry for an FDA-approved cell therapy product. A rising entrepreneur, her research consulting company Biopraise seeks to educate, motivate, and empower students, educators, administrators, and biotechnology stakeholders. She has designed and implemented three entry-level programs in the science, technology, engineering, and mathematics (STEM) fields to enhance and empower youth in disadvantaged areas to reach this goal. Her five favorite hobbies include international travel, outdoor adventures, middle- and long-distance running, watching documentaries and enjoying a great cup of coffee.

Mrignayani Kotecha, Ph.D.
President
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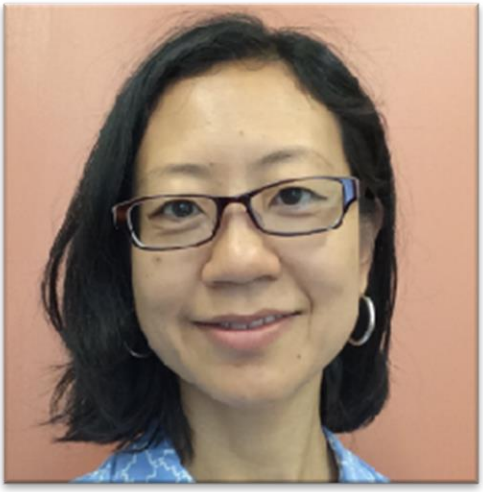
Dr. Mrignayani Kotecha is a founding member and the president of Chicago-based biotech company O2M Technologies, LLC. In this role, Dr. Kotecha provides guidance and leadership for developing the world's first EPR oxygen imaging preclinical and clinical instruments, accessories, synthesis of oxygen-sensitive spin-probes, scientific research, fundraising, and outreach. She leads the "Oxygen Measurement Core" research facility at O2M that performs cutting-edge research involving oxygen imaging in cancer and regenerative medicine. Dr. Kotecha holds a Ph.D. in Physics from Jabalpur University, India and has over 25 years of experience in magnetic resonance technologies. She has published over fifty peer-reviewed articles and is the lead editor of the 2017 Wiley book "Magnetic Resonance Imaging in Tissue Engineering".

Nondestructive Cell Viability Assessment Using Oxygen Imaging

Abstract: Cell viability is an essential parameter for cell therapy, tissue engineering, drug screening, and many other biological processes and products. These products rely on viable, healthy, and functional cells to work as intended for solving various medical conditions, such as cancer, type I diabetes, arthritis, liver, kidney, bone damage, neurodegenerative, cardiovascular damage, etc. However, current methods that rely on assays to measure cell viability are destructive and inadequate for three-dimensional tissues. Besides, these methods do not assess cell functionality, a key parameter for cell therapy and tissue engineering medical products. In addition, these methods have not been tested for their interference with biomaterials commonly used in the field, therefore, may provide an inaccurate assessment when used with artificial tissue grafts involving scaffolds. Electron paramagnetic resonance oxygen imaging (EPROI) is a noninvasive oxygen mapping method with high precision and absolute accuracy. Similar to nuclear magnetic resonance imaging (MRI), EPRI uses magnetic field gradients to generate the spatial distribution of electron spins. In contrast to conventional MRI, EPRI relies on a much smaller magnetic field (in the milli Tesla range), generated by cryogen-free magnets and gradients that do not change during signal detection. EPROI uses the linear relationship between electron spin-lattice relaxation rate and partial oxygen pressure (pO2) of an injectable non-toxic soluble contrast agent, trityl OX071, for obtaining oxygen maps in tissues. We have developed the world's first dedicated 25 mT preclinical EPROI instrument JIVA-25™, which operates at 720 MHz radiofrequency.
I will present the concept and data showing how EPROI can be used for noninvasive cell viability assessment and why it is superior to current methods of cell viability measurements. This is the first demonstration of noninvasive cell viability assessment in a three-dimensional system without destroying the cells or scaffold. The method can be extended to perform cell viability and functionality assessment for all tissue engineering medical products of any size and dimensions.



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Dr. Sheng Lin-Gibson is the Chief of the NIST Biosystems and Biomaterials Division. She oversees a multidisciplinary research portfolio that includes regenerative medicine and advanced therapies, precision medicine, synthetic biology, and complex microbial systems. She leads and coordinates the development of global standards for emerging biotechnology, many of which support regenerative medicine and advanced therapy. She has coauthored over 80 peer-reviewed publications, serves on many Interagency Working Groups as well as numerous expert review panels and advisory boards. She has received two Department of Commerce Gold Medals.

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Dr. Mary Clare McCorry is the Director for Technology and Process Development at the Advanced Regenerative Manufacturing Institute (ARMI). At ARMI, Dr. McCorry is advising the development of several scalable, modular, automated and closed tissue manufacturing production lines as well as leading the development of novel manufacturing technologies. As part of her role, Dr. McCorry is responsible for directing Institute funded technical projects and strategic partnerships to advance manufacturing technologies in cell, tissue, and organ engineering. Prior to joining ARMI, she was an American Institute for Medical and Biological Engineering (AIMBE) Scholar at the U.S. Food and Drug Administration in the Center for Devices and Radiological Health (CDRH). As an AIMBE Scholar, she led science policy initiatives and coordinated collaborations between experts in academia, industry, government and non-profit organizations. Mary Clare joined FDA from Cornell University where she designed cell-based assays to study biomechanical/chemical mechanisms of action of cells in tissue engineered constructs. She also consulted for industry on the design of specialized single use tissue bioreactors. Mary Clare received her Ph.D. from Cornell University and her BS in Biomedical Engineering from Worcester Polytechnic Institute.

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Richard McFarland is an immunopathologist and the Chief Regulatory Officer at the Advanced Regenerative Manufacturing Institute (ARMI) where he over the regulatory affairs for ARMI and its BioFabUSA program. Dr. McFarland is also a Principal Consultant at BioFabConsulting where he consults with members on product classification, regulatory strategy, and CMC, preclinical and clinical studies. Prior to joining ARMI as its first post-award hire in 2017, Dr. McFarland was Associate Director for Policy (ADP) of the Office of Tissues and Advanced Therapies (and its predecessor office) at the Food and Drug Administration's Center for Biologics Evaluation and Research (FDA/CBER) for eleven years after six years a reviewer in FDA/CBER. In addition he, served on the federal government's interagency for tissue engineering and regenerative medicine, the Multi-agency Tissue Engineering Sciences group (MATES) for fifteen years, including five years as its Chair. Dr. McFarland received his undergraduate, graduate, and medical school training at the University of North Carolina-Chapel and his post-graduate medical specialty training in anatomic/clinical pathology and subspeciality training in immunopathology at University of Texas Southwestern Medical Center in Dallas.

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As the founder of ChromoLogic, Dr. Menon is passionate about developing novel biomedical solutions that not only lead to superior patient outcomes but also ensure that the solutions are cost effective and affordable. He received his PhD in Physics from Purdue University with an emphasis in sensor fabrication, instrumentation and novel data analytic methods that were applied at multiple national and international laboratories towards fundamental physics discoveries. His early career was spent at Corning Incorporated and Northrop Grumman Mission Systems where he was groomed for leadership positions in multiple businesses.

Founded in 2007, ChromoLogic is a boutique product focused innovation center developing solutions that save lives and make the world secure. The Biomedical Solutions division develops point of care solutions with the goal of delivering best health outcomes at the lowest cost. Their capabilities span four key verticals: Wound Care and Infectious Disease, Diagnostics/Screening, Drug Delivery, and Telehealth. Their customers and collaborators include medical manufacturers, academic institutions, government agencies, and care providers. To meet the needs of this broad customer and market base, they bring together the brightest minds from every engineering and science discipline and form collaborations across academia and industry. Since 2019, ChromoLogic has made significant investments in cell therapy, in terms of therapeutics as well as instrumentation. Their current programs include a novel genetically modified bacteria that delivers cytokines to manage side effects from cancer treatment and an optical system that can non-invasively monitor cell growth, concentration & viability within bioreactors in real-time.

Non-invasive non-contact real-time monitoring of cells within bio-reactors by direct imaging with optical coherence tomography

Abstract: We have developed OCTiCell for monitoring cell growth in suspended agitated bioreactors based on optical coherence tomography. OCTiCell is an in-line, completely non-invasive instrument that can operate on any suspended-cell bioreactor with a window or transparent wall. In traditional optical coherence tomography, the imaging beam is rastered over the sample to form a three-dimensional image. OCTiCell, instead uses a fixed imaging beam and takes advantage of the motion of the media to move the cells across the interrogating optical beam.

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Dr. Bao-Ngoc Nguyen is a Biomedical Engineer in the Tissue Engineering Branch (TEB) of the Division of Cellular and Gene Therapies (DCGT) in the Office of Tissues and Advanced Therapies (OTAT)/Center for Biologics Evaluation and Research (CBER). She conducts regulatory review of cellular therapies, tissue engineered products, and devices regulated in OTAT, focusing on the chemistry, manufacturing, and controls of these products. Dr. Nguyen earned her B.S. and Ph.D. in Bioengineering at the University of Maryland, College Park.

Characterization of Tissue Engineered Medical Products

Abstract: Tissue engineered medical products (TEMPs) are complex and require assessment of the cells, scaffold, and final cell-scaffold product. Depending on the TEMP, final product release testing may require use of parts or entire final products. When only parts of the final product or surrogate products are used, sufficient supporting data may be necessary to demonstrate that they adequately represent the clinical product. Early consideration of final product release testing methods is critical in supporting the safety and effectiveness of TEMPs.

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Dr. Kirsten Parratt is a Biomedical Engineer in the Biosystems and Biomaterials Division at the National Institute of Standards and Technology (NIST). Currently, she develops flow cytometry experimental and computational methods to characterize live, whole cell, microbial materials. This work supports biomanufacturing stakeholders, for example, those interested in Live Biotherapeutic Products and Rapid Microbial Testing Methods for advanced therapy products. Kirsten obtained her BSE in Chemical Engineering from Princeton University. She obtained her MS in Materials Science and Engineering, and PhD in Bioengineering from the Georgia Institute of Technology, where her graduate dissertation was related to stem cell biomanufacturing and tissue engineering.

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Marian S. Piekarczyk is a Senior Regenerative Medicine Technical Specialist with Thermo Fisher Scientific within their Life Sciences Division. Her background is in stem cell science and biology and immunology. Marian currently leads business development for cell therapy and translational medicine applications in the central Midwest region of the United States. Her career spans over 30 years in academic research, small biotech, and industry related research, technical, and commercial operations.

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Laura Pierce is a Biomedical Engineer in the Biomaterials Group at the National Institute of Standards and Technology. She is responsible for technical planning and conducting studies to support measurement capabilities and assurance for cell therapy products. In that capacity, she routinely performs cell counting measurements on a variety of lab instrumentation typically used in the Regenerative Medicine field, and she supports analysis and dissection of data with collaborators to define the points in their experimental workflow which introduce measurement error and uncertainty and offers recommendations to improve precision and robustness of measurements. Laura has supported the development of the Cell Counting Part II ISO standard and COMET application for comparison of cell counting methods, and is currently involved in the development of a draft Cell Viability consensus standard through the International Standards Organization.

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Dr. Potter joined the Office of Research and Development at the Department of Veterans Affairs in 2011, where she is the Scientific Portfolio Manager of Surgery, Trauma, and Restorative Medicine. She currently serves as the VA representative on the Forum for Regenerative Medicine at the National Academies of Sciences, Engineering, and Medicine, the Armed Forces Institute of Regenerative Medicine Oversight Committee, and CDMRP's Programmatic panel for the Reconstructive Transplantation Research Program. She received her undergraduate degree in Engineering Chemistry from Queen's University in Canada and her Ph.D. from Cambridge University in England. She joined the National Institutes of Health as a visiting scientist and she spent 10 years at the Armed Forces Institute of Pathology as the Technical Director of the Magnetic Resonance Microscopy Facility where she applied non-invasive imaging techniques to the study of forensic, pathologic, and engineered tissues. Dr. Potter credits her training in Chemical Engineering, Chemistry, Medical Imaging, and Tissue Engineering as the ideal framework to support the translation of biofabrication solutions to the operating room.

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Dr. Namro Redwan holds a PhD degree in Chemistry with emphasis on Medicinal/Organic Chemistry from the University of Gothenburg. She obtained her Postdoctoral training in Chemical Biology at the Gladstone Institutes in San Francisco. She was an Assistant Professor at the Clinical Chemistry and Transfusion Medicine at the University of Gotehnburg prior to joining CELLINK as a Senior Principal Scientist/Scientific Officer. Today, Itedale is the Chief Scientific Officer, currently leading the Science and Applications team in the R&D department at CELLINK.
CELLINK is the world leading Bioprinting company and Itedale´s team has commercialized 45+ bioinks and published 15+ application notes in the field of Biofabrication.

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Eugenia (Jane) Romantseva is a staff engineer supporting the Cellular Engineering Group at the National Institute of Standards and Technology (NIST). Jane leads NIST's efforts to develop measurement assurance and tools towards improving reproducibility in cell-free expression. Jane is also part of the collaborative effort to leverage automation, specifically the NIST Living Measurement Systems Foundry, for high throughput measurements to advance genetic sensor engineering and address challenges in scalability for engineering with living measurement systems. Jane received a B.S. in Mechanical Engineering from Boston University and a M.S. in Material Science and Engineering from Johns Hopkins University.

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Dr. Jonathan Seppala leads the Polymer Additive Manufacturing and Rheology Project, developing multi-modal and in situ measurements that enable control over the complex non-equilibrium material dynamics that characterize soft matter processing. His current research uses infrared thermography, rheology, polarized light, fracture mechanics, and neutron and x-ray reflectivity and scattering to study the polymer physics of thermoplastic additive manufacturing processes. Jonathan earned a B.S. in Chemical Engineering from Michigan Technological University and a Ph.D. in Chemical Engineering from Michigan State University studying the rheology and thermodynamics of polymer nanocomposites. Following his Ph.D., Jonathan worked as a Postdoctoral Researcher studying thin film self-assembly of block copolymers and equilibrium dynamics of amphiphilic micelles at the University of Delaware. Before joining the Additive Manufacturing and Rheology Project, Jonathan studied ballistic witness materials and shear thickening fluids as part of NIST's Personal Body Armor Project.

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Dr. Shirwaiker is a Professor and Pleasant Faculty Scholar of Industrial & Systems Engineering and Associate Director of the Comparative Medicine Institute at NC State University. His research program focuses on the development and optimization of manufacturing processes and quality monitoring techniques to create and assess engineered tissues for a variety of biomedical and cellular agriculture applications. His research has been supported by the NSF, NIH, DOD, and the industry. Shirwaiker is a recipient of the NSF CAREER Award, SME Outstanding Young Manufacturing Engineer Award, and IISE Manufacturing & Design Outstanding Young Investigator Award. He currently serves on different boards and committees of IISE, SME, ASME, and ASTM.

Dielectric spectroscopy for in line monitoring of engineered tissue constructs

Abstract: This talk will highlight the application of dielectric spectroscopy, which leverages the responses of living cells to alternating electric fields, for the monitoring of engineered tissue constructs. Examples of mapping of dielectric parameters to critical quality attributes of constructs under scenarios ranging from static culture of cell-seeded scaffolds to perfusion bioreactor-based maturation of bioprinted constructs will be presented. Application of machine learning for more effective dielectric data analysis and decision-making will also be discussed.

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Dr. Simon is a biologist in the Biomaterials Group at the National Institute of Standards & Technology. He leads projects on characterization of tissue engineered medical products, cell-material interactions and tissue engineering scaffolds. Dr. Simon is active in the Society for Biomaterials and is Chair of ASTM Committee F04.43 "Cells and Tissue-Engineered Constructs" where documentary standards are being advanced to support the development of medical products.

Optical Coherence Tomography Imaging for Label-Free Measurement of Cell Viability in Scaffolds

Abstract: In the field of tissue engineering, 3D scaffolds and cells are often combined to yield constructs that are used as therapeutics to restore tissue function in patients. Viable cells may be required to achieve the intended mechanism of action for the therapy, where the live cells may build new tissue or may release factors that induce tissue regeneration. Thus, there is a need to reliably measure cell viability in 3D scaffolds as a quality attribute of a tissue-engineered medical product. Here, we developed a label-free, 3D optical coherence tomography (OCT) method to image large sample volumes (1 mm^3) to quantitatively assess cell viability and distribution within scaffolds. OCT imaging was used to assess a model scaffold-cell system consisting of a polysaccharide-based hydrogel seeded with human Jurkat cells. Four test systems were used: i) hydrogel seeded with live cells, ii-iii)hydrogel seeded with heat-shocked or fixed dead cells and iv) hydrogel without any cells. OCT images revealed time-dependent changes in the refractive index (RI) within live cells that were due to intracellular movement of organelles (referred to as speckling patterns). The time-dependent changes in RI (speckle patterns) were not observed for hydrogels without cells or with hydrogels loaded with dead cells. The changes in speckle patterns were used to generate live-cell contrast by image subtraction where objects with large changes in RI were binned as live cells. When using 3D OCT imaging to count live cells within a gel volume, the results were within 13% of the expected value derived from the number of live cells that were seeded into the gels. Additionally, the 3D distribution of live cells was mapped within a hydrogel scaffold to assess the uniformity of their distribution across the volume. These results demonstrate a label-free method to assess the spatial distribution of live cells within a 3D scaffold that may be useful for assessing tissue-engineered medical products.

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Kaiming Ye is a SUNY Distinguished Professor, Chair of the BME Department, and Director, Center of Biomanufacturing for Regenerative Medicine at Binghamton University, SUNY. He is Fellow of BMES and AIMBE. He is past Chair of the Council of Chairs of Biomedical Engineering and a funding Chair of BMES Advanced Biomanufacturing SIG (ABioM-SIG). He has contributed significantly to national policy-making in science and engineering. During his tenure at NSF, he directed a biomedical engineering program. He was a member of the Interagency Workgroup for Neuroscience, Interagency Modeling and Analysis Workgroup, and Multiagency Tissue Engineering and Regenerative Medicine Workgroup. He served on NIH/NIDDK Rebuilding Kidney Consortium's Advisory Committee. Ye pioneered human islet organoid development from pluripotent stem cells (PSCs). His group is the first one demonstrated the feasibility of generating the whole human islets from PSCs. His work in 3D tissue bioprinting was featured in Prism in 2015. He is one of the pioneers in developing fluorescence resonance energy transfer nanosensors for continuous glucose monitoring. As a researcher, he has secured more than $43 million grants as PI or co-PI. He has published more than 100 research articles, book chapters, and reports. He has chaired and co-chaired more than 18 international and national conferences and delivered more than 150 keynote/plenary/invited speeches in international and national conferences and graduate seminars in more than 100 universities.