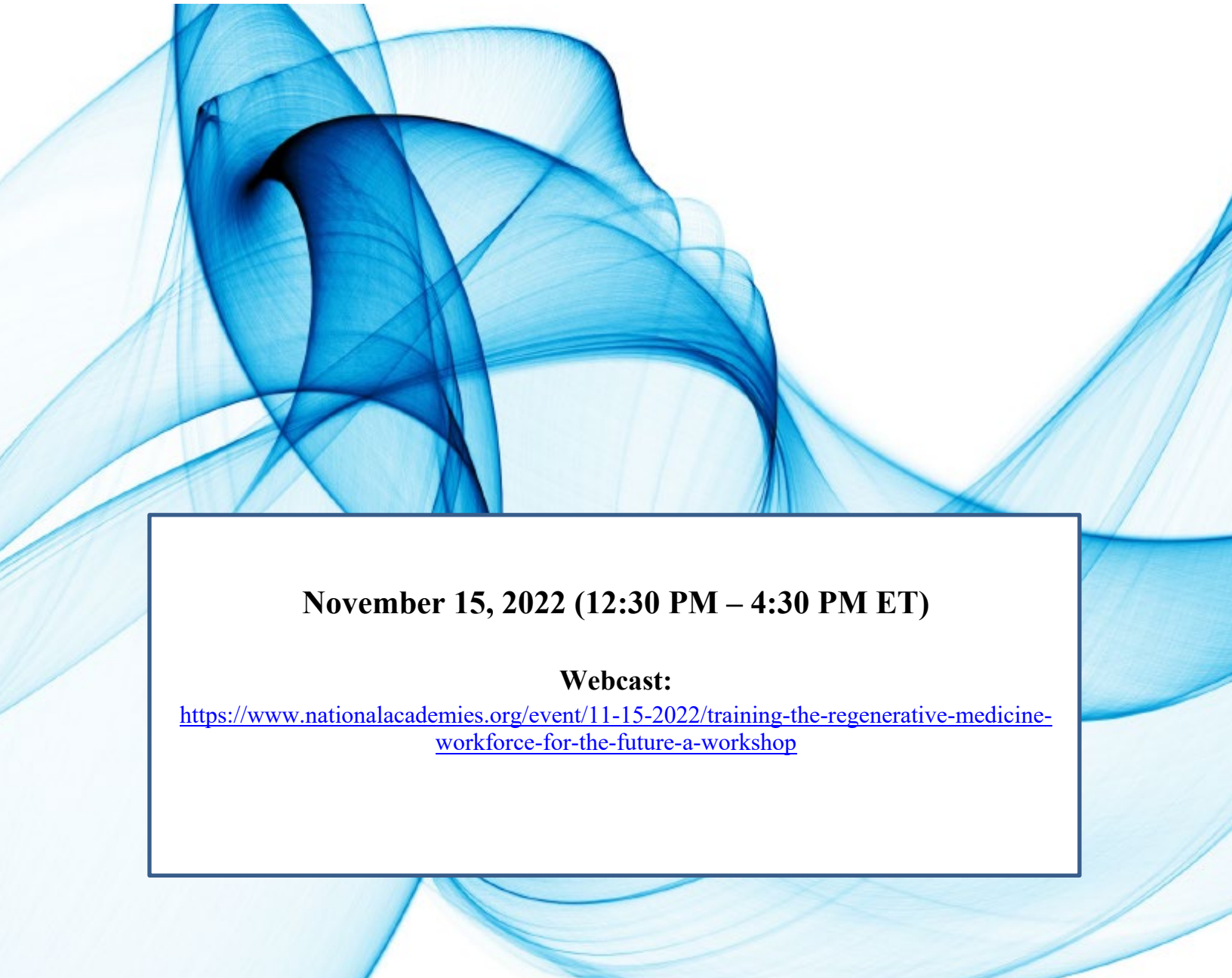
NATIONAL ACADEMIES Sciences Engineering Medicine

Board on Health Sciences Policy

Forum on Regenerative Medicine

Training the Regenerative Medicine Workforce for the Future: A Workshop



November 15, 2022 (12:30 PM – 4:30 PM ET)

Webcast:
https://www.nationalacademies.org/event/11-15-2022/training-the-regenerative-medicine-workforce-for-the-future-a-workshop

NATIONAL ACADEMIES Sciences Engineering Medicine

Board on Health Sciences Policy

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Training the Regenerative Medicine Workforce for the Future: A Workshop
November 15, 2022

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AGENDA

Training the Regenerative Medicine Workforce for the Future: A Workshop

November 15, 2022: 12:30 PM – 4:30 PM

Virtual Workshop

STATEMENT OF TASK

A planning committee of the National Academies of Science, Engineering, and Medicine will organize a public workshop to explore how the changing landscape and increasingly interdisciplinary nature of regenerative medicine creates unique workforce demands for the field and how these needs may be met through professional development and education.

Workshop presentations and discussions may address the following topics:
- professional development and educational interests of current trainees in regenerative medicine
- unmet needs for a skilled technical workforce in regenerative medicine
- incentives and disincentives for expanding the workforce and retaining skilled individuals in the field
- issues related to current lack of workforce diversity and improving diversity
- ongoing work and possible next steps by universities, professional societies, or other stakeholders to support workforce development in regenerative medicine

The planning committee will organize the workshop, select and invite speakers, and moderate discussions. Proceedings of the workshop—in brief will be prepared by a designated rapporteur in accordance with institutional guidelines.

Please join us via webcast: https://www.nationalacademies.org/event/11-15-2022/training-the-regenerative-medicine-workforce-for-the-future-a-workshop

Opening Remarks

12:30 PM ET

Welcoming Remarks

Tim Coetzee, *Forum Co-Chair*
Chief Advocacy, Services, and Science Officer
National Multiple Sclerosis Society

Katherine Tsokas, *Forum Co-Chair*
Vice President
Regulatory, Quality, Risk Management and Drug Safety
Janssen Inc. Canada

12:40 PM

Introduction and Charge to the Workshop Speakers and Participants

Patrick Hanley, *Workshop Planning Committee Co-Chair*
Chief & Director, Cellular Therapy Program
Children's National Hospital
Associate Professor of Pediatrics
The George Washington University

Krishanu Saha, *Workshop Planning Committee Co-Chair*
Associate Professor of Biomedical Engineering
Retina Research Foundation Kathryn and Latimer Murfee Chair
University of Wisconsin-Madison

SESSION I: Systems-Level Gaps and Solutions in Workforce Development in the Regenerative Medicine Ecosystem

Moderator: Jack Mosher, Scientific Advisor, International Society for Stem Cell Research

Session Objectives:

- Explore systems-level gaps and solutions to better address workforce development in regenerative medicine
- Discuss skillsets needed across different sectors of regenerative medicine
- Explore incentives for expanding the workforce, including improving diversity and inclusion

12:50 PM **Initial Remarks (10 minutes each)**

Robert Deans
Chief Scientific Officer
Synthego

Linnea Fletcher
Department Chair, Biotechnology
Austin Community College

Barry Bates
Bioscience Program Coordinator
Atlanta Technical College

Brigid Hogan
Professor, Department of Cell Biology and Development and Stem Cell Biology Program
Duke Medical School

Meagan Pasternak
Senior Manager, Workforce Training and Regional Development
International Society for Cell & Gene Therapy

J. Kaitlin Morrison
Assistant Professor of Medicine
Executive Director, LCCC Clinical Research
UNC Lineberger Comprehensive Cancer Center
University of North Carolina School of Medicine

2:05 PM **Panel Discussion**

2:45 PM **Break**

SESSION II: Early Career Perspectives on Opportunities in Regenerative Medicine

Co-Moderators: Kaivalya Molugu, Scientist, Editas Medicine & Clinton Smith, Graduate Research Assistant, University of Florida

Session Objectives:

- Learn about training experiences that have been influential in the professional development of early-career individuals

- Discuss gaps in expertise or support that individuals experience at key junctures early in their careers
- Explore solutions to career-related challenges that may encourage and inspire other students

3:00 PM **Initial Remarks (5 minutes each)**

Maryam Pasdar
Cellular Therapy Laboratory Associate
Children's National Hospital

Elana Cooper
PhD Candidate in Biomedical Engineering
Georgia Institute of Technology
Mentoring Chair, North America Regional Executive Board
International Society for Cell & Gene Therapy

Xinh-Xinh Nguyen
Translational Science Interagency Fellow
National Center for Advancing Translational Science
National Institutes of Health

Nisha Iyer
Assistant Professor
Tufts University

Evan Graham
Applications Consulting Scientist
Biosero
Chair, Early Career Scientist Committee
International Society for Stem Cell Research

3:35 PM **Panel Discussion**

4:15 PM **Reflections from the Workshop and Final Comments**
Patrick Hanley, *Workshop Planning Committee Co-Chair*
Chief & Director, Cellular Therapy Program
Children's National Hospital
Associate Professor of Pediatrics
The George Washington University

Krishanu Saha, *Workshop Planning Committee Co-Chair*
Associate Professor of Biomedical Engineering
Retina Research Foundation Kathryn and Latimer Murfee Chair
University of Wisconsin-Madison

4:30 PM **Adjourn Workshop**

FORUM INFORMATION

NATIONAL ACADEMIES Sciences Engineering Medicine

Forum on Regenerative Medicine

The National Academies of Sciences, Engineering, and Medicine's Forum on Regenerative Medicine provides a convening mechanism for interested parties from academia, industry, government, patient and provider organizations, regulators, foundations, and others to meet and discuss sensitive and difficult issues in a neutral setting in order to engage in dialogue and discussions that address the challenges facing the application of, and the opportunities for, regenerative medicine to improve health through the development of effective new therapies. The Forum identifies existing and potential barriers to scientific and therapeutic advances; identifies and discusses opportunities to assist in facilitating more effective partnerships among key stakeholders; examines the impact that current policies have on the discovery, development, and translation of regenerative medicine therapies; examines the unique challenges of identifying, validating, and bringing regenerative medicine applications to market; and explores the ethical, legal, and social issues posed by regenerative medicine advances.

Regenerative medicine holds the potential to create living, functional tissues which can be used to repair or replace those that have suffered irreparable damage due to disease, age, traumatic injury, or congenital defects. Whether through tissue-engineering, synthetic constructs, or cellular therapies, the field holds the promise of providing relief to those suffering from traumatic injuries to neurodegenerative diseases. However, the enormous potential health and economic benefits this relatively new field could potentiate upon society must be balanced by the enactment of the proper policies and procedures to assure these therapies are safe and effective for use.

There are a number of key issues that must be explored and illuminated in order to realize the full potential of regenerative medicine. Ethical, legal, and social issues pose potential challenges with much debate still taking place around the use of adult, embryonic, and induced pluripotent stem cells for research and therapy. Additionally, many prospective advances, while developed for disease treatment, have the potential to be used for enhancement of physical attributes or anti-aging therapy. There is also a concern about possible unanticipated consequences of these treatments and products and the potential for stockpiling of and unequal access to organs. Ensuring the ethical application of regenerative medicine advances will be critical to not only progress the field but also to improve the health of individuals and the public.

Scientific and technical hurdles also exist for which a better fundamental understanding of the underlying cell biology is necessary. This knowledge will allow for more specific engineering of tissues and organs and will diminish the chance of transplant rejection by ensuring biocompatibility with the host tissue. Similarly, it is necessary to understand the cellular response to biomaterials and scaffolds to ensure that the desired biological function is developed and retained. While great advances have been realized to date, to take full advantage of regenerative medicine, the barriers to scientific advance will need to be delineated and potential solutions discussed.

Guidelines for the safe and proper use of regenerative medicine advances will need to be developed, translational barriers identified, and the regulatory environment clearly defined. Commercial aspects will need to be addressed including: the development of cost-effectiveness strategies for growing cells and organs at an industrial capacity; assessments of effectiveness, quality, and biosafety developed; and products certified. Greater dialogue and coordination of efforts between the public and private sectors will enable regenerative medicine products to be brought to market in a safe, effective, and swift manner.

Forum sponsors include federal agencies, medical and scientific associations, foundations, research organizations, patient groups, and industry representatives. For more information about the Forum on Regenerative Medicine, please visit our website at nas.edu/RegenMedForum or contact Sarah Beachy at 202-334-2217, or by email at sbeachy@nas.edu.

NATIONAL ACADEMIES *Sciences Engineering Medicine*

Forum on Regenerative Medicine

Membership

Co-Chairs: Timothy Coetzee, Ph.D., National MS Society
Katherine Tsokas, J.D., Janssen Inc. Canada

Rena D'Souza, DDS, M.D., Ph.D., National Institute of Dental and Craniofacial Research

Larry Goldstein, Ph.D., Sanford Consortium for Regenerative Medicine; UCSD School of Medicine

Thomas Greenwell, Ph.D., National Eye Institute

Candace Kerr, Ph.D., National Institute of Aging

Cato T. Laurencin, M.D., Ph.D., The Connecticut Convergence Institute for Translation in Regenerative Engineering; The University of Connecticut

Timothy LaVaute, Ph.D., National Institute of Neurological Disorders and Stroke

Michael May, Ph.D., Centre for Commercialization of Regenerative Medicine

Richard McFarland, Ph.D., M.D., Advanced Regenerative Manufacturing Institute

Jack Mosher, Ph.D., International Society for Stem Cell Research

Amy Patterson, M.D., National Heart, Lung, and Blood Institute

Duanqing Pei, Ph.D., Chinese Academy of Sciences

Thomas Petersen, M.D., Ph.D., United Therapeutics

Anne Plant, Ph.D., National Institute of Standards and Technology

Kimberlee Potter, Ph.D., Department of Veterans Affairs

David Rampulla, Ph.D., National Institute of Biomedical Imaging and Bioengineering

Derek Robertson, M.B.A., J.D., CHC, Maryland Sickle Cell Disease Association

Kelly Rose, Ph.D., Burroughs Wellcome Fund

Krishnendu Roy, Ph.D., Georgia Institute of Technology

Krishanu Saha, Ph.D., University of Wisconsin-Madison

Rachel Salzman, D.V.M., American Society of Gene & Cell Therapy

Ivonne Schulman, M.D., National Institute of Diabetes and Digestive and Kidney Diseases

Eric Sid, M.D., National Center for Advancing Translational Sciences

Jay Siegel, M.D., retired, Johnson & Johnson

Lana Skirboll, Ph.D., M.S., Sanofi

Susan L. Solomon, J.D., The New York Stem Cell Foundation

Sohel Talib, Ph.D., California Institute for Regenerative Medicine

Daniel Weiss, M.D., Ph.D., International Society for Cellular Therapy

Michael Werner, J.D., Alliance for Regenerative Medicine

Celia M. Witten, Ph.D., M.D., Food and Drug Administration

Claudia Zylberberg, Ph.D., Akron Biotech

Project Staff

Sarah Beachy, Ph.D., *Forum Director*
Samantha Schumm, Ph.D., *Associate Program Officer*
Meredith Hackmann, *Associate Program Officer*
Kathryn Asalone, Ph.D., *Associate Program Officer*
Lydia Teferra, *Research Assistant*
Aparna Cheran, *Senior Program Assistant*
Email: regenmed@nas.edu

NATIONAL ACADEMIES Sciences Engineering Medicine

FORUM ON REGENERATIVE MEDICINE

Our **purpose** is to spark exchange and inspire action among diverse stakeholders to advance regenerative medicine for the benefit of all.

Our actions are guided by the following principles:

Innovation	Intention	Collaboration	Integrity

We effect change using these strategies:

- Foster a diverse and inclusive future generation of thinkers and doers in the field
- Proactively discern critical scientific, medical, and social issues and provide fit-for-purpose venues for reflection and response
- Engage and collaborate with those whose work aligns with ours
- Translate and disseminate what we learn to catalyze action in the field

The priorities of our work:

Diversity, Equity & Inclusion	Workforce Development	Manufacturing & Supply Chain	Emerging Issues
Advance the Forum's commitment to diversity, equity, and inclusion	Examine incentives and disincentives for expanding the regenerative medicine workforce	Explore obstacles to the delivery of regenerative medicine to patients	Highlight emerging scientific, policy-related, or other issues in the field

We **commit** to upholding the Diversity and Inclusion Statement of the National Academies of Sciences, Engineering, and Medicine. Furthermore, we commit to developing a Diversity, Equity & Inclusion Statement that is more specific to our Forum's work.

The National Academies of Sciences, Engineering, and Medicine value diversity in our members, volunteers, and staff and strive for a culture of inclusion in our workplace and activities. Convening a diverse community to exchange ideas and perspectives enhances the quality of our work and increases our relevance as advisers to the nation about the most complex issues facing the nation and the world.

WORKSHOP INFORMATION

NATIONAL ACADEMIES Sciences Engineering Medicine

Board on Health Sciences Policy | *Forum on Regenerative Medicine*

Training the Regenerative Medicine Workforce for the Future: A Workshop

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Planning Committee Roster

Planning Committee Co-Chairs

Patrick Hanley, Ph.D.
Chief & Director, Cellular Therapy Program
Associate Professor of Pediatrics
Children's National Hospital
The George Washington University

Krishanu Saha, Ph.D.
Associate Professor
Retina Research Foundation Kathryn and Latimer Murfee Chair
Departments of Biomedical Engineering and Medical History & Bioethics
University of Wisconsin-Madison

Planning Committee Members

Qing "Sara" Lin, Ph.D.
Program Director, Division of Lung Diseases
National Heart, Lung, and Blood Institute (NHLBI)
National Institutes of Health (NIH)

Jack T. Mosher, Ph.D.
Scientific Advisor
International Society for Stem Cell Research

Kaivalya Molugu, Ph.D.
Scientist I
Editas Medicine

Clinton Smith
Graduate Research Assistant
J. Crayton Pruitt Family Department of Biomedical Engineering
University of Florida

Eric Sid, M.D.
Program Officer, Division of Rare Diseases Research Innovation
National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health (NIH)

Planning Committee Biographies

Patrick Hanley (co-chair), Ph.D., is an assistant professor of pediatrics and Chief & Director of the Cellular Therapy Program at Children's National Hospital. He oversees process development; translation; and manufacturing of cellular therapy products as well as follow up testing of patients enrolled on cellular therapy clinical trials. Trained as an Immunologist; Dr. Hanley has an extensive background and interest in cellular therapy and is passionate about improving regulations for cellular therapy; training the next generation of cell therapists; and facilitating the translation of new therapeutics. Over the past fifteen years he has helped to translate more than 20 cellular therapy protocols – ranging from mesenchymal stromal cells to cord blood virus-specific T cells and tumor-associated antigen specific T cells – into the clinic. Dr. Hanley serves on the Board of Directors of FACT and as the commissioning editor of the journal Cytotherapy. He is also active in ISCT; co-chairing the Immuno-Gene Therapy Committee; co-founding the Early Stage Professionals Committee; and he was recently elected Vice President-elect; North America. He; along with colleagues Drs. Catherine Bollard and Russell Cruz; co-founded Mana Therapeutics; a biotech company with the mission of educating immune cells and curing cancer.

Krishanu Saha (co-chair), Ph.D., is an associate professor in the Departments of Biomedical Engineering and Medical History & Bioethics at the University of Wisconsin-Madison. His interests lie in using human stem cells together with emerging engineering methods in material science and synthetic biology to make smarter therapeutics, model human disease, and advance personalized medicine. As a Society in Science-Branco Weiss Fellow, he worked with Sheila Jasanoff at Harvard University on "The Constitutional Foundations of Bioethics: A Cross-National Comparison" from September 2010 to December 2011. He is also affliated with Robert F. and Jean E. Holtz Center for Science & Technology Studies at the University of Wisconsin-Madison. Saha received his B.S. in Chemical Engineering and Chemistry from Cornell University (2001), his M.Phil in Biotechnology (Biological Sciences) from the University of Cambridge (2002) and his Ph.D. in Chemical Engineering from the University of California-Berkeley (2007).

Sara Lin, Ph.D., is the program director for the Division of Lung Diseases at the National Heart, Lung, and Blood Institute (NHLBI) where she guides international research efforts to study mechanisms of lung development and regeneration. Her work is part of a coordinated approach to identify therapies for conditions that affect the airways and lungs – from rare ones, like bronchopulmonary dysplasia (BPD), to more common ones, including asthma, the seasonal flu, and COVID-19.

Jack T. Mosher, Ph.D., the senior manager of scientific affairs for the International Society for Stem Cell Research (ISSCR). Jack, who joined the ISSCR in 2015, works closely with ISSCR committees, leadership and staff to provide scientific oversight for the public and professional educational, policy and communication programs.

Jack earned his Ph.D. in Neurobiology at UNC Chapel Hill and was a postdoctoral fellow in the laboratory of Dr. Sean Morrison at the University of Michigan. Jack's research interests have been focused on the development of the nervous system. As a graduate student, Jack studied the genetic regulation of early nervous system development in *Drosophila* and as a postdoctoral fellow he investigated the basic biology of neural crest stem cells and their contribution to the development and disease of the peripheral nervous system (PNS). This research included the role of stem cells in PNS tumors and the pathology and potential treatment of aganglionic megacolon.

Prior to joining the ISSCR, Jack was an Assistant Research Scientist at the University of Michigan where he became involved in scientific educational outreach efforts around the 2008 Michigan ballot initiative, Proposal 2, designed to protect legal forms of human embryonic stem cell research. This process reinforced the importance and need for clear and accurate information and education on stem cell research.

Kaivalya Molugu, Ph.D., (she/her/hers) is a Scientist in the Cell Engineering team with Editas Medicine. She received her B.S. (Biology Major, Materials Science Minor) from Indian Institute of Science and Ph.D. from University of Wisconsin-Madison (UW-Madison) in Biophysics. Her research interests lie in using interdisciplinary approaches to make smarter stem-cell based therapeutics and advance regenerative medicine. During her Ph.D., Dr. Molugu developed innovative and efficient technologies for reprogramming and CRISPR gene-editing of human induced pluripotent stem cells (iPSCs) to aid in the biomanufacturing of iPSC-based therapies. She expands on this research at Editas Medicine, where she is developing clinically translatable methods to engineer iPSCs for targeting solid tumors.

Clinton Smith is a graduate research assistant at the University of Florida. He received his B.S. in Biomedical/Medical Engineering from Georgia Institute of Technology and is working towards a Ph.D. in Bioengineering and Biomedical Engineering at the University of Florida. Before starting his Ph.D. he was a VelociGene R&D Intern at Regeneron.

Eric Sid, M.D., joined the National Center for Advancing Translational Science (NCATS) in the Division of Rare Diseases Research Innovation in 2017, for which he is currently a Program Director and manages a public health information center focuses on patients affected by rare diseases, coordinates other programs that enable patient organizations to actively engage in the research process by providing educational and training support, and as a scientist on projects targeted at improving diagnostics across genetic and rare diseases. Sid represents NCATS on the National Institutes of Health's (NIH) UNITE initiative, which was established to identify and address structural racism within the NIH-supported and greater scientific community, as well as the Trans-NIH Diversity, Equity, Inclusion, Accessibility Strategic Plan Working Group. Sid is the current chair for NCATS' Inclusion, Diversity, Equity in Action (IDEA) Council.

NATIONAL ACADEMIES Sciences Engineering Medicine

Board on Health Sciences Policy *Forum on Regenerative Medicine*

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Speaker Biographies

Barry Bates, M.S., is the Bioscience Program Coordinator at Atlanta Technical College. He received his B.S. degree in Biology from Morehouse College and M.S. in Biological Sciences from Purdue University. Following graduate school, Mr. Bates worked at Emory University as a Research Technician that later transitioned into a position with Merck and Co., in specialty sales. Afterwards, his career shifted to banking and eventually into full-time teaching in Biology. After his first year at Atlanta Technical College (ATC), Mr. Bates was promoted to the Department Chairperson for Natural Sciences and Mathematics. In 2012, he was selected to develop, implement and manage the college's new $4.8 million DOL H-1B grant-funded Bioscience Technology Program for ATC, including laboratory design and curricula for new programs. These efforts brought the exciting field of bioscience to the South Atlanta community to focus on building a highly-skilled and competitive workforce. Through this opportunity many students have pursued careers with major biotech companies and conducted undergraduate research with partnering universities. Continuing with this success, Mr. Bates is leading an effort through a new NSF grant to increase awareness of bioscience career opportunities among historically underserved high school students in Atlanta, GA with training and direct connections between students and industry in Atlanta. Mr. Bates is the recipient of the 2013 Atlanta Technical College Rick Perkins Teacher of the Year, the 2012 and 2013 National Institute of Staff and Organizational Development (NISOD) Excellence Awards, as well as the 2015 John & Suanne Roueche Excellence Award by the League for Innovation in the Community College. He actively serves on the Advisory Board for Georgia BioEd (a division of the Center for Global Health Innovation).

Elana Cooper, M.S., is a Ph.D. Candidate in Biomedical Engineering at Georgia Institute of Technology. Elana gained valuable experience in orthopedic tissue engineering and regenerative medicine throughout her 4 years of undergraduate research at the University of Pennsylvania. During her masters, at the City College of New York, she received a NSF Bridge to Doctorate Fellowship that afforded her clinical collaborations at the Hospital of Special Surgery and Mount Sinai School of Medicine. This work, researching biomechanical aspects of cartilage degradation and tissue repair strategies, garnered her growing interest in osteoarthritis (OA). Following an internship at Corning Inc. in MSC growth surface development, Elana received a GEM PhD Fellowship as a Corporate Product and Process Development Fellow to engage in doctoral research with commercialization potential. While at Georgia Tech she has evaluated OA along cell-tissue, tissue-joint, and joint-whole body levels through ex-vivo microcomputed tomography (uCT) and in vivo 3D joint kinematics via biplanar x-ray radiography. She is now expanding into the molecular realm within the Biomedical Systems Engineering Lab (BSEL) to evaluate potential OA cellular therapeutics for her PhD. Elana currently serves on the Early Stage Professionals Committee for the International Society of Cell and Gene Therapy (ISCT) where she is gaining further exposure to research, regulatory, and commercial aspects of cell therapy development. At BSEL, she has sights on applying these principles to her translational research. Her PhD research explores iMSC-derived, 3D in vitro models of OA, identifying metabolic targets that attenuate local inflammation and enhance joint repair.

Robert Deans, Ph.D., is the Chief Scientific Officer at Synthego, emphasizing translation development for gene edited therapeutics. He was previously Chief Technology Officer at BlueRock Therapeutics, where he participated in the creation of next-generation therapies through the use of pluripotent stem cell biology and gene editing tools. Dr. Deans has more than 30 years of experience developing stem cell and gene therapies, as well as translational science and global regulatory expertise. Dr. Deans received his B.Sc. in Molecular Biology from Massachusetts Institute of Technology and his Ph.D. in Microbiology from University of Michigan.

Linnea Fletcher, Ph.D., is Biotechnology Department Chair and Director of InnovATEBIO National Biotechnology Education Center at Austin Community College. She joined Austin Community College as a Department Chair in Biology, and started the Biotechnology Program in 1999. She joined the first NSF Funded National Biotechnology Education Center, Bio-Link and received her first NSF funded ATE grant to start Biotechnology high school programs in Texas. In 2015, she received an Emerging Technology Fund Grant to build a Bioscience Incubator at ACC and several Wagner Peyser Grants to equip it. Today the incubator is full of start up companies and students interning or working for these companies. She was PI of the AC2 Bio-Link Regional Center, and is now the PI of InnovATEBIO, the NSF funded National Biotechnology Center. Combining economic development with educational opportunities is her passion. She obtained her A.S. from El Camino Jr College, her B.S. in Biology, B.A. in Chemistry, and Masters in Biochemistry from University of California at Irvine, and her Ph.D. in Microbiology from the University of Texas.

Evan Graham, Ph.D., is an Applications Consulting Scientist at Biosero. He is also the Chair of the Early Career Scientist Committee at the International Society for Stem Cell Research. Before moving to Biosero, Dr. Graham previous held positions at BICO as Head of Learning & Development and BioLamina AB as an Application and Sales Specialist. He received his Bachelor of Science Engineering and Master of Engineering in Biological Engineering from Cornell University College of Engineering and his Ph.D. in Regenerative Medicine – Cardiac Regeneration from Karolinska Institutet.

Brigid Hogan, Ph.D., FRS is Professor and previous Chair of the Department of Cell Biology, Duke University School of Medicine. Dr. Hogan pioneered techniques for exploring the molecular and genetic basis of embryonic development and patterning in the mouse. Her lab identified key signaling pathways that direct the development and morphogenesis of several organs systems, including the eye, kidney, germ cells and lung, from undifferentiated progenitor cell populations. Her group also characterized stem cells present in the adult lung and devised mouse models, transplantation techniques and organoid culture systems to explore how they regenerate tissue after damage and how defective repair promotes fibrosis. Dr Hogan was co-founder of a Cold Spring Harbor practical course for teaching methods in mammalian development and organ regeneration that is still running after 40 years, and has trained and mentored graduate students, physician-scientists and numerous postdoctoral fellows. She has been a member of several public facing advisory panels related to stem cells and embryo research. She obtained her B.A. and Ph.D. from the University Cambridge, UK.

Nisha Iyer, Ph.D., is an Assistant Professor in the Department of Biomedical Engineering at Tufts University. Her research interests are at the intersection of developmental biology and regenerative medicine, using stem cells to understand and advance neural repair. As an NIH-NINDS F31 Predoctoral Fellow working with Dr. Shelly Sakiyama-Elbert, she used CRISPR gene-editing in mouse stem cells to generate spinal locomotor interneurons for in vitro modeling and transplantation. Dr. Iyer conducted her postdoctoral research with Randolph Ashton at the Wisconsin Institute for Discovery at the University of Wisconsin--Madison, where she was a Stem Cell and Regenerative Medicine Center and NIH-NINDS F32 Postdoctoral Fellow. There she developed translatable methods to derive regionally and phenotypically specified hindbrain, spinal cord, and peripheral tissues from human pluripotent stem cells. Her lab now

focuses on how regional specificity impacts development, degeneration, and regeneration in the central nervous system and beyond, developing biomanufacturing strategies and organoid technologies to direct cell therapy research. Dr. Iyer is also a passionate educator who seeks to lower barriers to higher education in STEM and to engage the broader community in conversations about science and society. She received her B.S. from Johns Hopkins University and Ph.D. from Washington University in St. Louis in Biomedical Engineering.

J. Kaitlin Morrison, Ph.D., is an Assistant Professor of Medicine and Executive Director of UNC Lineberger Clinical Research at University of North Carolina. Dr. Morrison's primary research interest is translation of basic and translational findings and discoveries from the bench into early phase clinical trials. She is responsible for the leadership and oversight of the LCCC clinical research infrastructure, and co-leads strategic planning driving clinical research infrastructure optimization, process improvements, recruitment/retention of employees and alignment of LCCC and UNC Healthcare system goals. Kaitlin is also responsible for the oversight of LCCC's clinical development program that includes investigator-initiated trials using investigational drugs/biologics provided by pharmaceutical partners, and UNC developed and/or manufactured investigational products. Her research interests focus on regulatory strategy, FDA interactions, clinical protocol development and patient education with a focus on developing clinical trials that are operationally feasible, data driven and patient friendly. She received her B.S. in Chemistry from the University of North Carolina Chapel Hill and her Ph.D. in Biochemistry and Molecular Biology from Brody School of Medicine at East Carolina University.

Xinh-Xinh Nguyen, Ph.D., is a Translational Science Interagency Fellow for the National Center for Advancing Translational Science at the NIH. Dr. Nguyen joined the Translational Science Interagency Fellowship (TSIF) program because it will provide her with an opportunity to gain expertise in translational research and research related to regulatory and drug development science and to further enhance her understanding of the translational relevance of basic research. These experiences will help her develop a broad perspective of the applicability of her science and establish diverse skills, potential research ideas, and future projects. Prior to joining NCATS, Nguyen's graduate research examined the role of insulin-like growth factor binding protein (IGFBP)-5 and lysyl oxidase (LOX) and whether they can serve as potential therapeutic targets in fibrotic diseases. Her short-term goal is to continue with a postdoctoral fellowship training program to further explore translational research opportunities and enhance her knowledge, strengthen her specialized research skills, and develop her critical thinking. Her long-term career aspiration is to understand the etiology of rare disorders — such as scleroderma — and to identify possible therapeutic treatments for the disease. She plans to provide knowledge to the field of fibrosis that can be translated into medical care for patients affected by these disorders. She earned her Ph.D. from the Medical University of South Carolina.

Maryam Pasdar, is a Cellular Therapy Laboratory Associate III at Children's National Hospital in Washington, DC. Their work deals largely with process development, clinical manufacturing cell culture, and cell/product characterization and analysis. They work with a team who provides T-cell therapy to patients across the nation. They received their B.S. from the University of Pittsburgh Department of Biological Science and plan to apply to medical school in the future. Their intent is to become a surgeon in an urban hospital. Their passion for medicine stems from their desire to serve the community. They are also a member on the International Society for Cell & Gene Therapy's Early Stage Professionals Committee which focuses on developing programs for new members of the cell and gene therapy field to network and enhance their understanding of and advancement in the field.

Meagan Pasternak, is the Senior Manager for Workforce Training and Regional Development at International Society for Cell & Gene Therapy. Meagan received a Bachelor's degree in International Relations and Affairs from the University of British Columbia.

Training the Regenerative Medicine Workforce for the Future: A Workshop

November 15, 2022
Virtual Workshop

TIMELINE:
12:30 PM – 4:30 PM

Speaker Guidance Questions

SESSION I. SYSTEMS-LEVEL GAPS AND SOLUTIONS IN WORKFORCE DEVELOPMENT IN THE REGENERATIVE MEDICINE ECOSYSTEM

Speakers:

Objectives

- Explore systems-level gaps and solutions to better address workforce development in regenerative medicine
- Discuss skillsets needed across different sectors of regenerative medicine
- Explore incentives for expanding the workforce, including improving diversity and inclusion

Key Questions for Speakers

1. From your unique perspective, what challenge in education or professional development deserves more attention? What potential solutions could help address this challenge? Are there solutions that have been working well to develop the workforce?
2. What are important incentives for expanding or retaining the workforce? What are some of the major disincentives that drain the workforce? What are ways to recruit new talent to the field and draw more students into the pipeline?
3. How do diversity of the workforce and inclusion act as on-ramps or off-ramps for developing and retaining the workforce?
4. What key career junctures need more support to better expand and retain the workforce in regenerative medicine? How do you define training throughout career paths?
5. What skillsets are needed across different sectors of regenerative medicine? What kind of education, training, or professional development programs could help address these needs?
6. How do you balance the need to develop the workforce immediately and the need to develop the workforce in an inclusive way?

SESSION II. EARLY CAREER PERSPECTIVES ON OPPORTUNITIES IN REGENERATIVE MEDICINE

Speakers:

Objectives

- Learn about training experiences that have been influential in the professional development of early-career individuals
- Discuss gaps in expertise or support that individuals experience at key junctures early in their careers
- Explore solutions to career-related challenges that may encourage and inspire other students

Key Questions for Speakers

1. Introduce yourself. What is your background and current role? Why are you interested in pursuing a career in regenerative medicine?
2. Discuss a training experience that has been influential in your career. Why was it impactful?
3. What is the role of mentorship and networking in your career? What was it about the mentor that was influential?
4. What is a challenge you have faced so far in your education or career? How did you overcome it? What support could have helped you mitigate or avoid this challenge? Are there challenges that you foresee in the development of your career?
5. What would you recommend to other students or early-career individuals? What advice would you give to someone facing similar challenges to those you did?
6. What one change would make the biggest difference for people getting started in regenerative medicine?

BACKGROUND INFORMATION

Links to Additional Resources

McNiece, I.K., et al. 2021. Standardization, workforce development and advocacy in cell and gene therapies: A summary of the 2020 Regenerative Medicine InterCHANGE. *Cytotherapy* 23(10): 886-893. https://doi.org/10.1016/j.jcyt.2021.02.004

Wyles, S.P., et al. 2021. Emerging workforce readiness in regenerative medicine. *Regen. Med.* 16(3): 197-206. https://www.futuremedicine.com/doi/pdf/10.2217/rme-2020-0137

Wyles, S.P., & A. Terzio. 2019. Building the regenerative medicine workforce of the future: an educational imperative. *Regen. Med.* 14(7). https://doi.org/10.2217/rme-2019-0072

International Society for Cell & Gene Therapy Home Page - (isctglobal.org)

International Society for Cell & Gene Therapy upcoming courses in Workforce Development in Biomanufacturing

CIRM: California's Stem Cell Agency – Internship Programs: SPARK and Bridges

The National Institute for Innovation in Manufacturing Biopharmaceuticals – Skill Standards and Curriculum for Cell and Gene Therapy Technicians

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PERSPECTIVES

RMMS Regenerative Medicine Manufacturing Society

STEM CELLS TRANSLATIONAL MEDICINE

Recommendations for workforce development in regenerative medicine biomanufacturing

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Abstract

In its 2019 report, *The Skilled Technical Workforce: Crafting America's Science and Engineering Enterprise*, the National Science Board recommended a national charge to create a skilled technical workforce (STW) driven by science and engineering. The RegenMed Development Organization (ReMDO), through its Regenerat*OR* Workforce Development Initiative, has taken on this challenge beginning with an assessment of regenerative medicine (RM) biomanufacturing knowledge, skills, and abilities (KSAs) needed for successful employment. While STW often refers only to associate degree or other prebaccalaureate prepared technicians, the RM biomanufacturing survey included responses related to baccalaureate prepared technicians. Three levels of preparation were articulated in the research: basic employability skills, core bioscience skills, and RM biomanufacturing technical skills. The first two of these skill levels have been defined by previous research and are generally accepted as foundational—the Common Employability Skills developed by the National Network of Business and Industry Associations and the Core Skill Standards for Bioscience Technicians developed by the National Center for the Biotechnology Workforce. Fifteen skill sets addressing the specialized needs of RM and related biotechnology sectors were identified in the ReMDO survey, defining a third level of KSAs needed for entry-level employment in RM biomanufacturing. The purpose of the article is to outline the KSAs necessary for RM biomanufacturing, quantify the skills gap that currently exists between skills required by employers and those acquired by employees and available in the labor market, and make recommendations for the application of these findings.

Significance statement

This perspective addresses workforce development in regenerative medicine, providing an overview of the skills needed for the technical workforce and an assessment of the current skills gap between the skills needed and those present in the incumbent workforce or available in the labor market. The article will inform faculty development, curriculum development and alignment, RM work-based learning, and efforts to develop a diverse and inclusive workforce. It will also provide rationale for federal and state workforce development policy and investments.

1 | INTRODUCTION

In its 2019 report, *The Skilled Technical Workforce: Crafting America's Science and Engineering Enterprise*, the National Science Board lays down a national charge to create the skilled technical workforce (STW) for a workplace driven by science and engineering—"We must 'step-up' our game and nurture and expand our domestic talent along the entire science and engineering worker-value chain from the STW to the Ph.D. if our workforce is to remain competitive."[1] The report reflects a recurring theme in technology-based workforce development. The World Economic Forum in its 2020 research and commentary reinforces the international scale of the skilled workforce challenge across technology-driven economic sectors.[2]

The emergence of the COVID-19 pandemic in 2020 and its disruption of the economy has expanded the workforce development challenge of developing or acquiring the needed knowledge, skills, and abilities (KSAs) for regenerative medicine (RM) biomanufacturing, increasing the competition for a skilled workforce, and accelerating technological change in the field. While the pandemic has dramatically increased unemployment worldwide, the focus on vaccines and therapies associated with the virus has increased the demand for the STW to support R&D, clinical translation, and the scaling up of operations across biomanufacturing and biopharmaceutical enterprises, including the RM sector. Some of the immediate applications for RM in developing therapies and the emerging technologies that make development and scaling possible were recently articulated.[3] The response of academic institutions to COVID has by necessity dramatically accelerated online and hybrid learning models.

RM biomanufacturing represents one of the emerging technology-driven growth sectors. With recent and projected future growth in RM, the availability of a knowledgeable and skilled workforce is increasingly a critical success factor for business and academic organizations. As the field progresses from research to clinical translation and from translation to biomanufacturing, the skill requirements are evolving. The Regenerat*OR* initiative of the RegenMed Development Organization (ReMDO) has undertaken a necessary early step in addressing the challenge with the articulation of the KSAs needed to align education and workforce development programs with employer needs. The purpose of the article is to outline the KSAs necessary for RM biomanufacturing, to quantify the skills gap that currently exists between skills required by employers and skills acquired by employees and available in the labor market and make recommendations for the application of these findings.

2 | BACKGROUND

Over the past decade, significant work has been done to address the need for highly skilled technicians for advanced manufacturing, including biomanufacturing. Defining the basic employability skills (soft skills) and core sector skills (eg, core bioscience technician skills) are essential to addressing the skill needs and skills gap. The National Network of Business and Industry Associations (NNBIA) Common Employability Skills (CES) has defined the foundational skills needed by employers across the economic spectrum. The CES is organized around four categories—personal skills, people skills, applied knowledge, and workplace skills—with 20 specific KSAs further defined by behaviors and actions.[4] The assessment and statement of these skills provide a common language for employers, educators and workforce developers, and students/employees to articulate what is needed for employment and workplace success for all economic sectors.

The National Center for the Biotechnology Workforce (NCBW), in a project funded by the US Department of Labor, published the *Core Skills Standards for Bioscience Technicians*[5] in 2016. These core bioscience technical skills are organized around six "critical work functions"—maintaining a safe and productive work environment, providing routine facility support, performing measurements/tests/assays, complying with applicable regulations and standards, managing, and communicating information, and performing mathematical manipulations—and form the foundational technical skills for RM biomanufacturing. These bioscience skill standards have been confirmed by NCBW with the recent work of the National Science Foundation-sponsored Biomedical Emerging Technology Application Skills (BETA Skills) project.[6] Subsequent work in skills standards, including the Regenerat*OR* skills survey has been grounded in these seminal efforts and they continue to provide an accepted definition of foundational skills required in the workplace generally and biotechnology/biomanufacturing in particular.

2.1 | Regenerat*OR* RegenMed biomanufacturing KSAs

In January 2020, the Regenerat*OR* Workforce Development Initiative was launched by the ReMDO at the annual meeting of the Regenerative Medicine Manufacturing Society (RMMS). The initiative was created to develop a national workforce development ecosystem in RM biomanufacturing by developing, leveraging, and brokering educational and training resources grounded in the unique, world-class R&D and translational science of ReMDO and its partners. The initiative recognizes that the development of the scientific and engineering talent driving knowledge and discovery of RM, including RM biomanufacturing process and product development, is national and international in scope, but the STW is regionally centered and developed around hubs of RM research, clinical translation, and emerging RM biomanufacturing.

While research and clinical translation with their inherent rewards of scientific challenge and discovery provide intrinsic motivation for career development, the scaled RM biomanufacturing environment relies on routinized, repetitious processes where problem solving and excellence in execution are defined by lack of variability in the process.[7] Thus, the starting point for developing the STW for RM biomanufacturing workforce is the definition of the skills and competencies needed for highly regulated production processes and current Good Manufacturing Practices. The appropriate academic preparation for the entry-level STW will likely be the technical associate degree, with immersive preparation in a lab or bioproduction setting mirroring the workplace. The associate degree will be articulated with an appropriate baccalaureate degree that will provide the employed, early career technician with development opportunities, strengthening the theoretical grounding in bioscience or bioengineering needed for career advancement.

Drawing on the work of NNBIA CES and NCBW Core Skills, ReMDO surveyed academic and private sector enterprises in RM regarding the skills needed for the emerging RM biomanufacturing workforce. The survey development began with a review of the previous skill standards work noted above by a select group of academic and business leaders. This review confirmed the current validity of the NNBIA CES and the NCBW Core Skill Standards. A list of 36 technical skill items was compiled from technical skill items generated by the BETA Skills project; associate degree and baccalaureate curricula in biotechnology, applied biology, bioprocessing, or bioengineering at selected community colleges and universities with recognized programs; and expert review. To facilitate the survey, these skill items were clustered into 15 skill sets.

Survey participants were asked to assess each of the skill sets along two dimensions—importance of the skill set (skill need) and, if important, whether the skill set was available in their workforce or the labor market (skills gap). Three response choices were included to determine the skill needs and the skills gap for each skill set. Possible responses were: (1) skill set is not important for my technical workforce; (2) skill set is important for my technical workforce, and I currently have it or can acquire it; or (3) skill set is important for my technical workforce, but I do not have it or have difficulty acquiring it. The skill need dimension addresses current status of the workforce; the skills gap dimension articulates where attention is needed for the current and near-future workforce.

Previous efforts by practitioners and researchers to survey representative participants in the field to specify the skill needs and skill gaps for the RM biomanufacturing STW were challenged by small numbers of responses with some response numbers barely above single digits. The response number issue was addressed with the ReMDO survey by including a large population of research, translation, and biomanufacturing practitioners in the RM field. The survey was administered using Survey Monkey and was broadly distributed to members and contacts of the RMMS, the industry-led Regenerative Manufacturing Innovation Consortium, and the members of ReMDO. The initial distribution of the survey was followed by a reminder 10 days later. Of the 3792 recipients who opened the survey, 149 individuals responded (4%).

The RM biomanufacturing STW skill sets generally align with the needs of the survey participants, reflecting the current capabilities required of the STW. Seventy percent or more of respondents indicating a need for 14 of the 15 skill sets (only half of the respondents needed chromatography skills) (Figure 1).

Skill sets in highest demand are focused on manufacturing operations management and cell science. The manufacturing operations management KSAs needed by skilled technicians such as documentation (needed by 93.9%), validation (91.8%), standards (88.4%), and regulation (85.7%) make up a cluster of skills identified as being the most critically important skills for the RM biomanufacturing workforce. These skill sets exhibit the greatest unmet need with 30% to 40% of respondents reporting that they are unavailable in their current workforce or in the labor market.

Not surprisingly, technical skills related to basic cell biology are also essential to RM biomanufacturing with 92% of respondents indicating that cell biology related skills—the ability to prepare cell cultures, perform tissue culture and or cell-based assays, confocal microscopy, and flow cytometry—were important skills to their operations. However, employers responding report that these basic cell biology skills are generally available in their workforce or in the labor market, indicating that the preparation of technicians in cell science in community college associate degree programs and university baccalaureate programs are providing the technical skills that are needed. Only 10% of respondents report an unmet need. The molecular biology KSAs (eg, the ability to perform basic recombinant DNA techniques, including analysis and purification, protein and enzyme assays, polymerase chain reaction (PCR), polyacrylamide gel electrophoresis (PGE), Western Blot, enzyme-linked immunosorbent assay (ELISA), mass spectrometry and immunological assays) are viewed as important by a strong majority of respondents in RM biomanufacturing (87%), but 72% indicate that the KSAs needed are available, while less than 15% have an unmet need. Just over half of employers responding indicate a need for biochemistry skills, chromatography specifically (the lowest stated need of the 15 skill sets); however, those respondents who do need chromatography skills report that the skills are often unavailable with 24% of all respondents having an unmet need. Understanding stem cell concepts and applications (a knowledge of adult stem cells, induced pluripotent stem cells

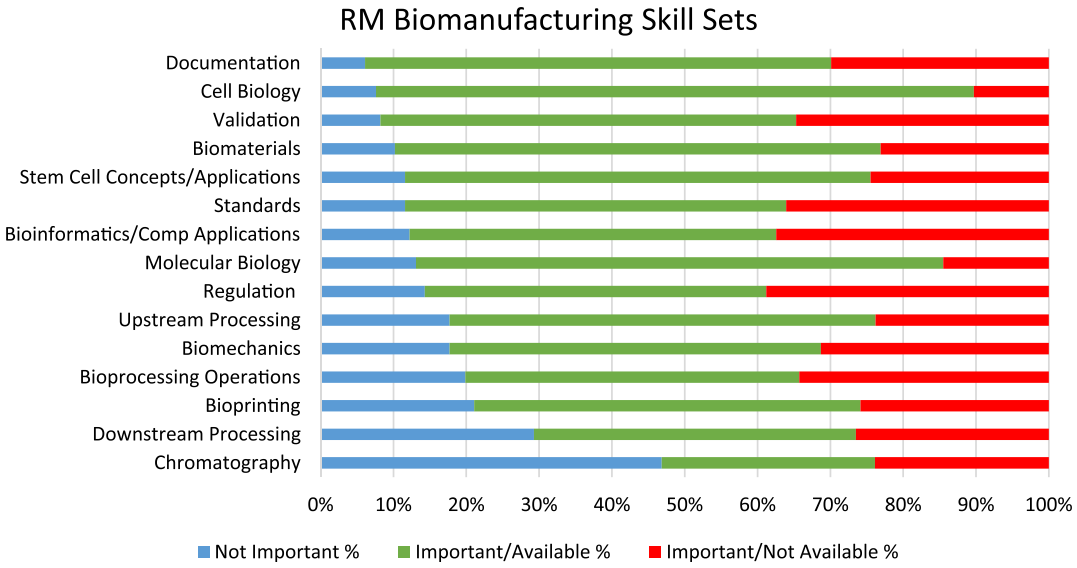

FIGURE 1 Illustrates the ReMDO survey results that address skills needs (green and red) and skill gaps (red only) for the 15 identified skill sets for the regenerative medicine skilled technical workforce

technologies, cell signaling pathways, and cell differentiation and differentiating human embryonic stem cells are needed by 88% of the employers surveyed—a high need within the cell science cluster—and a quarter of all respondents indicate that needed stem cell KSAs are unavailable in their current technician workforce and the labor market.

A third cluster of RM biomanufacturing KSAs—bioprocessing (the application and scaling of processes and production techniques, including bioreactor operations, to produce cell-based products) was divided on the survey into upstream bioprocess technology, bioprocess operations (bioreactors), and downstream bioprocess technology to ensure that these operations were adequately captured as a central biomanufacturing process. Upstream processing skills, from cell isolation and cultivation to cell banking and culture expansion of the cells to harvesting, including inoculum development, were identified as needed by over 80% of the respondents. Bioreactor operations were a need for a similar number of survey participants. However, fewer respondents viewed KSAs related to downstream processes—cell disruption, purification, and polishing—as important to their operations than upstream/bioreactor processes with 71% indicating a need for downstream processing skills. This finding makes sense as the RM industry does not generally try to capture and purify active pharmaceutical indredients from genetically engineered cell platforms but instead uses cells as therapeutics.

The multidisciplinary nature of RM as a field and the convergence of technologies needed for successful RM biomanufacturing creates complexity in the development of the highly skilled RM biomanufacturing worker. In addition to the KSAs needed in biomanufacturing operations management, cell science, and bioprocessing, several technologies converge with biotechnology to define needed KSAs. Four such skill sets were identified in the survey—biomaterials, biomechanics, bioinformatics/computer applications, and bioprinting. Biomaterials—the convergence of cell biology, bioengineering/tissue engineering, and materials science—is among the skills sets most in demand for RM biomanufacturing. Ninety percent of respondents need employees who have KSAs associated with biomaterials (eg, can perform biomaterial synthesis and analysis, have knowledge of biochemical composition, degradation, density, thickness, leachables, residuals and stability; can assess mechanical strength and perform burst tests; and can apply nanotechnology tools and methods). The intersection of bioscience and mechanics requires the application the principles of biomechanics to RM processes and products and application of biofluid dynamics in RM biomanufacturing. Of the respondents, 82% had a need for these skills, and more than 30% find that skills in biomechanics are missing in the current workforce and labor market.

In today's manufacturing environment, all manufacturing is digital and RM biomanufacturing is no different. A workforce is needed that can collect data and perform data analysis, use numerical analysis (including modeling, computer simulation, and experimental measurements), perform digital image capture and analysis, and maintain cyberbiosecurity standards and practices. Eighty-eight percent of survey respondents expressed a need for biotech/IT convergent skills and almost 40% say that they do not have and cannot acquire the bioinformatics and IT skills needed. Bioprinting, with its origins in digital text and image printing, is an increasingly important RM digital technology in biomanufacturing and technical staff in the emerging biomanufacturing space will be required to have a knowledge base in these processes. It is no surprise that 80% of employers responding indicate a need for bioprinting skills and that many—almost 30%—find the skills lacking in the workforce.

Overall survey results indicate that, while RM biomanufacturing is experiencing rapid growth, a pronounced skill gap exists wherein 20% to 40% of employers in RM are reporting a lack of needed skills sets in their workforce and an inability to hire for those skills in the labor market (in all skill sets except cell biology and molecular biology where needed skills are more likely to be met). Clearly more and better education and training is need in regulatory processes, standards, and

validation where a third of employers do not have and cannot hire for the skills needed. Also, the survey puts educators and trainers on notice that digital and data skills are increasingly part of the convergent technologies with RM.

2.2 | Recommendations for developing RM biomanufacturing KSAs

According to a May 2020 report published by McKinsey Global Institute, "Demand for people with expertise in genetics, bioinformatics, biochemistry, bioengineering, machine learning, and data analytics skill will rise as talent starts to drive commercialization. A key question is how to ensure that these skills are available to organizations that can develop beneficial applications."[8] While the PhD/MD preparation for researchers and clinicians is international in scale and scope, the development of the technical skill workforce is centered regionally. Efforts to ensure the availability of the workforce KSAs that are important to RM biomanufacturing begin with the educational and workforce development ecosystem.

Five recommendations are proposed to develop of the workforce development ecosystem.

1. Provide faculty development opportunities in RM for K-12, community college, and universities (including 4-year colleges) that are aligned with industry needs that support grade/level appropriate learning.

Faculty development in RM for K-12 STEM teachers generally, and biology and chemistry specifically, can support the introduction of RM to students in middle and high school courses and appropriate work-based learning in the latter years of high school. Increased K-12 faculty knowledge of the RM KSAs brings exposure to the foundations of RM and RM-related products to students, strengthens middle school/high school curricula, and improves alignment with community college and undergraduate university degree programs. Community college faculty in biotechnology and RM convergent technologies, who are increasingly responsible for entry-level technician education, must be knowledgeable of RM science and processes (including rapidly changing technologies) and their application in the lab or production facility. These faculties often have limited access to hands-on professional development opportunities and state-of-the-art facilities. University faculty through their degree programs also prepare technicians and, in the ecosystem noted in Figure 2, provide greater depth of knowledge in the field and learning at the intersection of converging technologies. Faculty development aligned with the defined RM KSAs is the foundation for curriculum development and learning in RM.

2. Incorporate RM principles and applications in STEM-related academic curricula, recognizing the multidisciplinary nature of the field.

Entry-level RM biomanufacturing functions will increasingly be performed by skilled staff with the associate degree, although innovation and rapidly changing processes will require continuous learning, including additional degree or credential attainment for the incumbent workforce. The KSAs can guide an aligned, progressive approach to curricula in the ecosystem—core STEM curricula in K-12 with exposure to RM principles and applications; technical curricula in community college including didactic and significant hands-on laboratory and work-based learning; and in-depth didactic as well as hands-on lab and multidisciplinary learning in university curricula. This aligned, progressive ecosystem is supported by dual enrollment and Early College initiatives between K-12 institutions and systems and higher

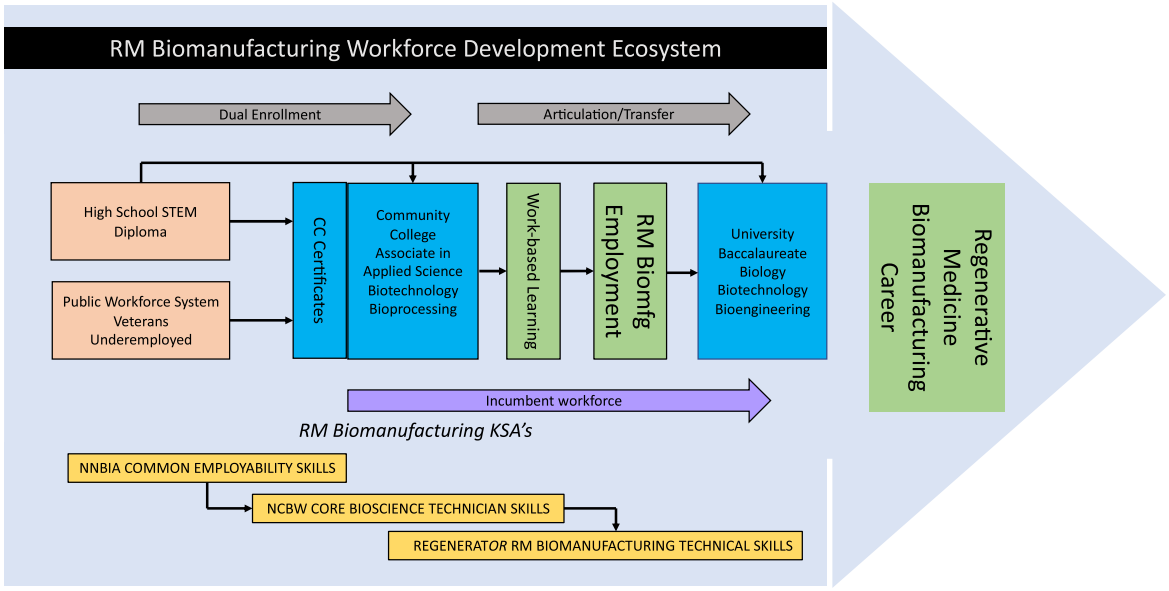

FIGURE 2 Depicts a model of the educational ecosystem for the skilled technical workforce for regenerative medicine biomanufacturing including the educational continuum from K-12 to university, the connectors that close the seams in the educational pathway (dual enrollment and articulation), and the defined KSAs that guide curricula

education institutions and bilateral transfer and articulation agreements between community colleges and universities, initiatives that accelerate STW preparation and support continuous learning for technical careers in RM.

3. Provide progressive levels of work-based learning in RM, K-12 to university.

RM biomanufacturing also requires employers to think differently about their STW if they are to meet their business goals. For employers to have work-ready, skilled staff with minimal internal training needed at employment and to develop the incumbent STW, work-based learning is an essential component of the academic and internal learning experience. Employers, working with their regional education ecosystem—K-12 to graduate school—need to participate in a work-based learning system that ranges from "low touch" learning - the brief "career day" or facility and operations tours—to "high touch," highly structured employer-recognized or registered apprenticeships.[9]

As the demand for STW grows greater, employers may structure technical positions to meet the varying capabilities of the entry-level and experienced workers based on education and continuing development, borrowing a concept from the clinical side of health sciences—"scope of practice"—whereby nurses, for example, can perform defined tasks that are aligned with their preparation and their positions are aligned with the standard of preparation that scope of practice represents.

4. Pursue a diverse and inclusive STW in RM.

Aligning academic curricula and positions for skilled RM technical staff with standard KSAs supports another goal and value of employers—an inclusive work environment with a diverse workforce. The traditional reliance on institutional reputation to develop the workforce makes fulfilling the goal of inclusiveness difficult for employers as higher education becomes increasingly differentiated along racial, ethnic, and class lines.[10] With community colleges, historically black colleges and universities, (and other minority-serving institutions), and regional universities graduating a majority of students of color, immigrants, career-transitioning adults, and low-income students, RM employers will be required to look to them to provide the diverse workforce they need, including the their STW, as the labor market continue to tighten with the growth of the bioscience sector in general. The adoption of common technical skill standards by these institutions in bioscience-related programs provide employers with a level of confidence in the employment of graduates for RM biomanufacturing and a path to a diverse workforce and inclusive workplace.

5. Advocate for policy and investments in RM and convergent technology workforce development.

U.S. government policy has recognized the need for investment in workforce development strategies associated with emerging technology-based sectors such as RM and convergent technologies. The George W. Bush administration's President's High Growth Job Initiative and Workforce Innovations for Regional Economic Development program and the Obama administration's Trade Adjustment Act Community College and Career Training programs funded regional and sector projects that grew the national capacity for workforce development. More recently, the Department of Defense, National Science Foundation, and other agencies have articulated the projected need for the STW in bioscience, including RM, a need quantified by the skills gap assessment. The skills gap assessment provides valuable data and support for academic institutions and their educational ecosystem partners to advocate for appropriate scale federal and state investments to support the national RM ecosystem and regional sector education and training.

3 | CONCLUSION

Preparing the highly STW for RM biomanufacturing begins with defining the KSAs required to execute highly regulated, routinized production processes. The articulation of the foundational skill sets of previous workforce development efforts and the Regenerat*OR* skill sets provides the starting point for institutions of higher education, working with their employer partners, to adapt curricula to meet these needs and share best practices in doing so. The skill gaps in the current workforce and labor market are clear and will inform the educational process as well. Addressing the five recommendations for developing the RM STW—faculty development, curriculum development, work-based learning adoption, workforce inclusiveness, and educational ecosystem investment—will support for the ultimate goal of RM biomanufacturing—improving lives.

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CONFLICT OF INTEREST

The authors declared no potential conflicts of interest.

AUTHOR CONTRIBUTIONS

G.M.G., R.R.: conception and design, collection and/or assembly of data, data analysis and interpretation, manuscript writing; S.L.: collection and assembly of data, manuscript review and editing; T.T.: conception and design, data analysis and interpretation; J.G.H.: conception and design, administrative support, manuscript review and editing; A.A.: conception and design, collection and/or assembly of data, final manuscript approval.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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