Successes and Challenges in Biomanufacturing

Proceedings of a Workshop—in Brief

WORKSHOP BREAKOUT GROUP HIGHLIGHTS[1]

Highlights from workshop breakout discussions are shown below, roughly organized by topic. Some examples and cross-cutting themes—like the importance of coordination and communication—were discussed by participants in the context of multiple topics and multiple sectors of biomanufacturing.

[1] These boxes list some examples of challenges and key takeaways by workshop participants. For brevity, boxes do not include all of the ideas mentioned and should not be interpreted as consensus conclusions or recommendations of the National Academies. Please see the workshop website for additional information: https://www.nationalacademies.org/event/10-24-2022/successes-and-challenges-in-biomanufacturing-a-workshop.

Biomanufacturing for Sustainability and a Circular Bioeconomy

Examples of Challenges Discussed

- Aligning financial incentives and technical capabilities to move toward more sustainable practices.
- Aligning domestic and international policies for sustainability and the inclusion of biomanufacturing in those policies.
- Communicating to consumers about the benefits of biomanufacturing, including for health, the economy, the environment, and security.
- Building trust among the general public around biomanufacturing practices and products.

Examples of Key Takeaways Discussed

- Clear and common terminology and definitions for what it means for a product to be bio-based or renewable could be helpful.
- Compiling case studies showing that moving toward sustainability does not necessarily mean increasing costs could help debunk myths around a "green premium."
- Valorizing bio-based feedstocks and waste streams could assist in promoting a circular bioeconomy.
- Engaging with non-traditional voices to represent the bioeconomy could help demystify the industry and identify unmet needs.

Economic Considerations and Challenges for Biomanufacturing

Examples of Challenges Discussed

- Identifying cost structures and the economics of biomanufactured materials in parallel with research and development.
- Leveraging partnerships, including cross-sector partnerships, with available resources and incentives to foster collaboration.
- Aligning incentives related to intellectual property, especially within partnerships.
- Developing mechanisms for measuring success in the bioeconomy.

Examples of Key Takeaways Discussed

- Industry and venture capital alone likely cannot effectively move the needle in advancing the bioeconomy without government support and public–private partnerships.
- Government procurement could be a powerful incentive for biomanufacturing.
- Innovators could conduct techno-economic and life-cycle assessment as early as possible to help ensure future economic viability and success.
- Partnerships could be created in the noncompetitive or precompetitive space for small companies to share scale-up capacity and co-develop biomanufacturing processes.

Regulation and Standards for Biomanufacturing

Examples of Challenges Discussed

- Defining and measuring critical quality attributes and ensuring a shared understanding of these attributes among companies, regulatory bodies, and analytical equipment providers.
- Developing process, product, and data standards that enable iterative improvement and integration and competition with traditional manufacturing processes.
- Enabling standards and the regulatory landscape to keep up with the pace of change in science and technology.
- Creating and applying standards to biology because biology is not immutable.
- Building technical and workforce capacity for standards development and regulatory needs.

Examples of Key Takeaways

- Fragmented regulatory processes could be streamlined to help enable clear and open conversations between regulators and developers.
- New approaches that define acceptable parameters for new products and generate shared understanding of success could help move the bioeconomy forward.
- Centers of excellence could help to enable reproducibility through standardization and best practices for quality control, scaling, and analytics.

Biomanufacturing Workforce Development and Education

Examples of Challenges Discussed

- Coordinating all levels of education, including K-12, community colleges, and universities to foster equitable development of a biomanufacturing workforce.
- Ensuring the biomanufacturing workforce is trained in critical skills, including data science and analytics, process engineering, quality management, technoeconomic analysis, life cycle assessment.
- Aligning incentives for talent, including educators who train the biomanufacturing workforce.

Examples of Key Takeaways Discussed

- Efforts to establish tomorrow's biomanufacturing workforce could be integrated into mainstream educational programs.
- Without inclusive communication and efforts, certain political, cultural, or religious groups might not feel welcome to participate in biomanufacturing. These efforts could make biomanufacturing more appealing across groups and decrease the risk of programs not being able to sustainably recruit students, as has been seen in parts of the country.
- Aligning workforce development efforts to regional industry needs, regional cultures, and local conditions, like retraining programs targeted to support workers displaced by sunsetting technology, could help advance the bioeconomy.
- Experiential learning beyond summer internships could be implemented at all levels of education.
- Cross-generational communication could help efforts in workforce development.
- Engaging with non-traditional voices to represent different sectors of the bioeconomy could help demystify the industry and attract talent.

Biomanufacturing Ecosystems, Research and Development, and Data

Examples of Challenges Discussed

- Translating basic science results into new applications and practical capabilities.
- Breaking down silos within and across bioindustrial and biopharmaceutical manufacturing to enable the sharing of processes and data.
- For bioindustrial manufacturing, identifying and “domesticating” organisms beyond today’s limited collection to enable new biomanufacturing capabilities.
- For tissue engineering applications, bringing forward enabling technology for automation.
- For cell therapies, identifying critical direct and indirect biomarker measurements and associated detection methods needed for quality control.

Examples of Key Takeaways Discussed

- Industry, academia, and regulatory agencies could be proactive and more effective at sharing data and lessons learned, including for both successes and failures.
- A central portal for sharing resources, successes, and failures could improve communication across industry, academia, government, and the public.
- Biomanufacturing could learn from other areas of manufacturing.
- Incentives to identify novel organisms for biomanufacturing, and standards and regulatory guidelines for organisms, could accelerate commercialization efforts.
- Regulatory agencies and journals could encourage data sharing beyond publications.
- Incorporating perspectives from as many stakeholders as possible, including from across different biomanufacturing sectors, could help move the bioeconomy forward.

Physical Infrastructure and Scale-Up Capacity

Examples of Challenges Discussed

- Establishing the physical infrastructure needed to move biomanufacturing forward.
- Creating regional infrastructure and regional supply chains.
- Communicating nuances of “scale up” as workflows across scales (e.g., pilot, commercial) span different orders of magnitude for different products and applications, and ensuring that the needs for each kind of scale up are considered.

Examples of Key Takeaways Discussed

- Capacity for scale up, development, and production may be lacking with critical gaps in physical infrastructure.
- Customized regional strategies for biomanufacturing, informed by regional business needs, infrastructure, and availability of resources (e.g., feedstock including waste streams, workforce) could be developed.

DISCLAIMER This Proceedings of a Workshop—in Brief was prepared by **JOE ALPER, STEVEN MOSS,** and **ANDREW BREMER** as a factual summary of what occurred at the workshop. The statements made are those of the rapporteurs or individual workshop participants and do not necessarily represent the views of all workshop participants; the planning committee; or the National Academies of Sciences, Engineering, and Medicine.

WORKSHOP PLANNING COMMITTEE **KRISTALA L. J. PRATHER** (*Chair*), MIT; **EMILY GREENHAGEN,** Ginkgo Bioworks; **BRIAN D. KELLEY,** VIR Biotechnology; **JAMES PHILP,** OECD; **SARAH RICHARDSON,** MicroByre; **KRISHNENDU ROY,** Georgia Institute of Technology; and **DEEPTI TANJORE,** ABPDU.

REVIEWERS To ensure that it meets institutional standards for quality and objectivity, this Proceedings of a Workshop—in Brief was reviewed by **JEFFREY BAKER,** NIIMBL; **PATRICK M. BOYLE,** Ginkgo Bioworks; and **KRISTALA L. J. PRATHER,** MIT. **LAUREN EVERETT,** National Academies of Sciences, Engineering, and Medicine, served as the review coordinator.

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