Scientific, Industry, Innovation, and Governance Landscape for Biotechnology Research and Development in the United States and India

A Virtual Workshop

WORKSHOP SERIES GOALS AND OBJECTIVES

The National Academies will convene an ad hoc planning committee to organize and facilitate a virtual workshop exploring the research and development, innovation, investment, and policy landscapes for biotechnology and biomanufacturing in the United States and India and highlighting joint and/or collaborative efforts in these areas. The committee will comprise established and early-career experts from the United States and India who work in fields and organizations relevant to the bio-based economy in both countries. The workshop will focus on various topics that promote and protect research, development, commercialization, and application of biotechnology and biomanufacturing for the bio-based economy. Topics may include:

a) scientific and technological developments.
b) research institutions, commercial and/or biomanufacturing industry, and users of bioeconomy knowledge and products.
c) policies and practices for governing bioeconomy-related research and development in the US., India, and internationally.
d) specific enablers of the bioeconomy ecosystems in both countries.
e) hurdles in the bioeconomy innovation ecosystem and any solutions to those hurdles.

VIRTUAL WORKSHOP

August 21-22, 2024
9:00 am – 12:00 pm ET
6:30 – 9:30 pm IST

DAY 1: WEDNESDAY, AUGUST 21, 2024

9:00 am ET
6:30 pm IST
Welcome and Opening Remarks
Ms. Carmen Shaw, NASEM (Project Lead)

9:05 am ET
6:35 pm IST
Introduction and Workshop Objectives
Dr. Deepti Tanjore, Lawrence Berkeley National Laboratory (Co-Chair)
Ms. Shefali Misra, Biocon (Co-Chair)

9:15 am ET
6:45 pm IST
Overview: State of India-USA Collaboration
Dr. Sanjay Mishra, Department of Biotechnology
Dr. Kate Stevens, U.S. Department of State

9:35 am ET
7:05 pm IST
Panel 1: What are the Future Trends in Biotechnology and Biomanufacturing within the India-U.S. Bioeconomy?
Moderated by: Dr. Sarah Carter, Science Policy Consulting LLC (Committee)

Goals:

- Define a successful bioeconomy through U.S., India, and international collaborations.
- Identify key opportunities and challenges in biotechnology and biomanufacturing.

- Explore the latest innovations and trends in industrial biomanufacturing, including emerging technologies.

Discussion Questions:

1. What are the key characteristics of a successful and sustainable future bioeconomy
2. What key policy and scientific strategies should India and the U.S. prioritize to ensure a robust and sustainable bioeconomy, as it relates to biotechnology R&D?
3. How can the U.S. and India collaborate to advance bioenergy technologies and biomanufacturing, and what role do these collaborations play in transitioning to a sustainable bioeconomy?
4. What are the challenges and opportunities in biomanufacturing that can drive the affordability and accessibility of biotherapeutics in both India and the U.S.? How can industry leaders collaborate to address these challenges?

Speakers:
Dr. K. Vijay Raghavan
Former Principal Science Advisor, Government of India
National Centre for Biological Sciences (NCBS)

Dr. Valerie Sarisky-Reed
Director, Bioenergy Technologies Office
U.S. Department of Energy (DOE)

Mr. Shreehas Tambe
Chief Executive Officer and Managing Director
Biocon Biologics Limited

Dr. Anurag Rathore
Professor, Department of Chemical Engineering
Indian Institute of Technology, Delhi

Dr. Sunil Chandran
Chief Science Officer
Impossible Foods

10:20 am ET
7:50 pm IST

Discussion

10:45 am EST
8:15 pm IST

Panel 2: What Policies and Strategies are Needed for International Cooperation?
Moderated by: Dr. Anil Sawant, Merck & Co. (Committee)

Goals:

- Identify key policies and strategies needed to enhance international cooperation in biotechnology and biomanufacturing.
- Discuss the role of government, regulatory bodies, and scientific organizations in facilitating collaborations between the U.S. and India.
- Explore best practices and case studies of international cooperation in the bioeconomy sector.

Discussion Questions:

1. What role do academic, and research institutions play in shaping international policies for biotechnology and biomanufacturing? How can India and the U.S. leverage their collaborations to influence global bioeconomy strategies?
2. What strategies align industry practices with international policies to boost global biotechnology cooperation? How can consulting firms bridge gaps between industry and policy to enhance India-U.S. collaborations?
3. What are key regulatory challenges for international collaborations, and how can India's regulatory framework evolve to better support U.S.-India biomanufacturing cooperation?
4. How can regulations be harmonized with international standards while ensuring biomanufactured products meet global standards? How can regulatory bodies balance innovation with safety in the bioeconomy?

Speakers:
Ms. Shruti Sharma
Fellow, Technology and Society Program
Chief Coordinator, Global Technology Summit
Carnegie India

Ms. Pushpa Vijayaraghavan
Director, Life Sciences Advisory, Sathguru Management Consultants
Governance Board Member, Medicines Patent Pool
Member, Therapeutics Working Group, 100 Day Mission

Dr. Ritu Nalubola
Deputy Director
Office of Policy, Legislation, and International Affairs (OPLIA)
Food and Drug Administration (FDA)

Mr. Kashish Aneja
Lead, Initiatives in Asia
O'Neill Institute for National and Global Health Law
Georgetown University Law Center

11:45 am ET
9:15 pm IST
Discussion

12:00 pm ET
9:30 pm IST
Adjourn

DAY 2: THURSDAY, AUGUST 22, 2024

9:00 am ET
6:30 pm IST
Welcome and Opening Remarks
Ms. Carmen Shaw, NASEM (Project Lead)

9:05 am ET
6:35 pm IST
Panel 3: How Can the Bioeconomy Impact Biosafety, National Security, and Trade?
Moderated by: Prof. Srividhya Ragavan, Texas A&M University (Committee)
Goals:

- Develop best practices for promoting, protecting, and sustaining bioeconomy innovation.

- Analyze the impact of global geopolitical changes related to trade, security, and regulatory exclusivity.
- Evaluate the influence of the bioeconomy on national security and export control.

Discussion Questions:

1. What are the key legal and regulatory challenges that need to be addressed to ensure that innovations in the bioeconomy contribute positively to national security without hindering global trade?
2. How can international information-sharing mechanisms be strengthened to mitigate biosafety risks and enhance national security in the bioeconomy? What role should industry and government play in this effort?
3. In what ways can global geopolitical shifts impact the bioeconomy, as it relates to trade and export controls? How should countries like India and the U.S. navigate these changes to maintain competitiveness while ensuring security?
4. What best practices can be developed to ensure that biosafety and biosecurity are prioritized in the rapid advancement of the bioeconomy?

Speakers:
Dr. Malathi Lakshmikumaran
Executive Director and Practice Head
Lakshmikumaran & Sridharan Attorneys

Ms. Whitney Bowman-Zatzkin
Co-Founder and Director
Bioeconomy Information Sharing and Analysis Center (BIO-ISAC)
Executive Director and CEO, Rare Dots, Inc.

Ms. Tessa Alexanian
Technical Lead, Common Mechanism
International Biosecurity and Biosafety Initiative for Science (IBBIS)

9:50 am ET
7:20 pm IST

Discussion

10:00 am ET
7:30 pm IST

Panel 4: What are the Drivers of R&D Accessibility and Trends in Biotechnology Investments?
Moderated by: Dr. Taslimarif Saiyed, Centre for Cellular and Molecular Platforms (C-CAMP) (Committee)

Goals:

- Identify key drivers of R&D accessibility and how they influence biotechnology investments.
- Discuss current trends and challenges in securing and allocating funding for biotechnology R&D.
- Evaluate the impact of international cooperation on enhancing R&D capabilities and investment opportunities.

Discussion Questions:

1. What are the critical factors driving R&D accessibility in biotechnology, and how do these influence investment decisions? How can public and private sectors collaborate to enhance these drivers?

2. What are the current trends and challenges in securing funding for biotechnology R&D? How can emerging markets like India attract more investments in this sector?
3. How can foundations and venture capitalists drive innovation in biotechnology R&D while ensuring accessibility and equity in research outcomes?

Speakers:
Dr. Renu Swarup
Former Secretary
Department of Biotechnology (DBT), Government of India

Dr. Megan Frisk
Director, Division for International Affairs
Advanced Research Projects Agency for Health (ARPA-H)

Dr. Premnath Venugopalan
Founder Director at Venture Center
Head, NCL Innovations, CSIR-NCL
Co-Founder and Director, Serigen Mediproducts

Dr. Stephen Chambers
Managing Director at IndieBio
General Partner at SOSV

Dr. Rajeshwari Adhiseshan
Senior Program Officer, Chemistry Manufacturing & Controls
Vaccine Development, Global Health
Bill & Melinda Gates Foundation

10:45 am ET
8:15 pm IST

Discussion

11:00 am ET
8:30 pm IST

Panel 5: What Education and Workforce Development Programs are Essential for Scaling Up Biomanufacturing and Biotechnology?
Moderated by: Dr. Jitendra Kumar, Biotechnology Industry Research Assistant Council (BIRAC)

Goals:

- Identify essential educational and training programs for developing a skilled biomanufacturing and biotechnology workforce.
- Explore strategies for integrating academic and industry partnerships to enhance workforce development and scale-up.
- Analyze the role of government, private sector, and industry collaborations in advancing talent and innovation.

Discussion Questions:

1. What are the most critical educational and training programs needed to develop a skilled workforce in biomanufacturing and biotechnology? How can these programs be designed to meet industry needs?
2. How can academic and industry partnerships be effectively integrated to enhance workforce development in biomanufacturing? What successful models or case studies can guide these efforts?

3. What role do government and private sector collaborations play in advancing workforce development and scaling innovation in the biotechnology sector?

Speakers:
Ms. Ivy Louis
Founder
Vienni Training & Consulting

Dr. Celeste Carter
Program Director
National Science Foundation (NSF)

Dr. Markandeya Gorantla
Executive Chairman & Managing Director
ATGC Biotech Pvt. Ltd

Dr. Kelvin Lee
Institute Director, National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) and Professor of Chemical & Biomolecular Engineering, University of Delaware

11:40 am ET
9:10 pm IST
Discussion

11:50 am ET
9:20 pm IST
Closing Remarks and Main Takeaways
Ms. Shefali Misra, Biocon (Co-Chair)
Dr. Deepti Tanjore, Lawrence Berkeley National Laboratory (Co-Chair)
Ms. Carmen Shaw, NASEM (Project Lead)

12:00 pm ET
9:30 pm IST
Adjourn