



BIOTECHNOLOGY COOPERATION FOR THE U.S.-INDIA INITIATIVE ON CRITICAL AND EMERGING TECHNOLOGY (iCET) WORKSHOP SERIES

In Person WORKSHOP

U.S.-India Biotechnology Cooperation: Realizing Benefits, Reducing Risks

**September 9-11, 2024
New Delhi, India**

The U.S. National Academies of Sciences, Engineering, and Medicine (NASEM), together with the Indian National Science Academy (INSA), will convene experts from both countries for two virtual workshops and one in-person workshop.

Workshop Goals and Objectives

The primary goal of this workshop series is to identify short-, medium-, and long-term opportunities for U.S.- India biotechnology cooperation consistent with the initiative on Critical and Emerging Technology (iCET) and beyond.

To accomplish this goal, workshop participants will discuss areas particularly well suited for bilateral biotechnology cooperation. For example, genomics, synthetic biology, biomanufacturing, protection of critical biotechnology data and information, knowledge exchange on relevant safety and security practices, toward developing efficient, effective, and harmonized regulatory approaches across a diversity of relevant sectors will be among the areas considered for enhanced cooperation.

Following these discussions, a peer-reviewed workshop proceedings will be published and available online free of charge.

Strategic Indo-U.S. Partnership, Strategic Biotechnology Cooperation

Day One: September 9, 2024

9:00–9:05 am Welcome and Opening Remarks

Dr. Narinder Kumar Mehra (*in person*)
Vice President for International Affairs
Indian National Science Academy and Former Dean
All India Institute of Medical Sciences, New Delhi

Dr. Jennifer Nguyen (*in person*)
Program Advisor
U.S. Department of State

Dr. Rita S. Guenther (*in person*)
Senior Program Officer (Project Lead)
U.S. National Academies of Sciences, Engineering, and Medicine

9:05–9:15 am Workshop Goals and Objectives

Dr. Michele Garfinkel (Workshop Series Planning Committee Co-Chair)
(*virtual*)
Independent Researcher

Dr. Pawan Dhar (Workshop Series Planning Committee Co-Chair)
(*in person*)
Executive Director
CVJ Centre for Synthetic Biology & Biomanufacturing

9:15–9:45 am Indo -U.S. Strategic Partnership: Maximizing the Benefits of Biotechnology Cooperation

- What are the high-level biotechnology priorities of India and the United States?
- Why India? Why the United States? In what ways does enhanced biotechnology cooperation support the strategic partnership?
- Within the broader biotechnology priorities of India and the United States, which areas are poised for the most effective and beneficial bilateral cooperation?
- As Indo-U.S. biotechnology cooperation encounters inevitable challenges, what practical, implementable solutions may be proposed?

Moderator: Dr. Ramaswamy Subramanian
(Workshop Series Planning Committee Member, *in person*)
Professor
Department of Biological Sciences
Purdue University

Dr. Dhananjay K. Tiwary (*virtual*)
Advisor
Department of Biotechnology
Ministry of Science and Technology
Government of India
Currently on Academic Leave as Senior Fellow
School of Public Health
Brown University

Dr. Jitendra Kumar (*in person*)
Managing Director
Biotechnology Industry Research Assistance Council

Dr. P. M. Murali (*virtual*)
President
ABLE Council of Presidents

K.J. Mukherjee (*in person*)
Professor
Department of Biochemical Engineering and Biotechnology
Indian Institute of Technology, Delhi

Dr. Katy Christiansen (*virtual*)
Area Deputy for Science
Head
Strategic Programs Development Group Biosciences Area
Lawrence Berkeley National Laboratory

Dr. Michael Fischer (*virtual*)
Science and Technology Policy
U.S. Department of Energy

Dr. Rajesh S. Gokhale (*invited*)
Secretary
Department of Biotechnology
Ministry of Science and Technology
Government of India

9:45–11:00 am Focusing Cooperation: The “Read, Write, Construct, Manufacture” Biotechnology Framework

- Across this biotechnology framework, which areas (e.g., multi-omics, synthetic biology, and biomanufacturing) are most promising for biotechnology cooperation?
- In particular, how can collaboration enhance techniques for optimizing production processes, scaling up from laboratory to industrial scale, and ensuring quality control and efficiency in biomanufacturing products?
- How might Indian and U.S. experts collaborate to bridge the gaps between laboratory research and practical technological applications?

Moderator: Dr. Pawan Dhar (Workshop Series Planning Committee Co-Chair)
(in person)

Executive Director

CVJ Centre for Synthetic Biology & Biomanufacturing

Dr. Blake A. Simmons *(virtual)*

Division Director

Biological Systems & Engineering

Lawrence Berkeley Lab

Dr. Guhan Jayaraman *(in person)*

Professor

Bhupat and Jyoti Mehta School of Biosciences

Indian Institute of Technology Madras

Dr. Anurag Rathore *(in person)*

Professor

Department of Chemical Engineering

Indian Institute of Technology New Delhi

Dr. Vijay Chandru Reddy *(in person)*

Co-founder and Chairman

Strand Life Sciences, Bangaluru

11:00–11:15 am Tea Break

**11:15 am –
12:30 pm**

Preparing for the Next Challenge: Pandemics and Public Health Crises

- What steps might India and the United States wish they had taken now to prepare for when the next pandemic arrives?
- What should government, industry, and academic experts in the United States and India do over the short and medium terms to ensure high-quality data collection and analysis to support sustained preparedness and rapid response?

- What government-to-government mechanisms should be established today to ensure a robust exchange of data and information in advance of and during future pandemics and public health crises?
- What actions can industry and academia take to develop and maintain the necessary infrastructure for preparing for and responding to future public health crises, including investments in R&D, building manufacturing capacity, fostering public-private partnerships, and facilitating workforce development?

Moderator: Dr. Harshini Mukundan (Workshop Series Planning Committee Member, *in person*)

*Lead, Chemical and Biological Technologies
Office of National and Homeland Security
Scientist, Biological Sciences Directorate
Lawrence Berkeley National Laboratory
Visiting Scientist, Los Alamos National Laboratory
Adjunct Professor, University of New Mexico*

Dr. Soumya Swaminathan (*in person*)
*Former Chief Scientist
World Health Organization
Former Director General and Secretary of the Department of Health Research
Indian Council of Medical Research*

Dr. Matthew Hepburn (*virtual*)
*Vaccine Development Lead
Countermeasures Acceleration Group
White House Office of Pandemic Preparedness and Response Policy*

Dr. Richard Hatchett (*virtual*)
*CEO
Coalition for Epidemic Preparedness Innovations*

Dr. Jennifer Nuzzo (*virtual*)
*Director of the Pandemic Center
Professor of Epidemiology
Brown University School of Public Health*

Dr. Narinder Kumar Mehra (*in person*)
*Vice President
Indian National Science Academy
Former Dean
All India Institute of Medical Sciences*

Dr. Anil Kaul (*in person*)
*Director
Indian Institute of Public Health*

12:30–1:30 pm Lunch Break

1:30–2:45 pm Preparing for the Next Challenge: Balancing the Risks and Rewards of Agrobiotechnology

- How can India and the United States harness their agricultural biotechnology expertise, including gene editing and advanced breeding technologies?
- What specific steps should government, industry, and academic experts in the United States and India take to ensure high-quality data collection and analysis to support sustained agricultural biotechnology development?
- What government-to-government mechanisms should be established to ensure a robust exchange of data and information across the agrobiotechnology ecosystem, particularly regarding regulatory frameworks, development of standards, and biosafety and biosecurity practices?
- What actions can industry and academia take to develop and maintain the necessary infrastructure for advancing agriculture biotechnology cooperation, including tech transfer, addressing supply chain limitations, and supporting new bio-incubation centers?

Moderator: Dr. Rajeev Nayan Bahuguna (Workshop Series Planning Committee Member, *in person*)

Scientist D

National Agri-Food Biotechnology Institute

Dr. Bharat Char (*in person*)

Chief Science Officer

Mahyco

Dr. Markandeya Gorantla (*in person*)

Executive Chairman & Managing Director

ATGC Biotech Pvt. Ltd.

Dr. Renu Swarup (*in person*)

Former Secretary

Department of Biotechnology

Ministry of Science and Technology

Government of India

Dr. Andrew Roberts (*virtual*)

Chief Executive Officer

Agriculture & Food Systems Institute

Dr. Ajay Koli (*video address*)

Deputy Director

General Research

International Rice Research Institute

2:45–3:00 pm **Tea Break**

3:00–4:15 pm **Biosafety and Biosecurity (BS/BS): Foundational Pillars of the Biotechnology Ecosystem**

- How can experts contribute to the safe and secure expansion of biotechnology cooperation, particularly in areas such as risk assessment and BS/BS principles and guidelines?
- How can knowledge be exchanged on risk assessments, biosafety, and biosecurity related to biotechnologies?
- How can the United States and India integrate biosafety and biosecurity principles from the earliest stages of biotechnology development to ensure safe and effective innovations?

Moderator: Dr. Jaishree Garhyan (Workshop Series Planning Committee Member, *in person*)

*Director
High Containment Laboratory
School of Medicine
Stanford University*

Dr. Suryesh Namdeo (*virtual*)
*Project Scientist
DST Centre for Policy Research
Indian Institute of Science*

Dr. Sarah Carter (*virtual*)
*Senior Fellow for the Bioeconomy
Federation of American Scientists*

Dr. Nancy Connell (*virtual*)
*Scholar
U.S. National Academies of Sciences, Engineering, and Medicine*

4:15–5:00 pm **Enhancing Policy Frameworks to Facilitate Biotechnology Cooperation**

- Highlighting key points from Day One discussion
- Preparing discussion for Day Two

Dr. Narinder Kumar Mehra (*in person*)
*Vice President for International Affairs
Indian National Science Academy and
Former Dean
All India Institute of Medical Sciences, New Delhi*

5:00 pm **Adjourn**

From 'In Principle' to 'In Practice'

Day Two: September 10, 2024

9:00–9:05 am Welcome and Opening Remarks

Dr. Ashutosh Sharma (*in person*)
President
Indian National Science Academy

Dr. Rita S. Guenther (*in person*)
Senior Program Officer (Project Lead)
U.S. National Academies of Sciences, Engineering, and Medicine

9:05–9:15 am Workshop Goals and Objectives

Dr. Michele Garfinkel (Workshop Series Planning Committee Co-Chair)
(*virtual*)
Independent Researcher

Dr. Pawan Dhar (Workshop Series Planning Committee Co-Chair, *in person*)
Executive Director
CVJ Centre for Synthetic Biology & Biomanufacturing

9:15–10:30 am Persistent Challenges: Right-Sizing Regulations and Setting Standards

- How can regulatory frameworks for biotechnology be streamlined while ensuring rigorous safety and efficacy standards? Which regulatory areas would benefit most from streamlining and/or right-sizing?
- What strategies can be employed to streamline the regulatory approval process for novel products and technologies? How can the United States and India collaborate to address these challenges?
- How can the U.S. and India improve coordination and harmonization of regulations and certifications to facilitate biotechnology innovation and trade?
- What adjustments are needed in regulatory processes to accommodate rapid advancements in biotechnology, such as during a pandemic, to ensure timely access to new technologies and vaccines?
- What central mechanisms could be established for tracking and updating regulatory changes

Moderator: Dr. Sumathy Kandaswamy (Workshop Series Planning Committee Member, *in person*)

Director and Head
Research and Development
Bharat Biotech Intl Ltd.

Dr. Chandrasekhar Ranga (*in person*)
Joint Drugs Controller
The Central Drugs Standard Control Organisation

Dr. Krishna Ravi Srinivas (*in person*)
Consultant
Research and Information System for Developing Countries

Dr. Anup Singh (*virtual*)
Principal Associate Lab Director
Lawrence Livermore National Lab

Dr. Rakesh Mishra (*in person*)
Director
Tata Institute for Genetics and Society

Dr. Yogendra Kumar Gupta (*invited*)
Professor
All India Institutes of Medical Sciences

10:30–10:45 am Tea Break

10:45 am – 12:00 pm Persistent Challenges: Right-Sizing Regulations and Setting Standards beyond the Biomedical Sphere

- How can regulatory frameworks for biotechnology be streamlined while ensuring rigorous safety and efficacy standards? Which regulatory areas would benefit most from streamlining and/or right-sizing?
- What strategies can be employed to streamline the regulatory approval process for novel products and technologies? How can the United States and India collaborate to address these challenges?
- How can the U.S. and India improve coordination and harmonization of regulations and certifications to facilitate biotechnology innovation and trade?
- What adjustments are needed in regulatory processes to accommodate rapid advancements in biotechnology, such as during a pandemic, to ensure timely access to new technologies and vaccines?
- What central mechanisms could be established for tracking and updating regulatory changes?

Moderator: Dr. Vibha Ahuja (Workshop Series Planning Committee Member)
(in person)
Chief General Manager
Biotech Consortium India Limited

Dr. Ratnesh Jain (*in person*)
UGC Assistant Professor
Biological Sciences and Biotechnology
Institute of Chemical Technology, Mumbai

Dr. Ashwani Pareek (*in person*)
Executive Director
National Agri-Food Biotechnology Institute

Dr. Shankar Musunuri (*virtual*)
Chairman, Chief Executive Officer, and Co-Founder
Ocugen

Dr. Chris Mungall (*virtual*)
Department Head, Biosystems Data Sciences
Computational Senior Scientist
Lawrence Berkeley National Laboratory

Dr. Rebecca Nelson (*virtual*)
Professor
School of Integrative Plant Science Plant Pathology and Plant-Microbe
Biology Section
Professor
Department of Global Development
Cornell University

Sofia Moreira Infante (*virtual*)
MPS Student
School of Integrative Plant Science
Cornell University

12:00–1:15 pm Lunch Break

1:15–2:30 pm Lessons from U.S.-Indian Biotechnology Cooperation: Case Studies

- What have been the greatest successes in bilateral biotechnology cooperation and to what can those successes be attributed?
- Likewise, what have been the most significant challenges (e.g., inconsistent funding, IP, regulatory/administrative burdens, limited prioritization of fundamental as well as upstream biomanufacturing research, scale up, supply chain resilience, gaps between academia and industry, and lack of sufficient skilled workforce)? Was it possible to surmount those challenges and if so, how?
- What lessons can be extrapolated from these experiences and, importantly, how can they be applied to future bilateral cooperation to increase success in the short, medium, and long term?

Moderator: Dr. Ramaswamy Subramanian (Workshop Series Planning Committee Member, *in person*)
Professor
Department of Biological Sciences
Purdue University

Dr. Alka Sharma (*in person*)
Health Interventions & Equity
Department of Biotechnology
Ministry of Science and Technology
Government of India

Dr. Aseem Ansari (*virtual*)
Chair
Chemical Biology & Therapeutics
R. J. Ulrich Endowed Chair
Department of Chemical Biology & Therapeutics
St. Jude Children's Research Hospital

Dr. Mohd. Ashraf Ganie (*virtual*)
Director
Sher-I-Kashmir Institute of Medical Sciences, Srinagar

Dr. Brajesh Barse (*in person*)
Director
MedTech, Lifesciences. Food & Agriculture
U.S. India Business Council

Dr. Srividhya Ragavan (*in person*)
Professor of Law and Director of India Programs
Texas A&M University School of Law

Shripathi Ravindra Bhat (*in person*)
Former Judge
Supreme Court of India

Dr. Taslim Syed (*virtual*)
Director and CEO
C-Camp, Bangaluru

2:30 – 2:45 pm Tea Break

2:45–4:15 pm **Concurrent Break Out Sessions**

Session 1: Spreading the Wealth: Aligning Funding with Research, Commercialization, and Scale-up Needs

Session 2: Closing the Gap: Developing a Robust Biotechnology Workforce

Session 3: IT's Coming: AI and the Future of Biotechnology

Dr. Sanjay Mishra (*in person*)
Senior Advisor
Department of Biotechnology
Ministry of Science and Technology
Government of India

Dr. Nivedita Gupta (*in person*)
Head of Virology
Indian Council of Medical Research

4:15–5:00 pm **Safe and Secure Science-Driven Cooperation**

- Highlighting key points from Day Two discussion
- Preparing discussion for Day Three

Dr. Pawan Dhar (Workshop Series Planning Committee Co-Chair)
(*in person*)
Executive Director
CVJ Centre for Synthetic Biology & Biomanufacturing

5:00 pm **Adjourn**

Sustaining Partnership and Sustaining iCET

Day Three: September 11, 2024

9:00–9:05 am Welcome and Opening Remarks

Dr. Narinder Kumar Mehra (*in person*)
Vice President for International Affairs
Indian National Science Academy and
Former Dean
All India Institute of Medical Sciences, New Delhi

9:05–9:15 am Workshop Goals and Objectives

Dr. Michele Garfinkel (Workshop Series Planning Committee Co-Chair)
(*virtual*)
Independent Researcher

Dr. Pawan Dhar (Workshop Series Planning Committee Co-Chair)
(*in person*)
Executive Director
CVJ Centre for Synthetic Biology & Biomanufacturing

9:15–10:30 am Breakout Group Reports: Charting the Path Forward with Pragmatic and Practical Steps

- Which steps need to be taken and by whom in the short, medium, and long term to strengthen biotech cooperation?
- How will routine and anticipated challenges be overcome?
- How will successes be reported and shared? To whom?
- How will lessons learned be broadly shared and applied?

10:30–10:45 am Tea Break

10:45 am – 12:00 pm Capstone Panel: Sustaining Indo-U.S. Biotechnology Cooperation through iCET

- Within the broader biotechnology priorities of India and the United States, which areas are poised for the most effective and beneficial bilateral cooperation?
- How can these bilateral priorities be enhanced and supported via iCET?
- What factors contribute to the success of the most productive ongoing iCET efforts, and how can these features be leveraged to strengthen biotechnology cooperation?
- What practical and implementable solutions can be proposed to address the known and anticipated challenges in sustaining Indo-U.S. biotechnology partnerships?

Moderator: Dr. Pawan Dhar (Workshop Series Planning Committee Co-Chair)
(in person)
Executive Director
CVJ Centre for Synthetic Biology & Biomanufacturing

Mr. Mohit Tewari *(in person)*
Director
National Security Council Secretariat
Government of India

Mr. Lekhan Thakkar *(in person)*
Joint Secretary
National Security Council Secretariat
Government of India

Ms. Shwetha Rao B *(in person)*
Director
National Security Council Secretariat
Government of India

Dr. Sanjay Mishra *(in person)*
Senior Advisor
Department of Biotechnology
Ministry of Science and Technology
Government of India

Ms. Shruti Sharma *(in person)*
Fellow
Technology and Society Program
Carnegie India

Dr. Kelly Seagraves *(invited)*
Senior Advisor
Office of the Special Envoy for Critical and Emerging Technology
U.S. Department of State

**12:00–
12:30 pm**

Closing Remarks

Dr. Ashutosh Sharma *(in person)*
President
Indian National Science Academy

Dr. Jennifer Nguyen *(in person)*
Program Advisor
U.S. Department of State

Dr. Michele Garfinkel (Workshop Series Planning Committee Co-Chair)
(virtual)
Independent Researcher

Dr. Pawan Dhar (Workshop Series Planning Committee Co-Chair)
(in person)
Executive Director
CVJ Centre for Synthetic Biology & Biomanufacturing

12:30–1:30 pm **Lunch Break**

1:30–4:00 pm **Site Visit**

4:00 pm **Adjourn**