

South Asia Biosafety Program

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INDIA Biotechnology Cooperation for the U.S.-India Initiative on Critical and Emerging Technology (iCET): A Workshop Series

Dr. Vibha Ahuja, Chief General Manager, Biotech Consortium India Limited, New Delhi

The U.S. National Academies of Sciences, Engineering, and Medicine, together with Indian partners, convened experts from both countries for two virtual workshops and one in-person workshop. The primary goal

of this workshop series was 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.



Dr. Jitendra Kumar, Managing Director, Biotechnology Industry Research Assistance Council (BIRAC) and Dr. Pawan K. Dhar, Chief Executive Officer, CVJ Centre for Synthetic Biology and Biomanufacturing, attending the workshop (9 September 2024).

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About the U.S.-India initiative on Critical and Emerging Technology (iCET)

United States President Joseph Biden Jr. and Indian Prime Minister Narendra Modi announced the establishment of iCET to elevate and expand the strategic technology partnership and defence industrial cooperation between the governments, businesses, and academic institutions of the two countries by fostering an open, accessible, and secure technology ecosystem, based on mutual trust and confidence, that will reinforce democratic values and institutions.

More information about the workshop series is available at:

<https://www.nationalacademies.org/our-work/scientific-support-to-india-u-s-cooperation-on-biosafety-and-biosecurity-workshop-series>

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Group photo of participants at the workshop (9 September 2024).

The topics and dates for activities under the workshop series are listed below.

- **Virtual Workshop 1:** Maximizing the Potential for Bilateral Collaboration - Opportunities for Biotechnology Cooperation (28 August 2024)
- **Virtual Workshop 2:** Critical and Emerging Biotechnologies - Scientific Landscape in India and the United States (30 August 2024)
- **In-Person Workshop:** U.S.-India Biotechnology Cooperation - Realizing Benefits, Reducing Risks (9-11 September 2024, New Delhi, India)

Participants in the workshop series included senior experts from the government, academia, industry, and independent organizations from both India and the USA.

Participants in the workshop series included senior experts from the government, academia, industry, and independent organizations from both India and the USA. During these meetings, participants discussed areas of bilateral cooperation, including genomics, synthetic biology, bioprocessing, next generation sequencing, protection of critical biotechnology information, and efficient and effective regulatory approaches across a diversity of relevant sectors.

Dr. Vibha Ahuja, Chief General Manager, Biotech Consortium India Limited (BCIL) and Dr. Andrew Roberts, Chief Executive Officer, Agriculture & Food Systems Institute (AFSI) participated and shared their views, including experiences from the South Asia Biosafety Program.

INDIA

Recent Initiatives on Data Acceptance by the Indian Drug Regulatory Authority

Dr. Arlene Asthana Ali, Senior Project Executive, Biotech Consortium India Limited

The Central Drug Standard Control Organization (CDSCO), India's drug regulatory authority, recently allowed the acceptance of certain data from other countries, in a move to streamline the drug approval process in India and reduce redundant testing, while maintaining international safety standards.

Below are the two notifications issued by the Drugs Controller General (India):

1. **Circular No. 12-01/24-DC(Pt-104)**, dated 29 July 2024: In the case of New Drugs, Subsequent New Drugs (SNDs) and Fixed Dose Combinations (FDCs), excluding biological products and Investigational New Drugs (INDs), repeated dose toxicity studies in India might not be necessary if equivalent data as per specifications in the New Drugs and Clinical Trials (NDCT) Rules, 2019 has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug, except in cases where there are specific concerns in writing. It has been indicated that the acceptance of this data will depend on its quality and the credibility of the laboratory where it was generated.
2. **Order No. DC-DT-15011(11)/85/2024**, dated 7 August 2024: It has been indicated that the requirement for clinical trials in India be waived if the drugs are approved in the United States, United Kingdom, Japan, Australia, Canada, and European Union. Drugs that fall in the following categories will be considered under the waiver— orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, new drugs used for special defence purposes, and new drugs having significant therapeutic advances over the current standard care. The new move aims to expedite the availability of life-saving drugs and reduce costs.

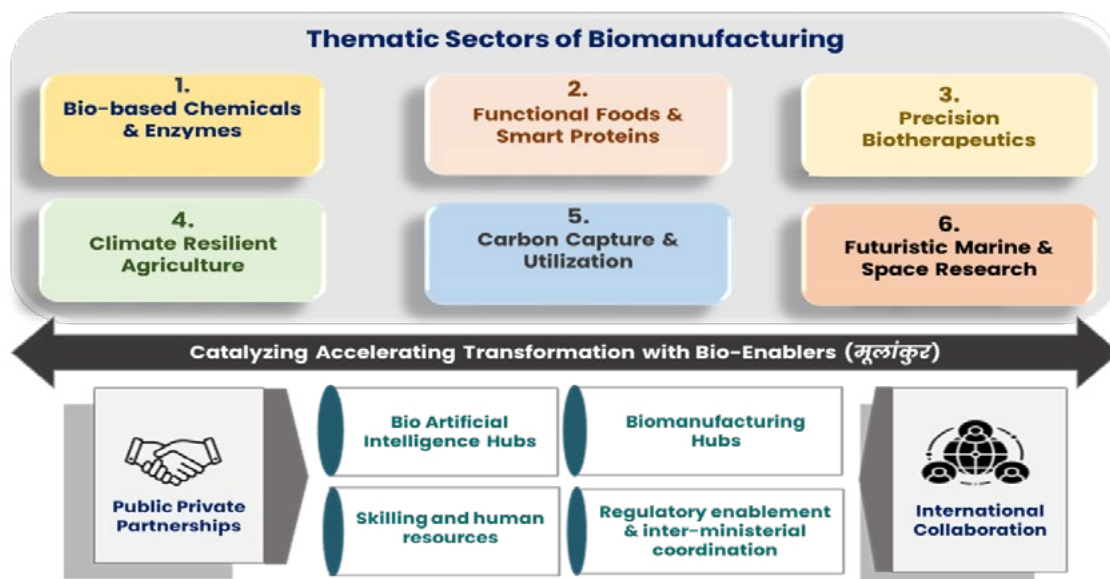
The notifications issued by CDSCO are available at:

Circular No. 12-01/24-DC(Pt-104) - https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE00TA

Order No. DC-DT-15011(11)/85/2024 - https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTE10DI

India's New BioE3 Policy for Fostering High-Performance Biomanufacturing

Dr. Arlene Asthana Ali, Senior Project Executive, Biotech Consortium India Limited



Overview of the BioE3Policy 2024.

An integrated *Biotechnology for Economy, Environment and Employment (BioE3) Policy* for fostering high-performance biomanufacturing was released to facilitate a green, clean, prosperous, and self-reliant Bharat. The *BioE3 Policy* provides a framework to empower Indian institutions, universities, startups, and industries to engage in transformative innovations by:

- Intensifying research and innovation to address challenges, such as climate change mitigation and achieving de-carbonization.
- Boosting domestic biomanufacturing capability by enabling synergy between science, technology, engineering, and manufacturing
- Accelerating the transition to biomanufacturing by promoting integrated use of artificial intelligence (AI) and digitalization with “omics” and upstream biotechnology innovations.
- Setting up the facilities (biomanufacturing hubs/biofoundries/bio-AIs) for scaling-up and pre-commercial manufacturing, co-located with resources and infrastructure for fostering high-performance biomanufacturing
- Nurturing a highly skilled workforce.

The overall objective is to set forth a framework that ensures the adoption of cutting-edge advanced technologies, accelerate the development and production of bio-based high-value products, and align innovative research aimed at revolutionizing biomanufacturing processes for enhanced efficiency, sustainability, and quality.

The *BioE3 Policy* proposes to catalyze these research and translational activities through “Bio-Enablers” in six thematic sectors, viz. high-value bio-based chemicals, biopolymers and enzymes, functional foods and smart proteins, precision biotherapeutics, climate resilient agriculture, carbon capture and its utilization, and marine and space research. Strategies to promote biomanufacturing in the country *inter alia* also include addressing regulatory roadblocks for the biomanufacturing of genetically modified organism-based processes.

The policy emphasizes the need for strategy reforms harmonized with regulatory reforms and global standards for facilitating the production and commercialization of novel bio-based products. It has been emphasized that regulatory reforms should maintain the same stringency but ensure an increase in the pace at which these products can reach the market. This *BioE3 Policy* will enhance inter-ministerial coordination to ensure the fostering of an enabling environment with seamless integration of biosafety and biosecurity considerations.

LINK



The full text of the policy can be accessed at:
https://static.investindia.gov.in/s3fs-public/2024-09/bioe3_policy.pdf

CALENDAR OF EVENTS

EVENT	ORGANIZED BY	DATE	WEBSITE
INDIA			
ThinkAg Harvesting Tomorrow Summit 2024	ThinkAg	24-26 September 2024 Goa	https://thinkag.co.in/harvesting-tomorrow-summit/
Hands-On Training on Genome Editing Technologies in Crops	ICAR-Indian Institute of Rice Research (IIRR)	14 – 23 October 2024 Hyderabad	https://www.icar-iirr.org/index.php/en/
Hands-On Training Program on Plant Tissue Culture & Transgenics	Gujarat Biotechnology Research Centre (GBRC) and the Indian Institute of Technology	14-25 October 2024 Gandhinagar	https://io.gbrc.res.in/ptc
International Conference on Trailblazing Trends in Sustainable Climate Resilient Precision Agriculture Through Artificial Intelligence and Remote Sensing	Centre of Excellence on Soil & Water Management Research Testing and Training Centre at Junagadh Agricultural University	23-24 January 2025 Junagadh	https://www.ictpairs.in/
National Conference-cum-Workshop on Sustainable Biotech Solutions for Global Challenges	Jamia Hamdard University	19-21 February 2025 New Delhi	http://jamiahamdard.edu
INTERNATIONAL			
Informational Webinar on Risk Assessment and Risk Management: Looking Ahead to CP-MOP 1	Korea Institute for Promoting Asia Biosafety Cooperation (KIPABiC), in collaboration with UNEP and Bangladesh, India, Mongolia, and the Philippines	27 September 2024 Virtual	https://us06web.zoom.us/webinar/register/WN_IPctheemTyCWStzzkYiySw#/registration
Global Capacity-Building Workshop on Operationalizing Access and Benefit-Sharing National Frameworks under the Nagoya Protocol	CBD Secretariat	30 September-3 October 2024 Bonn, Germany	https://www.cbd.int/meetings/NP-CB-WS-2024-01
11 th Meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety	CBD Secretariat	21 October-1 November 2024 Cali, Colombia	https://www.cbd.int/conferences/2024
Biosafety Clearing-House Training Workshop	CBD Secretariat	26 October 2024 Cali, Colombia	https://www.cbd.int/meetings/CP-BCH-WS-2024-01
Asian Seed Congress 2024	Asia & Pacific Seed Alliance (APSA) and the China National Seed Trade Association (CNSTA)	2-6 December 2024 Sanya, China	https://web.apsaseed.org/asc2024



SOUTH ASIA
BIOSAFETY PROGRAM

The South Asia Biosafety Program (SABP) is an international development program implemented in India and Bangladesh by the Agriculture & Food Systems Institute (AFSI). SABP aims to work with national governmental agencies and other public sector partners to facilitate the implementation of transparent, efficient, and responsive regulatory frameworks for products of modern biotechnology that meet national goals as regards the safety of novel foods and feeds, and environmental protection.



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