

BIOMANUFACTURING: SCIENCE & TECHNOLOGY

NEWS: AI and biomanufacturing: can India's policies match its ambitions?

WHAT'S IN THE NEWS?

India is emerging as a global biomanufacturing hub, particularly in vaccine production, and is now integrating Artificial Intelligence (AI) to enhance efficiency, innovation, and precision in the sector. However, policy gaps, lack of infrastructure, and ethical concerns around AI regulation pose significant challenges to scaling AI-powered biomanufacturing.

What is Biomanufacturing?

- Biomanufacturing involves the use of biological systems such as living cells, enzymes, or microorganisms to produce commercially valuable products.
- Products include vaccines, monoclonal antibodies, antibiotics, enzymes, biodegradable plastics, biofuels, and nutraceuticals.
- Modern biomanufacturing blends traditional biotechnology with cutting-edge tools like synthetic biology and artificial intelligence (AI).
- It plays a transformative role in sectors like healthcare (biopharmaceuticals), agriculture (bio-fertilizers), food processing, and materials science.

India's Strength in Biomanufacturing

- India produces over 60% of the global vaccines — including those for measles, rubella, and COVID-19 — affirming its nickname as the "Pharmacy of the World".
- Home to over 5,300 biotechnology startups as of 2024, India has a growing biotech innovation ecosystem.
- Major hubs include Hyderabad, Bengaluru, Pune, and NCR, supported by biotechnology parks, academic institutions, and DBT initiatives.

Role of AI in Biomanufacturing

- **AI-Powered Process Optimization:**
 - AI can optimize bioreactor conditions like temperature, pH, and oxygen levels for higher yield and quality.
 - Machine learning algorithms monitor real-time data to reduce waste and energy usage.
- **Accelerated Drug Discovery & Vaccine Design:**
 - AI expedites drug design by simulating protein-drug interactions and predicting the best candidates.

- During pandemics, AI helped fast-track mRNA vaccine design using viral genome sequences.
- **Smart Manufacturing and Predictive Maintenance:**
 - AI forecasts equipment failures, schedules maintenance, and minimizes downtime.
 - Robotics combined with AI handle precision tasks like cell culture, improving consistency and sterility.
- **Supply Chain Efficiency:**
 - AI platforms manage inventory, predict demand spikes, and optimize cold-chain logistics.
 - When integrated with blockchain, AI can ensure traceability and safety across supply chains.

Challenges in AI-Biomanufacturing Integration in India

- **Fragmented Regulatory Framework:**
 - India lacks a consolidated regulatory regime for AI in biotech, leading to delays and uncertainty.
 - Ethical issues in AI-generated biotech applications (e.g., synthetic DNA) need legal clarity.
- **High Capital and Infrastructure Gaps:**
 - AI-based biomanufacturing is capital intensive due to costs in robotics, sensors, cloud computing, and biofoundries.
 - Startups often struggle with funding for scale-up due to long gestation periods and IP risks.
- **Workforce and Skill Gap:**
 - There is a scarcity of talent trained in both biology and data science.
 - Workforce upskilling in computational biology, systems biology, and bio-AI interface is needed urgently.
- **Intellectual Property and Data Ownership Issues:**
 - AI-assisted inventions challenge traditional patent frameworks — who owns the innovation: the algorithm, the developer, or the biotech firm?
 - Bio-data security and ownership also remain unresolved.

Key Government Initiatives

- **National Biomanufacturing Policy (Draft):**

- Aims to reduce India's dependency on petrochemical-based inputs by promoting bio-based alternatives.
- Encourages green chemicals, bioplastics, and fermentation-derived products.
- **Biomanufacturing Mission (2023):**
 - Focus on indigenous production, biofoundry development, international collaboration, and investment attraction.
- **PLI Scheme for Biotech Sector:**
 - Provides incentives for domestic production of high-value biotech products like enzymes, fermentation products, and biosimilars.
- **Academic-Industrial Synergy:**
 - Institutions like IITs, IISc, and Biotech Parks are now actively involved in pilot production, incubation, and translational research.

Policy Recommendations

- **Create a Unified AI-Biotech Regulatory Framework:**
 - Integrate AI and bioethics into existing biosafety regulations (DBT, CDSCO).
 - Form an inter-ministerial task force to oversee emerging AI-biotech innovations.
- **Foster Public–Private Partnerships (PPPs):**
 - Offer tax credits, risk-sharing models, and venture funding for bio-AI startups.
 - Collaborate with global biomanufacturing hubs (e.g., US, Singapore, Germany) for knowledge exchange.
- **Strengthen AI & Biotech R&D:**
 - Develop genomic databases and bioinformatics infrastructure.
 - Support AI tools for rapid prototyping of enzymes, proteins, and vaccines.
- **Use AI for Compliance and Oversight:**
 - AI can automate regulatory processes like biosafety compliance, GMP tracking, and adverse event monitoring.

Road Ahead

- Invest in national biofoundries with open-access infrastructure for synthetic biology startups.
- Encourage circular economy models in biomanufacturing (waste-to-biofuel, bio-remediation).

- Reform IP laws to accommodate AI-generated innovations while protecting national bio-resources.
- Ensure that AI-driven biomanufacturing becomes socially inclusive by enabling affordable access to innovations in healthcare, food, and energy.

Source: <https://www.thehindu.com/sci-tech/science/ai-in-biomanufacturing-can-india-policies-match-ambitions/article69697013.ece>