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UNIVERSITY

## ENVIRONMENTAL STUDIES AND LIFE SCIENCES

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## BIOENTREPRENEURSHIP

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Department of Biotechnology

- An entrepreneur is a person who starts an enterprise.
- An entrepreneur is someone who perceives opportunity, organizes resources needed for exploiting that opportunity and exploits it.
- Characteristics of an entrepreneur include spontaneous creativity, the ability and willingness to make decisions in the absence of solid data, and a generally risk-taking personality.
- An entrepreneur may be driven by a need to create something new or build something tangible.

- Entrepreneurship can be described as a process of action an entrepreneur undertakes to establish his enterprise.
- Entrepreneurship is a creative activity.
- It is the ability to create and build something from practically nothing.
- It is a knack of sensing opportunity where others see chaos, contradiction and confusion.
- Entrepreneurship is the attitude of mind to seek opportunities, take calculated risks and derive benefits by setting up a venture.
- It comprises of numerous activities involved in conception, creation and running an enterprise.
- According to Peter Drucker, Entrepreneurship is defined as 'a systematic innovation, which consists in the purposeful and organized search for changes, and it is the systematic analysis of the opportunities such changes might offer for economic and social innovation.'

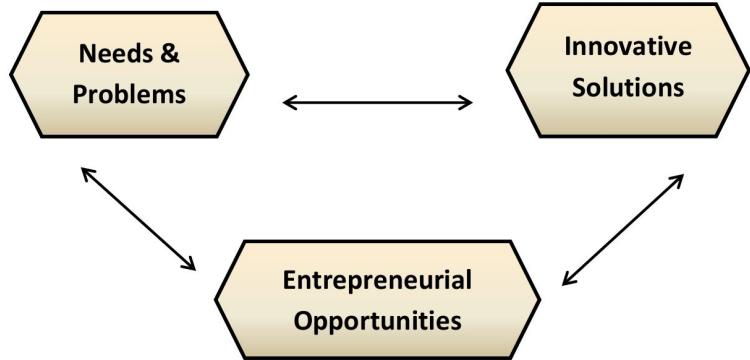
The entrepreneurial role encompasses the following responsibilities:

- Perception of market opportunities
- Gaining command over scarce resources
- Purchasing inputs
- Marketing the products
- Dealing with bureaucrats
- Managing human relations within the firm
- Managing customer and supplier relations
- Managing finance
- Managing production
- Acquiring and overseeing assembly of the factory
- Industrial engineering
- Upgrading process and product
- Introducing new production techniques and products

## Competencies of an Entrepreneur:

- Initiative
- Creativity and Innovation
- Risk Taking and Risk Management
- Problem Solving:
- Leadership
- Persistence
- Quality Performance
- Information Seeking
- Systematic Planning
- Persuasion and Influencing Others
- Enterprise Launching Competencies
- Enterprise Management Competencies

- Bioentrepreneurship can be described as creation of wealth derived from the application of the biosciences to the business context.
- Bioentrepreneurs look for commercial value in every aspect of technology that they utilize.
- Innovativeness is vital to the creation of a biotechnology venture while credibility remains the backbone of the bioentrepreneur's character.
- The challenges of financing from venture capitalists prove to be a constant struggle for the bioentrepreneur.
- Similarly, risk-taking comes from dealing with the uncertainties of R&D, a rapidly evolving marketplace and the nebulous field of intellectual property.



- i) Opportunity spotting by analyzing the needs and problems that exist in the environment
- ii) Evaluating the ideas received from different sources to find a creative solution
- iii) Identifying a product or service through innovation
- iv) Setting up a project and nurturing it to success.

Bioentrepreneurship is a dynamic and multifaceted field that sits at the intersection of biotechnology, business, and innovation. It encompasses the art and science of transforming scientific discoveries into viable commercial ventures.

- Bioentrepreneurship bridges the gap between laboratory research and market-ready products. It thrives on the synergy between scientific breakthroughs and entrepreneurial vision.
- Bioentrepreneurs must navigate complex regulatory pathways. Approvals from agencies like the FDA (Food and Drug Administration) are critical for product commercialization.
- Startups in the biotech sector face inherent risks—scientific, financial, and operational. Bioentrepreneurs must embrace uncertainty and adapt swiftly.
- Collaboration is key. Bioentrepreneurs forge partnerships with academia, industry, and other startups. Academic institutions provide research expertise, while industry partners offer market insights and distribution channels.

- Bioentrepreneurs thrive in innovation hubs, such as bioclusters, incubators, and accelerators. These ecosystems provide mentorship, infrastructure, and networking opportunities.
- Bioentrepreneurship isn't just about profits; it's about improving lives. Ethical considerations are paramount. Balancing profit motives with patient welfare and environmental sustainability is a delicate act.

## **Understanding the BioTech Industry**

Biotechnology at its core involves harnessing biological processes, genetic information, and cellular machinery to create novel solutions. Biotech ventures must navigate the complex terrain of intellectual property, regulatory approvals, and market dynamics.

## Market Research and Opportunity Assessment

In the dynamic landscape of biotech startups, market research and opportunity assessment play a pivotal role in shaping the trajectory of entrepreneurial ventures. These twin pillars provide the foundation upon which bioentrepreneurs can make informed decisions, allocate resources effectively, and identify gaps ripe for innovation.

## Forming Biotech Startup Team

1. Identify the necessary expertise
2. Seek complementary skill sets
3. Emphasize domain knowledge
4. Foster a culture of collaboration
5. Prioritize passion and commitment

## Navigating Regulatory Challenges

### 1. Understanding the Regulatory landscape:

Regulatory bodies such as the FDA (U.S. Food and Drug Administration), EMA (European Medicines Agency), and PMDA (Pharmaceuticals and Medical Devices Agency) in Japan play a pivotal role in ensuring patient safety, efficacy, and quality.

### 2. Clinical Trials and Data Requirements:

Conducting robust clinical trials is essential for regulatory approval. Startups must design trials that demonstrate safety, efficacy, and statistical significance.

### 3. Quality Systems and Manufacturing Compliance:

Ensuring product quality and consistency is paramount. Startups must adhere to cGMP (current Good Manufacturing Practices).

### 4. Market Access and Reimbursement:

Regulatory approval doesn't guarantee market access. Payers evaluate cost-effectiveness and clinical utility.

### 5. Post-Market Surveillance and Pharmacovigilance:

Monitoring product safety after launch is critical. Adverse events, labeling updates, and real-world evidence shape post-market decisions.

## Funding Strategies for Biotech Ventures

### 1. Venture Capital (VC) Funding:

Venture capital remains a popular choice for biotech startups seeking substantial capital injections. VCs invest in early-stage companies with high growth potential.

### 2. Angel Investors:

Angels are high-net-worth individuals who invest their personal funds in startups. They often provide mentorship and industry connections.

### 3. Government Grants and subsidies:

Many governments offer grants, tax incentives, and subsidies to promote biotech innovation.

### 4. Strategic Partnerships and collaborations:

Partnering with established pharma companies, research institutions, or other startups can provide funding and resources.

### 5. Crowdfunding and Tokenization:

Crowdfunding platforms allow the public to invest small amounts. Tokenization leverages blockchain for fractional ownership.

### 6. Debt Financing:

Biotech startups can secure loans or issue bonds.

## Intellectual Property and Technology Transfer

Intellectual Property and technology transfer play pivotal roles in the biotech startup landscape, shaping the trajectory of innovation, commercialization, and competitiveness.

### IP Protection Strategies:

- Patents: Bioentrepreneurs seek patent protection for their novel inventions, whether it's a groundbreaking therapeutic molecule, a diagnostic assay, or a gene-editing tool. Patents grant exclusive rights to the inventor, preventing others from making, using, or selling the invention without permission.
- Trade Secrets: While patents provide public disclosure, trade secrets remain confidential. Bioentrepreneurs may safeguard proprietary information related to formulations, manufacturing processes, or clinical trial data.
- Copyrights: Beyond patents, copyrights protect creative works such as software code, scientific publications, and educational materials. Bioinformatics tools, for instance, rely on copyrighted algorithms. Startups should navigate licensing agreements and fair use principles.
- Trademarks: Branding matters. A distinctive trademark can differentiate a biotech startup in a crowded market.

## Tech Transfer Offices (TTOs):

- Universities and research institutions serve as fertile grounds for biotech innovation. TTOs bridge academia and industry, facilitating the transfer of knowledge and technologies.

## Licensing and Spin-Offs:

- Licensing agreements enable startups to access patented technologies developed elsewhere. Consider a biotech company licensing a promising cancer drug candidate from a research institute. These agreements define royalties, milestones, and sublicensing terms.

## Challenges and Ethical considerations:

- Balancing openness and protection: Bioentrepreneurs must decide when to publish research findings versus keeping them confidential. Early disclosure can attract investors but risks weakening IP.

## BioAsia 2024 honours 5 startups revolutionising healthcare in India

29 February 2024 | News

Amidst the vibrant atmosphere at BioAsia 2024 in Hyderabad, the spotlight shone brightly on five exceptional startups, out of 75 recognised nationwide, for their groundbreaking innovations in the healthcare sector. These top innovators were honoured for their outstanding contributions to advancing healthcare access, revolutionising technology, and enhancing patient care.

**Plebc Innovations Pvt Ltd:** This pioneering startup founded by Dr Krishna Prasad, is making waves with its teleoperated robotic ultrasound system, poised to revolutionise healthcare access in rural areas.

**ZedBlox ActiPod:** Leading the charge in cold chain solutions for healthcare, ZedBlox ActiPod led by Rao Korupolu - Co-Founder, CEO, has emerged as a trailblazer in developing unbreakable cold chain solutions.

**UR Advanced Therapeutics Pvt Ltd:** Spearheading innovation in biomaterials for tissue engineering, UR Advanced Therapeutics founded by Adinarayana Reddy Yerrapureddy and Reddy, focuses on endoregenerative cornea, offering transformative solutions for ocular health.

**Descign:** Harnessing the power of artificial intelligence, Descign from Hyderabad founded in 2020 by Dr Vishal Gupta, is at the forefront of digitalising life sciences and healthcare.

**Lamark Biotech:** Dedicated to bringing life-saving medicines within reach globally, Lamark Biotech from Tamil Nadu, led by Vaibhav Bhatia Ph.D., Co-Founder, Chief Executive Officer, is making significant strides in pharmaceutical innovation.

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Devised to transform India into a global innovation and manufacturing hub, GoI launched 'Make In India' program in September 2014.

DBT recognizes the necessity for entrepreneurship development among the youth in the country and hence has taken initiatives to build, support and promote Indian biotech ecosystem in healthcare, agriculture and industrial biotechnology by delegating responsibility to its Public Sector Enterprise, Biotechnology Industry Research Assistance Council (BIRAC) to establish a Make in India Facilitation Cell for Biotechnology Sector in 2016 with the following mandate:

- Facilitating Investments
- Fostering Innovations
- Protecting Intellectual Property
- Building best in class infrastructure
- Ease of doing Business
- Providing Employment in Manufacturing Sector
- State Partnerships to Expand Biotech Innovation Ecosystem
- Create Global Start-ups Connect





The infographic is titled "MAKE IN INDIA Biotechnology". It begins with a hand interacting with a cluster of colorful gears. Below this is a statement: "Make in India initiative was launched in 2014 by Hon'ble Prime Minister of India, Sh. Narendra Modi". The main content is presented in a list of eight items, each with an icon:

- Facilitating Investments (₹ symbol)
- Fostering Innovations (lightbulb icon)
- Protecting Intellectual Property (padlock icon)
- Building best in class infrastructure (gears icon)
- Ease of doing Business (handshake icon)
- Providing Employment in Manufacturing Sector (people icon)
- State Partnerships to Expand Biotech Innovation Ecosystem (globe icon)
- Create Global Start-ups Connect (globe icon)

\*Make in India Facilitation Cell for Biotechnology has been established at BIRAC by Deptt. of Biotechnology.

## Global Competitiveness of INDIA

India's ranking in Global Biotech Sector



## Enabling Policies at Center & State level

\$150 Bn Bioeconomy by FY 2024-25

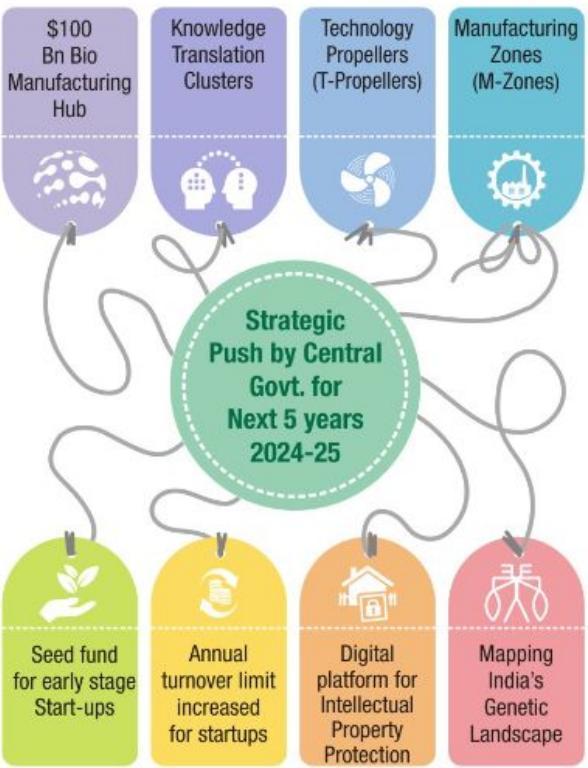
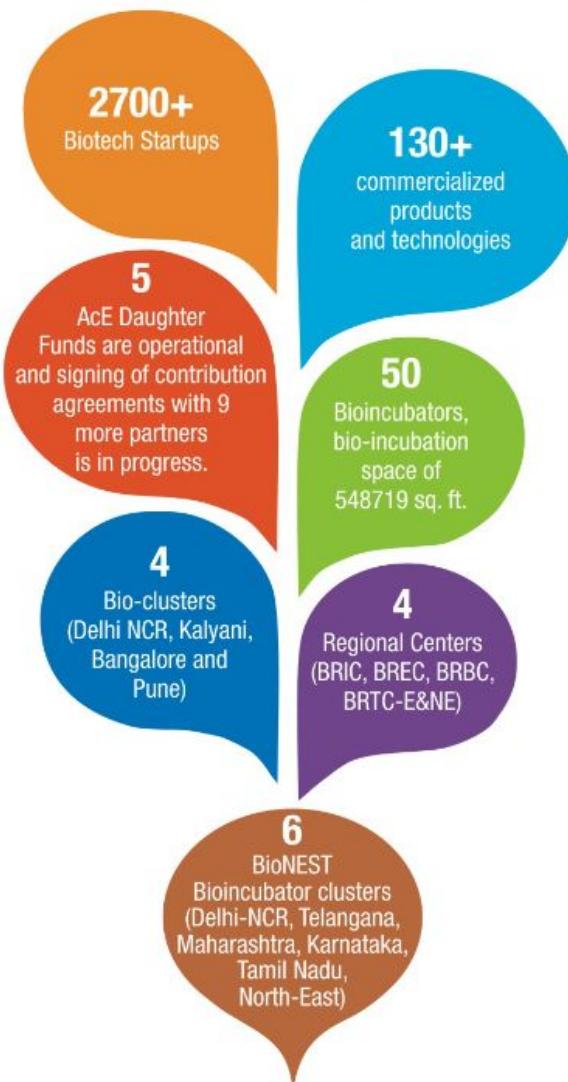
### Regulatory Policies at National/State level

- National Biotechnology Development Strategy 2015-2020
- FDI Policy 2017
- Medical Devices Rules 2017
- National Policy on Biofuels 2018
- Guidelines for Evaluation of Nano pharmaceuticals in India 2019
- National Guidelines for Gene Therapy, Product Development & Clinical Trials 2019
- Guidelines on Similar Biologics 2016

### Skill Developmental Policies

- Pradhan Mantri Kaushal Vikas Yojana Guidelines (2016-2020)
- Scheme for Facilitating Startups Intellectual Property Protection (SIPP) 2017
- National INNOVATION and STARTUP Policy 2019 for Students and Faculty in center

## STARTUP INDIA ACHIEVEMENTS





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## THANK YOU

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