



ОБЩЕСТВЕННОЕ ЗДОРОВЬЕ И ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ, СОЦИОЛОГИЯ И ИСТОРИЯ МЕДИЦИНЫ/PUBLIC HEALTH AND HEALTHCARE ORGANIZATION, SOCIOLOGY AND HISTORY OF MEDICINE

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TECHNOLOGICAL ENTREPRENEURSHIP IN MEDICAL BIOTECHNOLOGY: FOUNDATIONS, EDUCATIONAL PROJECTIONS, GLOBAL AND RUSSIAN PRACTICE

Review article

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Abstract

Technological entrepreneurship in biomedicine is a key driver for translating fundamental discoveries into commercial products. However, this global process is characterized by extreme risks, high capital intensity, and a complex regulatory environment. In Russia, despite a robust scientific foundation and state support, systemic barriers persist that necessitate the formation of a holistic innovation ecosystem.

To conduct a systematic review of the foundations, educational projections, and global and Russian practices of technological entrepreneurship in medical biotechnology to develop consolidated conclusions and recommendations for industry development.

A systematic review of 34 sources — including scientific articles, analytical reports, strategic documents, and publications in peer-reviewed journals and professional media — was performed. Source search and selection followed PRISMA guidelines, with emphasis on works published between 2015 and 2025. Qualitative content analysis with thematic categorization was applied, focusing on conceptual foundations, integration into education, global trends, and the specifics of the Russian market.

The essence and distinctive features of technological entrepreneurship in biomedicine are defined. Contemporary network models, open innovation strategies, and the role of venture financing are analyzed. Global trends (Pharma 4.0) and the practices of industry leaders (Bayer, AstraZeneca) are identified. Based on the analysis of Russian case studies (Vector-Best, BIOCAD, R-Pharm), both strengths (scientific foundation, state policy) and systemic challenges (the “valley of death,” lack of private capital, regulatory fragmentation) are revealed.

The development of technological entrepreneurship in Russia requires a comprehensive ecosystem approach that includes the consolidation of state efforts, stimulation of private investment, transformation of education, and active integration into global open innovation networks to achieve technological sovereignty.

Keywords: technological entrepreneurship, medical biotechnology, educational programs, commercialization, open innovation, venture financing, ecosystem.

ТЕХНОЛОГИЧЕСКОЕ ПРЕДПРИНИМАТЕЛЬСТВО В СФЕРЕ МЕДИЦИНСКИХ БИОТЕХНОЛОГИЙ: ОСНОВЫ, ОБРАЗОВАТЕЛЬНЫЕ ПРОЕКЦИИ, МИРОВАЯ И РОССИЙСКАЯ ПРАКТИКА

Обзор

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Аннотация

Технологическое предпринимательство в биомедицине является ключевым драйвером трансфера фундаментальных открытий в коммерческие продукты. На мировом уровне данный процесс характеризуется экстремальными рисками, капиталоемкостью и сложной регуляторной средой. В России, несмотря на сильный научный задел и государственную поддержку, сохраняются системные барьеры, требующие формирования целостной инновационной экосистемы.

Провести системный обзор основ, образовательных проекций, глобального и российского опыта технологического предпринимательства в сфере медицинских биотехнологий для выработки консолидированных выводов и рекомендаций по развитию отрасли.

Для достижения цели был проведен систематический обзорный анализ 34 источников, включая научные статьи, аналитические доклады, стратегические документы и публикации в рецензируемых журналах и профессиональных медиа. Поиск и отбор источников осуществлялся на основе принципов PRISMA, с акцентом на работы за период



2015–2025 гг. Был проведен качественный контент-анализ с категоризацией по ключевым темам: концептуальные основы, интеграция в образование, глобальные тренды и специфика российского рынка.

Определены сущность и отличительные черты технологического предпринимательства в биомедицине. Проанализированы современные сетевые модели, стратегии открытых инноваций и роль венчурного финансирования. Выделены мировые тренды (Pharma 4.0) и практики лидеров отрасли (Bayer, AstraZeneca). На основе анализа российских кейсов («Вектор-Бест», «Биокад», «Р-Фарм») выявлены сильные стороны (научный фундамент, госполитика), а также системные вызовы («долина смерти», дефицит частного капитала, фрагментация регулирования).

Развитие технологического предпринимательства в России требует комплексного экосистемного подхода, включающего консолидацию усилий государства, стимулирование частных инвестиций, трансформацию образования и активную интеграцию в глобальные сети открытых инноваций для достижения технологического суверенитета.

Ключевые слова: технологическое предпринимательство, медицинская биотехнология, образовательные программы, коммерциализация, открытые инновации, венчурное финансирование, экосистема.

Introduction

Contemporary healthcare is undergoing a period of fundamental transformation, driven by the convergence of biology, medicine, and engineering sciences. Medical biotechnology — encompassing regenerative medicine, gene therapy, the development of targeted pharmaceuticals, and personalized diagnostic systems — is emerging as a primary driver of progress. However, the path from a groundbreaking scientific idea to a clinically significant and commercially viable product remains exceptionally complex. Historically, a significant proportion of innovations has originated within the academic sphere: research indicates that approximately one-third of novel drugs and 20% of medical devices have been discovered or invented by university scientists and practicing physicians. Nevertheless, a persistent gap exists between scientific discovery and its successful commercialization, leading to the underutilization of researchers' potential [1], [2], [3].

The primary challenges and barriers to transferring innovations to the medical or pharmaceutical markets are systemic in nature. These include colossal financial costs — up to USD 4.5 billion to bring a new drug to market, accounting for potential failures — protracted regulatory cycles, and a high failure rate at all stages, with over 90% of investigated molecules and 75% of biotechnology startups never reaching the market [4], [5], [6]. A key constraining factor is the acute deficit of entrepreneurial competencies among the technology creators themselves — physicians, pharmacists, and biomedical researchers — who typically lack expertise in business modeling, intellectual property management, fundraising, and market strategy development [7], [8]. Overcoming this gap requires not merely the stimulation of innovation but the deliberate cultivation of technological entrepreneurship as a distinct discipline and professional trajectory [2], [9], [10].

The objective of this work is a comprehensive analysis of the foundations of technological entrepreneurship in the field of medical biotechnology, its implications for the system of medical education, and the specific features of its implementation in global and Russian practice. Based on a retrospective analysis of international experience and a synthesis of practical case studies from Russian companies, key principles and recommendations for building an effective biomedical innovation ecosystem are formulated [11], [12], [13].

Materials And Methods

This study is a systematic analytical review aimed at summarizing and critically analyzing the existing body of evidence and scholarly publications on technological entrepreneurship in medical biotechnology, with particular emphasis on the Russian context [5], [14], [15].

2.1. Search Strategy and Source Selection Criteria

A targeted and multi-source search strategy was employed to ensure comprehensive coverage. The search was not limited to a single database and combined several complementary approaches:

- Keyword-based targeted search: Publications were retrieved from the following electronic databases: Google Scholar, PubMed, eLIBRARY.RU, and CyberLeninka. The search combined key terms and phrases (in both English and Russian): "technological entrepreneurship in biomedicine," "biotech startup," "open innovation in pharma," "venture financing in biotechnology," "Russian biotechnological sector," "commercialization of medical innovations."

- Snowball sampling: Additional relevant works were identified through backward and forward citation tracking in the reference lists of key articles and reviews already included [14], [16].

- Inclusion of expert and analytical sources: The review incorporated reports by leading consulting firms, official strategic documents of state programs ("Pharma-2030," "Biotech-2030"), and expert publications in specialized media [11], [17], [18].

The inclusion criteria were as follows:

- Publications directly address entrepreneurship, commercialization, venture financing, intellectual property management, or educational programs in biomedicine and biotechnology.

- Sources contain empirical data, case studies, or theoretical frameworks relevant to the research topic.

- Publication period: primarily 2015–2025, with selective inclusion of earlier foundational works (e.g., H. Chesbrough's open innovation literature).

- Languages: English and Russian.

The exclusion criteria were:

- Purely technical papers focused solely on molecular mechanisms or clinical protocols without any commercialization component.

- Unverified news reports, blog posts, or gray literature without scholarly validation.

- Duplicate publications.

2.2. Final Sample of Sources



Following a multi-stage screening process, the final sample comprised 34 sources. The sample is representative and includes peer-reviewed journal articles (including those indexed in Scopus and Web of Science), book chapters and collective monographs, analytical market reports, official strategic program documents, and expert interviews with founders and executives of successful biotech companies [13], [19], [20].

2.3. Data Analysis Methodology

The selected sources were processed using qualitative content analysis.

A. Coding and categorization: All documents were systematically reviewed. Key ideas, statements, and data were extracted and assigned codes. Through iterative analysis, the codes were grouped into stable thematic categories that formed the structural backbone of the review:

- Conceptual foundations and distinctive features of technological entrepreneurship in biomedicine.
- Educational programs and formats.
- Global trends and models (Pharma 4.0, open innovation).
- Russian-specific context: potential, barriers, and company case studies.

B. Comparative and thematic synthesis: Within each category, the positions of different authors were compared; common patterns, contradictions, and research gaps were identified [5], [21]. Particular attention was paid to juxtaposing international experience with Russian practice [11], [17], [13].

C. Verification and interpretation: All conclusions were repeatedly cross-checked against the original texts to ensure fidelity. The interpretation was oriented toward achieving the review's primary objective — providing a coherent, integrated perspective on the problem and formulating evidence-based practical recommendations.

2.4. Study Limitations

The principal limitation stems from the very nature of a systematic review: its findings are derived exclusively from existing publications and may reflect their inherent biases [5], [14]. To mitigate this risk, maximum source diversity and representativeness were ensured. The study does not claim to offer a quantitative meta-analysis; instead, it emphasizes qualitative synthesis and conceptual generalization.

Results And Discussion

3.1. Definition and Distinctive Features

Technological entrepreneurship in biomedicine represents a promising interdisciplinary domain at the intersection of natural sciences (biology, chemistry, medicine) and entrepreneurial management [1], [7], [8]. This field necessitates the synthesis of two heterogeneous competencies: deep scientific expertise in the subject area (molecular biology, genetics, biochemistry, pharmacology) and proficiency in business modeling tools, project management, marketing, and finance [4], [22]. Accordingly, a biotech entrepreneur differs from a classical "businessman" as motivation is associated not only with profit extraction but also with addressing socially significant challenges — developing drugs for orphan diseases, creating affordable diagnostic tools, and ensuring biosafety [6], [19], [20]. Unlike classical entrepreneurship, which is oriented toward satisfying existing market demand, technological entrepreneurship in biotech creates new markets based on breakthrough scientific discoveries [4], [15]. Its objective is the transformation of a scientific discovery into a marketable product (drug, diagnostic system, or medical device) through the establishment and development of an innovative company. However, "a biomedical startup is not merely a company but a complex translational mechanism that converts the language of scientific hypotheses into the language of marketable products" [2], [10]. This process differs fundamentally from traditional business owing to several unique characteristics:

1. Rigid Stage Delineation. Based on source analysis, the following lifecycle model can be reconstructed [5], [6]:

Table 1 - Lifecycle model of BioTech Startups

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Stage	Content	Duration, years	Funding Sources	Risks
Seed	Laboratory research, proof of concept, patenting	1–3	Grants, Foundation for Assistance to Small Innovative Enterprises, Skolkovo, business angels	Very high (95% of projects do not reach the next stage)
Start-up	Preclinical studies, prototype development, team formation	2–4	Venture funds, corporate accelerators	High
Early growth	Clinical trials (Phases I–III), preparation for registration	3–7	Venture funds, strategic partnerships with Big Pharma	Medium
Expansion	Registration, production scaling, market launch	2–5	Private equity, IPO, bank loans	Moderate



The critical stage, termed the "valley of death," is the transition from the seed stage to start-up. It is at this juncture that the majority of promising scientific developments cease to exist due to lack of funding: grant resources are exhausted, yet venture investors remain unwilling to enter the project because of excessively high risks and the absence of a prototype [19], [20].

2. High Capital Intensity at Each Stage: R&D and clinical trial costs are measured in hundreds of millions of dollars, creating a high entry barrier [24], [25].

3. High Risks and Extended Timelines: The probability of successfully advancing a new chemical compound to market constitutes a fraction of a percent, while the development cycle may exceed 10–15 years [4], [6]. This demands exceptional patience and risk tolerance from both the entrepreneur and the investors.

4. Stringent Regulatory Environment: All products are subject to mandatory licensing and oversight by regulatory authorities (FDA, EMA, Ministry of Health of the Russian Federation), which dictates strict protocols at all stages [3], [13], [26].

5. Critical Role of Intellectual Property (IP): Patents on molecules, production technologies, or methods of application constitute the primary asset and key determinant of company value. Competent management of the IP portfolio is a strategic imperative [27]. Several key contradictions and challenges warrant emphasis:

- Conflict between the openness of science and the closed nature of business. The academic environment encourages publication and open discussion of results, whereas commercialization requires the preservation of trade secrets until the moment of patent filing [14], [15].

- Complexity of patenting in biotech. Not all outcomes are eligible for patent protection (e.g., discovered genes or naturally occurring proteins), necessitating the development of sophisticated licensing strategies [16].

- Networked collaborations and distributed intellectual property. In consortia such as the Structural Genomics Consortium, the problem of "dilution" of rights to results arises, requiring special agreements on joint ownership [15].

Consequently, the contemporary approach proposes the use of blockchain technology to record the stages of IP creation and allocate rights among collaboration participants — a solution already being tested in several international biotech projects [15], [23].

Another distinctive feature is that the biomedical industry has moved away from the isolated, "closed" model of innovation. The dominant paradigm has become networked cooperation [16]. This presupposes interaction among numerous independent yet interconnected actors: universities and research institutes, startups, large pharmaceutical companies (Big Pharma), venture funds, clinics, and government bodies [25], [28]. This model is closely linked to the concept of "Open Innovation" (OI), proposed by Henry Chesbrough. Its essence lies in the purposeful utilization of external and internal ideas and pathways for their commercialization [15]. In biomedicine, this is manifested in:

- Establishment of research consortia: For example, the international *Structural Genomics Consortium (SGC)*, which openly studies proteins of medical significance and publishes results in the public domain, thereby accelerating fundamental research for all market participants [15], [16].

- "Big Pharma–Startup" partnerships: A startup possessing a breakthrough technology at an early stage forms an alliance with a large company that possesses the resources to fund expensive clinical trials, production capacities, and distribution channels [20], [28].

- Licensing agreements: Universities license patents generated in their laboratories to biopharmaceutical companies for further development [23], [27].

A system-forming element in biotech development is venture financing. Venture capital acts as the key financial mechanism enabling the transition from a laboratory idea to a marketable product. It represents long-term, high-risk investments in exchange for an equity stake in promising companies at early stages [6], [10], [24]:

- Staged Financing: Investments are attracted in rounds tied to the achievement of key milestones (seed stage, completion of preclinical studies, success in Phases I, II, and III of clinical trials). Each successful milestone reduces risk and increases company valuation.

- Expert Involvement: Venture investors not only provide capital but also actively participate in the company's strategic management, leveraging their network of contacts and expertise.

- Exit: The investor's objective is to multiply capital five- to tenfold by selling their stake to a strategic buyer (e.g., a large pharmaceutical company), through an initial public offering (IPO), or via merger.

3.2. Integration into the Educational Process: From Theory to Practice

Medical education is undergoing a paradigmatic shift. The traditional model, aimed at training narrow clinicians or fundamental researchers, is deemed insufficient for addressing the challenges of modern healthcare [1], [8], [26]. It is being supplanted by the "Triple Helix" model, which presupposes the integration of education, science, and business [3], [27]. Leaders in this transformation include Stanford University, MIT, and Harvard, where the first programs in biomedical entrepreneurship were launched as early as the 2000s [2], [29]. Key elements of these programs include:

- Business fundamentals courses (finance, marketing, strategy) for medical and biology students [1], [7], [8].

- Practice-oriented projects (team-based learning), within which students develop real startup projects [4], [30], [31].

- Mentorship from practitioners — engagement of serial entrepreneurs and venture investors [2], [9], [10].

- Integration with accelerators and technoparks — creation of a "seamless" environment for the transition from an educational project to a commercial venture [8], [9], [32].

The training of scientist-entrepreneurs implies the formation of universal competencies, including:

- Business and Management Fundamentals: Project management, marketing, financial accounting and planning [1], [7], [8].



- Legal Aspects and IP Management: Patent law, drafting licensing agreements, protection of trade secrets [22], [27].
- Regulatory Affairs and Clinical Research: Understanding drug approval processes, clinical trial design, GxP or "Good Practice" requirements (GMP — Good Manufacturing Practice, GLP — Good Laboratory Practice) [3], [13].

Theoretical training is reinforced by intensive practice through novel educational formats:

- Acceleration programs based at universities and research centers assist student teams in validating business ideas, developing prototypes, and preparing pitches for investors. Examples include the Skolkovo Foundation accelerator and "Startup as Diploma" programs [8], [9], [32].
- Biotech hackathons (e.g., BioHack) bring together specialists from various fields to solve specific technological challenges posed by industrial partners within a limited timeframe, fostering teamwork and "rapid prototyping" skills [4], [22].
- Project-based learning becomes a cross-cutting element: students work on real-world cases from companies, conduct market analysis, formulate business models, and devise commercialization strategies for specific scientific developments [1], [30], [33].

In Russia, three models for integrating technological entrepreneurship into medical and biological education can be identified:

- Model 1: Specialized interdisciplinary master's programs. An example is the "Biomedical Technologies and Entrepreneurship" master's program at Novosibirsk State University (NSU) [8], [22], [32]. The program is implemented jointly with the Koltsovo Biotechnopark and includes modules on "Innovation Project Management," "Intellectual Property in Biotech," "Venture Financing," and "Regulatory Affairs." Students undergo internships at enterprises of the Novosibirsk Region biotechnology cluster. A key feature is the diploma in startup format: the final qualification work defense constitutes a business plan for a real project, complete with conducted marketing and laboratory research [8], [22].

- Model 2: Interdisciplinary electives and competency centers. Notably, the Center for Innovative Entrepreneurship in Medicine at Sechenov University [29], [32], [34] offers open courses for students from all faculties, as well as the "MedTech Innovation" acceleration program. Over five years of operation, more than 500 students have participated, 30 startups have been established, and 8 have attracted external financing. The uniqueness of the approach lies in integration with the clinical base: students can test their developments at the University Clinical Hospital [29], [34].

- Model 3: Cluster-based educational ecosystems. The "PharmTech" pharmaceutical cluster is not merely an educational program but a full-fledged educational and industrial ecosystem, uniting universities (Mendeleev University of Chemical Technology of Russia, MITHT), research centers, and industrial partners (BIOCAD, R-Pharm, Generium). The educational process is structured on the "learning by doing" principle: from their first year, students are involved in real R&D projects of partner companies. The cluster ensures end-to-end training: from school-level biotechnology classes to DBA programs for top managers of pharmaceutical companies [9], [14], [30].

Concurrently, leading specialized universities are transforming from "knowledge factories" into centers of innovation ecosystems [1], [19], which includes:

- Infrastructure Development: Organization of technoparks, business incubators, and shared resource centers with expensive equipment accessible to startups [9], [32].
- Community Building: Organization of networking events, inviting successful alumni-entrepreneurs, investors, and industry representatives to interact with students [8], [34].
- Stimulation of Entrepreneurial Activity: Implementation of flexible regulations allowing scientists and students to establish small innovative enterprises (SIEs) based at the university while maintaining ties with their alma mater [9], [14], [32].

Despite active transformation and evident successes, systemic problems exist in the integration of technological entrepreneurship into Russian medical education:

- Shortage of teaching personnel combining scientific and entrepreneurial competencies. Successful entrepreneurs rarely enter academia, while academic scientists lack business acumen [8], [22], [32].
- Bureaucratic barriers in establishing small innovative enterprises at universities: prolonged approval procedures, restrictions on fund disposal, difficulties in equipment procurement [9], [14], [32].
- Gap between educational and investment infrastructure: Student startups successfully defended at the university often fail to enter accelerators or secure seed funding due to non-compliance with formal criteria [9], [14], [32].

3.3. Global Context: Trends, Strategies, and Ecosystems

The Fourth Industrial Revolution (Industry 4.0) is penetrating the pharmaceutical sector, shaping the Pharma 4.0 ecosystem concept with digital platforms and orchestrators. The essence of Pharma 4.0 is the integration of cyber-physical systems, the Internet of Things (IoT), Big Data, and Artificial Intelligence (AI) across all stages: from drug discovery and clinical trial management to "smart" manufacturing and personalized patient interaction. Particular attention in Pharma 4.0 is devoted to the role of the ecosystem orchestrator. An orchestrator is an organization that, rather than producing the product, primarily coordinates participant interaction, sets standards, and allocates roles and value flows [23], [25]. In global healthcare, orchestrators include:

- Major technology platforms (Google Health, Apple Health) — through data aggregation and creation of user interfaces [23], [25], [29].
- Big Pharma (Roche, Novartis) — through startup acquisitions and development of in-house digital divisions [10], [25], [28].
- State platforms (e.g., the NHS in the UK) — through regulation and centralized procurement [25].

Consulting firms (McKinsey, BCG, Deloitte) are becoming key agents in shaping the Pharma 4.0 ecosystem, acting as analysts, integrators, and facilitators [25]. The breakthrough outcomes of such transformations and integrations include the emergence and implementation of the following approaches:



- Digital Twins: Creation of virtual models of biological processes or production lines for prediction and optimization [23], [25].
- Precision Medicine: AI-driven analysis of genomic and clinical data for biomarker identification, personalized therapy selection, and discovery of novel drug targets [23], [24], [25].
- Continuous Manufacturing: Transition from batch to continuous production, enhancing efficiency and quality control [25].

The transformation of business models in the global biopharmaceutical industry is characterized by a shift from the classical vertically integrated pharmaceutical company (in-house full-cycle R&D — production — marketing) to networked models and open innovation models. The latter can be represented in three configurational variants [15], [16], [28]:

- Domestic consortia: Unions of national research centers and companies to address a specific scientific problem (e.g., Structural Genomics Consortium) [15], [16].
- Supranational collaborations: International projects involving academic institutions, Big Pharma, and biotech startups (e.g., Bayer and AstraZeneca projects with universities) [16], [28].
- "Startup–Big Pharma" partnerships: Large companies act as customers and co-investors for small innovative firms, providing them with funding, expertise, and distribution channels [28].

Global pharmaceutical giants are increasingly outsourcing a significant portion of their research to the external environment [15], [20], [28]. This is realized through:

- Corporate Venture Capital (CVC) funds: Enable investment in dozens of promising early-stage startups, providing a "window" into new technologies (e.g., funds of Bayer, Novartis, J&J) [10], [29].
- Open Innovation platforms: Companies publish lists of their scientific and technical challenges, inviting researchers worldwide to propose solutions (crowdsourcing) [28].
- Alliances with Big Tech: Partnerships between pharmaceutical companies and IT giants (Google, Apple, Microsoft) for collaborative development of digital tools, data analysis, and creation of platforms for remote patient monitoring [23], [25].

Strategies of global leaders and institutional initiatives can be exemplified by specific market "unicorns" and strategic initiatives of intergovernmental institutions:

- Bayer: Actively employs the open innovation model through the G4A (Grants4Apps) program, acting as an accelerator and investor in digital health-tech projects, while establishing innovation hubs globally [10], [15].
- AstraZeneca: Has focused on establishing open research centers (e.g., in Cambridge, Boston) that are physically and intellectually integrated into local scientific clusters, attracting leading scientists [20], [28].
- Institutional Initiatives: Projects like the *Innovative Medicines Initiative (IMI)* in the EU unite universities, companies, and regulators to jointly address large-scale scientific challenges beyond the capacity of any single organization [15], [16].

3.4. The Russian Biotech Sector: Potential, Barriers, and Company Cases

The Russian biotechnology sector possesses several structural advantages for development, rooted in a powerful Soviet scientific school:

- Scientific and Technological Foundation: Presence of world-class research centers (State Research Center of Virology and Biotechnology "Vector," Institute of Bioorganic Chemistry of the Russian Academy of Sciences, Kurchatov Institute) possessing competencies in virology, genetics, synthetic biology, unique collections of microorganisms, biospecimens, and clinical databases [19], [20].
- Regional Clusters: Established ecosystems in Novosibirsk (Koltsovo), Moscow, St. Petersburg, Pushchino, Tomsk Region, and Nizhny Novgorod Region, where research institutes, universities, and technopark resident companies are concentrated [10], [11], [13].
- State Support and Strategic Vision: Adoption of development strategies ("Pharma-2030," "Biotech-2030," "Priority-2030"), the operation of development institutions (Skolkovo, RVC, Foundation for Assistance to Small Innovative Enterprises), and the launch of national projects ("Science," "Healthcare") create a favorable macroeconomic agenda [11], [18], [31].
- Window of Opportunity for Import Substitution: Sanction pressure stimulates demand for domestic solutions in pharmaceuticals, diagnostics, veterinary preparations, and biologically active additives [11], [13], [18].

Despite this potential, the sector confronts profound systemic problems that impede its growth:

- "Valley of Death": As discussed in Section 3.1, a critical gap exists between the stage of completed fundamental research (where grant support is available) and the stage at which the project becomes attractive to private investors (prototype ready, proof of concept established). The lack of funding at this pre-seed and seed stage destroys numerous promising developments [6], [9].
- Shortage of Qualified Managerial Personnel: An acute deficiency of specialists who simultaneously comprehend science and possess the tools of business management, marketing, and investment attraction [19], [20], [22].
- Complex and Opaque Regulation: Lengthy and bureaucratized procedures for the registration of medicines and medical devices, as well as outdated requirements for certain product types (e.g., dietary supplements or GMO-containing products), create high transaction costs [3], [13], [26].
- Fragmentation of Governance: Absence of a unified center of responsibility for the sector; authority is dispersed among the Ministry of Education and Science, the Ministry of Industry and Trade, the Ministry of Health, and the Ministry of Agriculture, leading to incoherence in support programs [11], [18].
- Problems with Intellectual Property and Technology Transfer: Russian universities and research institutes, which generate a significant volume of scientific results, manage intellectual property extremely inefficiently. The lack of world-class technology transfer offices, weak patenting activity, and the reluctance of scientists to engage in commercialization represent systemic constraints that have remained unresolved for over 30 years of market reforms [14], [15], [27].

Nevertheless, despite systemic barriers, Russian biotech demonstrates concrete examples of successful cases:



Vector-Best (Novosibirsk) — a classic example of a spin-off company emerging from a state research center. Founded in the 1990s based on the State Research Center of Virology and Biotechnology "Vector," it is currently one of Russia's largest companies in the field of *in vitro* diagnostics, a resident of the Koltsovo Biotechnopark, and specializes in the development and production of diagnostic test systems for enzyme immunoassay (EIA) and PCR diagnostics of infectious diseases. The company is a leader in the domestic market and successfully exports its products. Success factors of Vector-Best [11], [13], [19] include:

- Utilization of Vector's scientific legacy in virology and epidemiology.
- Orientation toward real market demand — diagnostics of socially significant infections (HIV, hepatitis, tuberculosis, TORCH infections).
- Establishment of an in-house production and distribution network.
- Entry into international markets (products exported to dozens of countries).

BIOCAD (St. Petersburg) — Russia's largest independent biotechnology company and a leader in Russian biopharmaceuticals in the development of original and biosimilar drugs for the treatment of oncological and autoimmune diseases. BIOCAD's products (rituximab, bevacizumab, trastuzumab, and other monoclonal antibody preparations) hold a dominant position in hospital procurement; the company ranks among the top 10 pharmaceutical manufacturers in Russia. It is actively developing CAR-T therapy and gene therapy directions. It invests in the full cycle: from research to its own state-of-the-art manufacturing facilities conforming to international standards. It benefits from state import substitution programs [10], [19], [20]. BIOCAD's business model includes:

- Full cycle: from scientific research to large-scale production and marketing.
- Significant R&D investments (in-house research center, over 500 researchers).
- Active patent strategy.
- Partnerships with international pharmaceutical companies.
- State procurement under import substitution programs.

Among the company's challenges are dependence on imported equipment and reagents for production and difficulties in entering foreign markets due to regulatory barriers and patent protection of original drugs [11].

R-Pharm (Moscow) — an example of successful business model transformation from a distributor to an innovative biopharmaceutical organization. The company transitioned to localizing production of drugs from international partners (e.g., Biogen) in Russia while concurrently developing its own R&D projects and a corporate venture capital fund, demonstrating a model of integration into global value chains. R-Pharm is one of the few Russian companies consistently implementing the open innovation model, integrating external developments into its portfolio. Company's development strategy [10], [11], [19] includes:

- Localization of production of international drugs (partnerships with Sun Pharma, Pfizer, AstraZeneca).
- Establishment of its own R&D center in Yaroslavl.
- Investments in biotech startups (corporate venture capital fund).
- Development of export potential (drug registration in CIS countries, Latin America, and the Middle East).

Sibbiofarm (Novosibirsk) — an example of a company in the agrobiotech and industrial biotechnology segment. The company's market niche is import substitution in the agro-industrial complex and environmentally friendly agriculture [11], [13]. Its product portfolio includes:

- Feed additives and probiotics for animal husbandry.
- Plant protection products (biopesticides).
- Preparations for biological water purification and soil remediation.

Sibbiofarm's success factors include reliance on its own collection of microorganisms, possession of in-house production facilities, and long-term contracts with agricultural holdings [11], [13].

Generium (Vladimir Region) — an example of science–business cooperation. Established with the participation of R-Pharm and the Institute of Bioorganic Chemistry of the Russian Academy of Sciences, it is one of the few Russian projects implemented under a public–private partnership model in biotech, exemplifying the integration of academic science (fundamental research) with industrial production (GMP plant). The company specializes in the development and production of recombinant proteins, enzymes, and monoclonal antibodies [10], [11].

Nanolek (Kirov Region) — a company specializing in vaccines and orphan drugs. It implements full-cycle production of vaccines (including within the framework of the National Immunization Schedule) and develops its own R&D program. Concurrently, high production capital intensity, a lengthy payback period, and dependence on state procurement may pose future challenges for the company [10], [11].

Fort (Ryazan Region) — part of the Rostec structure ("RT-Biotechprom"). Russia's largest manufacturer of immunobiological preparations. In 2014, it attracted substantial investments (over USD 30 million) from its parent structure. The company is an example of non-venture, corporate financing of a biotech project. The 2014 transaction distorted venture market statistics but demonstrated the potential for large-scale investments given political will [6], [11].

Based on the analysis of the presented cases, common factors determining the success of Russian biotech companies can be identified:

- Presence of a strong scientific foundation. All successful companies (Vector-Best, BIOCAD, Generium) emerged from academic science or are tightly integrated with it [13], [19], [20].
- Orientation toward real market demand. Successful companies do not attempt to "reinvent the wheel" but address specific healthcare and agro-industrial challenges (diagnostics, therapy of socially significant diseases, import substitution of feed additives) [11], [13].
- Competent patent and licensing strategy. Companies that manage to protect their intellectual property and correctly structure licensing relationships gain sustainable competitive advantages [15], [23], [27].



- State support. All presented cases are, in one way or another, connected with state financing, public procurement, or preferences [11], [18], [31].

- Effective management. Successful companies are led by or employ individuals from business schools and large corporations, possessing experience in project and team management [10], [19], [20].

Failure factors and barriers — based on analysis of companies not included in the case selection but mentioned in sources as "closed" or "frozen" projects [6], [19], [20] — include:

- Premature scaling. Attempting to construct a plant before completing R&D and product registration leads to resource depletion.

- Misunderstanding of the market. Developing a "brilliant technology" without answering the question "Who will pay?" is a typical mistake of scientist-founders.

- Team conflicts. Contradictions often arise between scientific founders and hired managers regarding development strategy, equity distribution, and compensation.

- Regulatory barriers. Delays in registration of two to three years can destroy any startup.

3.5. Venture Financing in the Global and Russian Biotech Sector

Analysis of the global venture investment market demonstrates sustained interest in the biotechnology sector. According to the consulting company SharesPro, investments in pharmaceuticals and biotechnology in the USA reached USD 14 billion in 2018 and continue to grow. Key trends in the global biotech venture market [6], [20], [24], [29] include:

- Growth of megarounds (deals exceeding USD 100 million). Investors concentrate capital on the most promising platform technologies (CRISPR/Cas9, CAR-T, mRNA vaccines).

- Expansion of corporate venture capital (CVC) funds. Almost every major pharmaceutical company possesses its own venture fund investing in external startups.

- Growing interest in "hardcore" technologies. Whereas in the 2010s the primary investment flow was directed toward digital health, telemedicine, and mobile applications, the 2020s see a shift in focus toward biological platforms, gene therapy, and regenerative medicine.

- Geographic diversification. Besides traditional centers (USA, Europe, Israel), active growth in venture activity is observed in China, Singapore, and South Korea.

The Russian venture market in biotech is characterized by structural imbalance [6], [24]:

- State dominance: The bulk of investment volume comes from funds with state participation (RVC, Skolkovo, VEB.RF). Private venture capital remains extremely cautious due to high risks, long payback periods, and underdeveloped exit mechanisms.

- Modest investment volumes: The aggregate volume of venture deals in Russian biotech is incomparable to US or European indicators. According to 2017 data, it amounted to approximately USD 14.7 million across 11 deals, whereas the USA alone attracted USD 14 billion in 2018.

- Exit market problem: The absence of a developed IPO market for technology companies in Russia and difficulties in selling to strategic investors constrain the motivation of venture funds.

Despite mentioned above, as detailed in Section 3.4, several Russian biotech companies (Vector-Best, BIOCAD, R-Pharm) have nevertheless achieved success through a combination of scientific excellence, market orientation, and, in some cases, state support, despite the challenging venture financing landscape [10], [13], [19].

3.6. Consolidated Perspective on the Future of the Industry

This systematic analysis demonstrates that technological entrepreneurship in biomedicine constitutes a distinct institutional practice, requiring the synthesis of scientific, managerial, and regulatory expertise [1], [2], [7]. Its development is impossible without the systemic integration of education, science, and business [3], [27]. Consequently, networked models of open innovation predominate in the global biotechnology sector [15], [16]. Large corporations are abandoning the closed R&D model in favor of partnerships with universities, startups, and state research centers [20], [28]. The Pharma 4.0 ecosystem is taking shape, into which the Russian biotechnology sector, possessing significant scientific potential, is being actively integrated, albeit finding itself in an institutional trap [11], [13], [19], [25]:

- World-class scientific developments exist.

- Market demand exists (import substitution, state procurement).

- Individual successful company cases exist.

- Yet a systemic environment for the reproduction of new biotech startups is absent.

Crucially, the key barriers are institutional, not technological. The deficit of venture financing, the gap between science and business, the shortage of managerial personnel, ineffective intellectual property management, and regulatory delays are all consequences of the immaturity of innovation support institutions [6], [14], [27].

The analysis conducted also enables the formulation of general recommendations for various stakeholders.

For the State and Development Institutions:

- Establish a unified coordination center for biotechnology policy (potentially under the Ministry of Industry and Trade or the Ministry of Education and Science) to overcome interdepartmental fragmentation.

- Develop and adopt a long-term biotechnology development strategy with clear KPIs, budget allocation, and designated responsible parties (replacing the unimplemented "Bio-2020").

- Launch a venture partnership program wherein the state shares risks with private investors at early stages (matching funds model), analogous to the Israeli Yozma program.

- Simplify and accelerate drug and medical device registration procedures, harmonizing them with international requirements.



- Establish technology transfer offices at leading universities and research institutes with adequate funding and qualified personnel.

For the Education System and Universities:

- Scale successful educational practices (the NSU master's program, the Sechenov University accelerator, the PharmTech cluster) to other higher education institutions.

- Introduce mandatory modules on technological entrepreneurship into medical and biological specialty curricula.

- Develop the institution of visiting practitioner professors — successful entrepreneurs and investors.

- Create intra-university accelerators and startup studios, ensuring a "seamless" transition from educational project to commercial venture.

For Investors and Corporations:

- Intensify corporate venture capital activity. Russian biopharmaceutical companies (BIOCAD, R-Pharm) already possess successful experience in startup investing — this practice requires expansion.

- Develop mentorship and coaching programs. Large companies could mentor promising startups, providing them with expertise and infrastructure access.

- Form "seed clubs" of business angels specializing in biotech.

For Research Teams and Startups:

- Learn to communicate in the language of business. A scientific article is not a business plan. Attracting investment requires the ability to formulate a value proposition, assess the market, and construct financial models.

- Protect intellectual property prior to publication. Patenting is the first step toward commercialization.

- Seek mentors and partners. A solitary scientist-founder has minimal chances of success. It is necessary to form teams incorporating entrepreneurial and managerial competencies.

Conclusion

Technological entrepreneurship in biomedicine has ceased to be a niche phenomenon and has transformed into the primary engine of progress in one of the most complex and socially significant sectors of the global economy [1], [2], [29]. Its success is determined by the capacity to establish effective linkages among science, capital, regulatory frameworks, and the end consumer [3], [26], [28]. For Russia, the pressing task is not merely the support of individual projects or companies but the purposeful construction of a comprehensive innovation ecosystem [11], [13], [18]. This requires:

- Consolidation of state efforts to create clear, stable, and incentivizing "rules of the game," including the modernization of the regulatory environment.

- Stimulation of private capital inflow through specialized risk mitigation instruments (co-investment, tax incentives) and the development of exit markets.

- Formation of a new generation of scientist-entrepreneurs through deep-seated educational transformation and the cultivation of a culture that incentivizes the commercialization of developments.

- Active integration into global open innovation networks, enabling risk-sharing, attraction of best practices and technologies, and the export of Russian products to the international market.

Only such a comprehensive, ecosystem-based approach will enable the conversion of existing substantial scientific potential into sustainable competitive advantages and ensure the country's technological sovereignty in the critically important field of biomedicine.

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Не указан.

Рецензия

Все статьи проходят рецензирование. Но рецензент или автор статьи предпочли не публиковать рецензию к этой статье в открытом доступе. Рецензия может быть предоставлена компетентным органам по запросу.

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Conflict of Interest

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Review

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