# TSUL LEGAL REPORT

INTERNATIONAL ELECTRONIC SCIENTIFIC JOURNAL

VOLUME 6
ISSUE 3
SEPTEMBER 2025

JOURNAL DOI: 10.51788/tsul.lr.
ISSUE DOI: 10.51788/tsul.lr.6.3.
E-ISSN: 2181-1024

Google Scholar doi Crossref Content Registration

**Founder: Tashkent State University of Law**

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«TSUL Legal Report» international electronic scientific journal was registered by the Press and Information Agency of Uzbekistan on April 21, 2020, with certificate number 1342.The journal is included in the list of journals of the Higher Attestation Commission under the Ministry of Higher Education, Science and Innovations of the Republic of Uzbekistan.


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**Publishing license**
№ 174625, 29.11.2023.

**E-ISSN: 2181-1024**

# CONTENTS

TSUL LEGAL REPORT
Journal home page: www.legalreport.tsul.uz

TSUL LEGAL REPORT
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Received: 25.08.2025 Accepted: 11.09.2025 Published: 26.09.2025

**DOI: 10.51788/tsul.lr.6.3./CBFP9413**

# BIOTECHNOLOGY SUBJECTS: MULTI-LEVEL LEGAL CLASSIFICATION

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**Abstract.** This research examines the complex multi-level system of civil law relations subjects operating within the biotechnology sector. The study addresses the theoretical foundations and practical aspects of biotechnology legal frameworks, analyzing the intricate relationships between primary, secondary, and regulatory actors in the biotechnology ecosystem. The research methodology encompasses comparative legal analysis, institutional economics approaches, and multi-helix innovation models to understand the distinctive characteristics of biotechnology civil law relations. The investigation reveals that biotechnology sector subjects fundamentally differ from traditional civil law classifications, requiring specialized theoretical approaches due to their interdisciplinary nature and complex multi-layered structure. Results demonstrate that successful biotechnology systems depend on balanced regulatory frameworks, multi-sectoral cooperation, and continuous adaptability principles. The research scope extends to international experiences from the United States, the European Union, and Japan, providing insights for developing nations. Key findings indicate that digital transformation creates new subject categories, including AI-powered drug discovery companies and blockchain-based solutions, fundamentally altering traditional biotechnology ecosystems. The study concludes that future biotechnology subject systems will become increasingly complex, with emerging fields like synthetic biology, convergent technologies, and quantum biotechnology requiring new legal frameworks and ethical considerations.

**Keywords:** biotechnology law, civil law relations, innovation ecosystem, legal classification, regulatory framework, multi-level system, biotechnology subjects, technology transfer

## Introduction

The development of the biotechnology sector in the contemporary world manifests as one of the primary driving forces of 21st-century economic and social transformations. The distinctive feature of this sector lies in its encompassing not only scientific and technological achievements but also complex legal, ethical, and social issues that require unprecedented legal solutions and regulatory approaches.

The system of civil law relations subjects in biotechnology represents a relatively new but rapidly developing direction in contemporary jurisprudence. This system's complexity and multi-layered nature fundamentally distinguish it from traditional civil law doctrines and demand specialized theoretical approaches that can address the unique challenges posed by biotechnological innovation.

Morrison's observation that "understanding the rules for transforming scientific achievements into business constitutes an essential and necessary part of scientific activity" illuminates the interdisciplinary nature of legal relationships in biotechnology and underscores the complex interconnections between scientific research and commercial activities [1]. This reality creates unprecedented challenges for legal practitioners, policymakers, and biotechnology entrepreneurs who must navigate increasingly complex regulatory environments while fostering innovation.

The absence of universally accepted biotechnology definitions across jurisdictions creates additional difficulties in subject determination and classification, as each jurisdiction maintains its own understanding of biotechnology concepts, creating challenges in international cooperation and trade. This definitional complexity necessitates comprehensive analysis of how different legal systems approach biotechnology subject classification and regulation.

The primary objective of this research is to analyze the multi-level system of civil law relations subjects in biotechnology, establishing theoretical foundations for understanding their legal nature and classification criteria. The study aims to solve the fundamental problem of identifying and systematizing biotechnology sector subjects while addressing the challenges posed by definitional inconsistencies and regulatory fragmentation across jurisdictions.

This research seeks to bridge the gap between traditional civil law frameworks and the emerging needs of biotechnology innovation ecosystems. The study addresses critical questions regarding how legal systems can effectively regulate biotechnology subjects while maintaining innovation incentives and protecting public interests. Additionally, the research aims to provide practical insights for legal practitioners, policymakers, and biotechnology entrepreneurs navigating complex regulatory environments.

The problem-solving approach focuses on developing comprehensive theoretical frameworks that can accommodate the dynamic nature of biotechnology innovation while ensuring legal certainty and regulatory effectiveness. This includes analyzing how different regulatory approaches impact subject classification systems and identifying best practices for creating effective biotechnology governance structures.

Contemporary innovation ecosystem theories provide crucial insights for understanding biotechnology subject systems. The Triple Helix innovation model, developed by Etzkowitz and Leydesdorff in the 1990s, describes the interaction between universities, industry, and government as drivers of economic and social development characterized by knowledge economy and knowledge society concepts [2]. The theoretical foundation was strengthened with the publication demonstrating how interactions between universities, industry, and

government create new intermediary institutions such as technology transfer offices and science parks [3]. This model reveals how biotechnology innovation requires unprecedented collaboration between traditionally separate sectors, creating new forms of legal relationships and institutional arrangements.

The Quadruple Helix model, proposed by Carayannis and Campbell in 2009, incorporates civil society and media-based public participation as a fourth component [4]. This model addresses gaps between innovation and societal needs while expanding universities' societal responsibilities beyond education and research. The inclusion of civil society reflects growing recognition that biotechnology innovation cannot occur in isolation from broader social concerns and ethical considerations.

The Quintuple Helix model, developed by the same authors in 2010, establishes connections between knowledge, innovation, and environment, presenting approaches consistent with sustainable development and social ecology [5]. This model recognizes the natural environment as a driving force for knowledge production and innovation in society and the economy, establishing socio-ecological opportunities for a knowledge society and knowledge economy.

Recent theoretical developments include the Neo-Triple Helix model proposed by Zheng and Cai, which views innovation ecosystems as systems developing through interactions between innovation dynamics, social structures, and the natural environment [6]. This model, inspired by Lewontin's gene-organism-environment triple helix metaphor, combines the strengths of various spiral models to create more effective theoretical foundations for understanding complex relationships in biotechnology. Porter's value chain concept provides an essential analytical framework for understanding subject participation in biological product and service creation [7]. This concept proves particularly relevant for biotechnology sector analysis as it incorporates the industry's distinctive characteristics realized through industrial processes, including research and development phases, manufacturing, testing, sales, and post-marketing services [7].

**Materials and methods**

The research methodology encompasses comprehensive analysis of biotechnology sector subjects through multiple theoretical frameworks and empirical case studies. The investigation utilizes multi-helix innovation models as primary analytical frameworks, recognizing their effectiveness in capturing complex interactions characteristic of biotechnology ecosystems.

The study examines primary sources including regulatory documents, corporate annual reports, academic publications, and policy frameworks from major biotechnology jurisdictions. Documentary analysis focuses on legislation, regulatory guidelines, court decisions, and administrative rulings that shape biotechnology subject classification and legal status determination.

Empirical data collection includes analysis of biotechnology company structures, university technology transfer operations, regulatory agency activities, and international cooperation agreements. The research incorporates statistical data on biotechnology sector performance, investment flows, patent applications, and regulatory approvals to provide a quantitative foundation for qualitative legal analysis.

Comparative analysis focuses on the United States, the European Union, and Japanese regulatory systems, representing different approaches to biotechnology governance and subject classification. These jurisdictions were selected based on their leadership in biotechnology innovation, comprehensive regulatory frameworks, and influence on global biotechnology governance standards.

The value chain analysis methodology proves particularly relevant for biotechnology sector classification, as it accounts for the industry's distinctive characteristics and multi-stage realization processes. This approach enables identification of subject roles and responsibilities at different stages of biotechnology product development and commercialization.

The comparative legal method enables examination of different regulatory approaches and their implications for subject classification systems. This methodology reveals how legal cultures, economic systems, and social values influence biotechnology subject regulation and provides insights for developing optimal regulatory frameworks.

Institutional economics perspectives provide insights into the role of intermediary organizations and support structures within biotechnology ecosystems. This approach explains how transaction costs, information asymmetries, and coordination challenges shape biotechnology subject relationships and institutional arrangements.

Research objects include universities and higher education institutions, private research institutes, biotechnology companies ranging from startups to large corporations, consulting firms, intellectual property agencies, financial and investment entities, insurance companies, clinical research organizations, and regulatory bodies across multiple jurisdictions.

The research methodology incorporates both qualitative and quantitative approaches to ensure comprehensive understanding of biotechnology subject systems. Qualitative analysis focuses on legal frameworks, institutional arrangements, and regulatory approaches, while quantitative analysis examines sector performance indicators, investment trends, and comparative statistical data.

**Research results**

Primary biotechnology sector subjects encompass organizations directly engaged in creating, producing, and selling biotechnology products and services. These subjects constitute the core elements of biotechnology ecosystems and play decisive roles in sector development. The distinctive characteristic of primary subjects is their direct participation in the value-creating portion of biotechnology value chains.

**Table 1**

**Classification of Primary Biotechnology Sector Subjects**

| Subject Category | Primary Functions | Legal Status | Key Examples |
|---|---|---|---|
| Universities | Research, Education, Technology Transfer | Public/Private Non-profit | Stanford, MIT, Cambridge |
| Research Institutes | Applied Research, Development | Public/Private | NIH, CiRA, Max Planck |
| Biotech Companies | Product Development, Commercialization | Private Corporations | Amgen, Moderna, BioNTech |
| Pharmaceutical Giants | Manufacturing, Distribution, Marketing | Public Corporations | Novartis, Roche, Pfizer |

**Universities and Higher Education Institutions in biotechnology.** Universities and higher education institutions serve as the most important research centers in biotechnology. Roychoudhury emphasizes that "universities function as primary platforms combining fundamental and applied research in biotechnology investigations" [8]. This definition clearly establishes the role of academic institutions in biotechnology innovations while highlighting the complexity of their legal status.

The dual role of universities in biotechnology creates significant legal

complexities. Universities simultaneously serve as educational institutions preparing new generations of specialists and as research centers conducting fundamental and applied investigations. This combination complicates their legal status, as they operate both as public service institutions and intellectual property creators.

Leading American institutions demonstrate global leadership in biotechnology research and education. Stanford University, Massachusetts Institute of Technology (MIT), and Harvard University achieve significant breakthroughs in biotechnology research and commercialization. Stanford University's Master of Laws program in Law, Science & Technology "encompasses biotechnology, e-commerce, intellectual property, cyberspace dispute resolution, venture capital, and numerous other fields" [9]. This program reflects the interdisciplinary nature of biotechnology law and plays an important role in preparing legal professionals for this rapidly evolving sector.

The Stanford approach demonstrates how leading universities integrate legal education with scientific and technological innovation. The university's proximity to Silicon Valley creates unique opportunities for students to engage with biotechnology companies, venture capital firms, and regulatory agencies, providing practical experience in biotechnology law and policy.

European institutions represent different approaches to biotechnology research and education, often emphasizing stronger state involvement and centralized coordination. Cambridge University, Oxford University, Sorbonne University, and ETH Zurich serve as leading biotechnology research centers. Research conducted at these universities receives support within the "Building the Future with Nature" strategy and Strategic Technologies for Europe Platform (STEP) framework [10]. The European approach differs from the American model by incorporating more state financing and centralized planning elements, affecting universities' legal status and operational autonomy.

The European model demonstrates how different political and economic systems shape university roles in biotechnology innovation. European universities often operate within stronger regulatory frameworks and receive more direct government funding, creating different incentive structures and accountability mechanisms compared to their American counterparts.

Japanese institutions exemplify yet another approach to university-based biotechnology research. The University of Tokyo, Kyoto University, and Osaka University serve as primary biotechnology research centers within Japan's national innovation strategy. The Center for iPS Cell Research and Application (CiRA), supported by the Japanese government, represents one of the world's leading regenerative medicine centers [11]. The Japanese model reflects a distinctive balance between state and private sectors, where universities are viewed more as components of national innovation strategy rather than independent actors.

**Legal Status and Intellectual Property Issues.** The legal status of universities and intellectual property issues possess particular complexity in biotechnology due to the high value and strategic importance of biotechnology innovations. The Bayh-Dole Act of 1980 fundamentally transformed American university roles by providing them with rights to commercialize inventions created through federal funding [12]. This legislation converted universities from merely educational and research institutions into technology transfer agents and commercial entities. The Act's impact proved extensive, providing universities with comprehensive rights, including ownership rights to research results (intellectual property) obtained through federal funding, rights to license inventions

to private companies, authority to collect and distribute royalty payments, and rights to establish spin-off companies.

However, these rights accompany substantial obligations, including mandatory reporting of all inventions to federal agencies, requirements to protect inventions with patents, obligations to give preference to small businesses in licensing agreements, and commitments to encourage local (U.S. territory) manufacturing.

The Bayh-Dole Act created what scholars describe as the "entrepreneurial university" model, where academic institutions actively pursue commercialization opportunities while maintaining their traditional education and research missions. This transformation raises complex questions about conflicts of interest, academic freedom, and the appropriate balance between public and private benefits from publicly funded research.

**Scientific Research Institutes.** Scientific research institutes serve as primary sources of biotechnology innovations, with legal status often differing significantly from universities. These institutions typically focus more intensively on applied research and development, often with closer connections to industry and more direct paths to commercialization.

In the United States experience, the National Institutes of Health (NIH) represents the largest federal-level research center, with a 2024 budget of $47 billion [13]. NIH comprises 27 institutes and centers, each specializing in specific biotechnology sectors, including the National Cancer Institute, National Institute of Mental Health, and National Institute of Allergy and Infectious Diseases [14].NIH's structure and activities provide important examples for understanding the legal status of state research institutes in biotechnology. Beyond conducting direct research, NIH finances universities and private research centers through external grant programs totaling over $30 billion annually. This dual function requires NIH to operate not only as a research institute but also as a scientific policy shaper and financial intermediary.

The Centers for Disease Control and Prevention (CDC) develops biotechnology solutions for infectious diseases and public health challenges. During the COVID-19 pandemic, the CDC played a crucial role in developing mRNA vaccine technologies and establishing protocols for biotechnology-based pandemic response [15]. CDC's role demonstrates that state research institutes engage not only in scientific research but also in direct public health protection and emergency response.

European research institutes operate within different legal and institutional frameworks. The Max Planck Society in Germany, CNRS in France, and EMBL (European Molecular Biology Laboratory) represent various approaches to organizing public research institutions. These organizations often emphasize international cooperation and long-term fundamental research, contrasting with the more application-oriented approach common in American institutions.

**Private Research Institutes and Corporate R&D.** Private research institutes possess legal status fundamentally different from state institutions, operating based on private financing with the primary goal of achieving commercial results. However, they may assume public obligations, particularly if they utilize state grants or tax privileges.

Advantages of private research institutes include financial flexibility enabling rapid redirection of research priorities, commercial orientation ensuring market-relevant research directions, innovative approaches unrestricted by traditional academic limitations, and international cooperation capabilities unconstrained by governmental restrictions.

However, private institutes also face significant disadvantages, including financial risks and investor accountability

pressures; short-term orientation pressures limiting long-term fundamental research; resource constraints affecting large-scale research capabilities; and market dependency requiring termination of unprofitable research directions.

Major pharmaceutical companies operate extensive private research institutes. Novartis Institutes for Biomedical Research, Roche Innovation Centers, and Pfizer Worldwide Research and Development represent billion-dollar research enterprises that rival or exceed many national research programs in scope and funding.

**Biotechnology Companies and Corporate Structures.** Biotechnology companies encompass a broad spectrum from startups to multinational corporations, each possessing distinctive legal status and operational characteristics. Morrison observes that "biotechnology companies operate in complex areas of patent law, regulatory approval, and contract law" [16]. This observation reflects the multifaceted legal environment in which biotechnology companies must navigate.

**Large Biotechnology Corporations.** Analysis of major companies operating in global markets demonstrates the diversity and complexity of the biotechnology sector. Amgen, established in 1980, represents one of the world's largest biotechnology companies, with 2023 net revenue of $28.1 billion [17]. Amgen's success illustrates how biotechnology companies can evolve from small startups to global corporations through introducing important biotechnology drugs, including erythropoietin (EPO) for anemia treatment and G-CSF for neutropenia management.

Amgen's legal status encompasses a complex corporate structure as a Delaware-incorporated company trading on NASDAQ. With patent portfolios covering over 150 countries, the company demonstrates a sophisticated global intellectual property strategy. Amgen actively participates in patent disputes with biosimilar companies, illustrating the critical importance of intellectual property protection in biotechnology sectors.

The company's legal challenges reflect broader industry issues. Amgen has faced numerous patent disputes, particularly regarding biosimilar versions of its blockbuster drugs. These legal battles demonstrate how intellectual property law serves as both a protection mechanism and a competitive battlefield in biotechnology sectors.

Moderna's history illustrates how biotechnology startups can rapidly transform into global-scale companies under exceptional circumstances. Established in 2010, the company remained relatively unknown until 2020, when the COVID-19 pandemic elevated it to one of the world's most prominent biotechnology companies [18]. Moderna's rapid rise demonstrates both the tremendous potential and inherent volatility of biotechnology sectors.

Moderna's legal strategy centers on creating extensive patent portfolios in mRNA technologies. The company filed over a thousand patent applications to protect its core technology platform, demonstrating the critical importance of intellectual property in biotechnology competitive strategies. During the pandemic, Moderna faced complex decisions regarding patent enforcement and global access to its vaccines, illustrating how biotechnology companies must balance commercial interests with public health responsibilities.

Genentech (now part of Roche) pioneered recombinant DNA technology, establishing itself in 1976 and developing the first recombinant insulin product. Genentech's history closely connects with the biotechnology industry's emergence, as it demonstrated the commercial viability of applying molecular biology discoveries to pharmaceutical development.

Following complete acquisition by Roche in 2009 for $46.8 billion, Genentech's

legal status changed to function as a subsidiary of the Swiss pharmaceutical giant. This acquisition demonstrates how successful biotechnology companies often become targets for acquisition by larger pharmaceutical corporations seeking to access innovative technologies and products.

**European and Asian Biotechnology Companies.** European biotechnology companies operate within different regulatory and market environments compared to their American counterparts. Novartis (Switzerland) achieved 2023 net revenue of $32.7 billion [19], operating in CAR-T cell therapy, gene therapy, and advanced pharmaceutical sectors. The company reflects the European pharmaceutical industry's biotechnology-oriented strategic transformation.

BioNTech (Germany) gained international prominence through its COVID-19 vaccine development in partnership with Pfizer. The company's success demonstrates European capabilities in biotechnology innovation while highlighting the importance of international partnerships in global biotechnology markets.

Japanese biotechnology companies often emphasize different strategic approaches, frequently focusing on precision medicine and regenerative therapies. Companies such as Takeda Pharmaceutical, Astellas Pharma, and Daiichi Sankyo demonstrate how Japanese firms integrate biotechnology innovations with traditional pharmaceutical strengths.

**Secondary Subjects System Analysis.** Secondary subjects represent organizations creating support services and infrastructure for biotechnology sector development. These subjects do not directly produce biotechnology products but provide essential services, resources, and knowledge enabling primary subjects' effective operations. The importance of secondary subjects increases as biotechnology ecosystems become more sophisticated and specialized.

**Table 2**

**Secondary Biotechnology Sector Subjects Classification**

| Subject Type | Primary Services | Market Focus | Key Players |
|---|---|---|---|
| Consulting Companies | Technical, Legal, Business Advisory | Specialized Expertise | McKinsey, BCG, Specialized Firms |
| IP Agencies | Patent Protection, Licensing | Intellectual Property | Law Firms, Patent Offices |
| Financial Services | Investment, Banking, Insurance | Capital Formation | VC Funds, Banks, Insurance |
| CRO Companies | Clinical Trials, Testing | Regulatory Compliance | IQVIA, Charles River |

**Biotechnology Consulting Companies.** Biotechnology consulting companies provide specialized technical, legal, and business advisory services addressing the unique challenges faced by biotechnology organizations. Guerra emphasizes that "due to the technical complexity of biotechnology achievements, a basic understanding of biotechnology scope definitions constitutes a useful entry point in each studied legal space" [20]. This observation reflects both the importance and complexity of consulting services in biotechnology sectors.

Technical consulting encompasses process optimization, product development,

and technology transfer services. Technical consultants typically possess PhD-level qualifications combined with industry experience, enabling them to bridge the gap between academic research and commercial application. These professionals help biotechnology companies optimize manufacturing processes, scale up production, and resolve technical challenges that emerge during product development.

Major technical consulting firms, including McKinsey & Company's pharmaceutical practice, Boston Consulting Group's biopharmaceutical division, and specialized firms such as BioPlan Associates, provide strategic guidance to biotechnology companies. These firms often employ former industry executives and regulatory officials who bring insider knowledge of industry practices and regulatory expectations.

Regulatory consulting represents one of the most specialized areas within biotechnology services. Regulatory consultants work with the FDA, EMA, and other regulatory agencies to guide companies through complex approval processes. This field demands exceptional complexity management skills, as regulatory requirements frequently change and each product category requires specific approaches.

Regulatory consultants typically include former regulatory agency employees who possess deep understanding of internal processes and informal practices. These professionals provide invaluable guidance on regulatory strategy, submission preparation, and agency communication. The value of regulatory consulting becomes particularly apparent during product approval processes, where expert guidance can significantly impact timelines and success rates.

Business consulting encompasses strategic planning, market analysis, and financial modeling services tailored to biotechnology sector characteristics. Biotechnology business consulting requires specialized expertise due to the industry's unique characteristics, including long investment cycles, high-risk levels, and low success probabilities.

Legal consulting covers intellectual property, contracts, licensing, and regulatory law specialized for biotechnology applications. Biotechnology legal consulting demands exceptional complexity management, requiring not only traditional corporate legal knowledge but also technical understanding of underlying scientific principles.

**Intellectual Property Agencies and Patent Services.** Intellectual property agencies provide patent and trademark protection services, representing critical importance for biotechnology companies, as intellectual property protection constitutes one of the sector's primary competitive advantages. The biotechnology industry's dependence on intellectual property protection creates substantial demand for specialized legal services.

Patent prosecution in biotechnology requires specialized expertise combining legal knowledge with technical understanding of complex biological systems and processes. Patent attorneys working in biotechnology typically possess both law degrees and advanced scientific degrees, enabling them to effectively communicate with inventors and patent examiners.

The complexity of biotechnology patents creates unique challenges in patent prosecution and litigation. Biotechnology inventions often involve complex biological systems, uncertain mechanisms of action, and broad potential applications, making patent claim drafting particularly challenging.

**Financial and Investment Entities System.** The financial and investment entities system plays crucial roles in biotechnology sector development, as biotechnology companies typically require substantial capital investment

over extended periods before achieving commercial success. Venture capital funds provide essential financing for startups and developing biotechnology companies.

Biotechnology sector investments totaled $22.3 billion in 2023, reflecting recovery from pandemic-related market disruptions [21]. This investment level demonstrates continued confidence in biotechnology innovation potential while highlighting the sector's capital-intensive nature.

Flagship Pioneering holds a unique position in biotechnology venture capital as the fund that created Moderna. The fund's "venture creation" model involves identifying promising scientific areas and building companies around them, rather than simply investing in existing companies. This approach enables the fund to capture value from the earliest stages of company development.

Third Rock Ventures specializes in biotechnology startups using the "scientific founder" model, directly collaborating with academic researchers to establish companies based on their discoveries. This model demonstrates how venture capital can serve as a bridge between academic research and commercial development.

Novartis Venture Fund, operated by Novartis AG, invests in biopharmaceuticals, digital healthcare, and platform technologies. Corporate venture capital funds like NVF provide not only financing but also strategic partnerships and market access opportunities for portfolio companies.

**Insurance Companies and Risk Management.** Insurance companies provide protection services related to biotechnology product risks and liabilities. The Genetic Information Nondiscrimination Act (GINA) prohibits "misuse of genetic information to prevent genetic testing and research advances from leading to unfair treatment" [22]. This legislation demonstrates how legal frameworks attempt to balance innovation incentives with protection against discriminatory practices.

Biotechnology insurance encompasses multiple specialized areas, including clinical trial insurance, product liability coverage, key person insurance for essential personnel, and intellectual property insurance protecting against infringement claims. The specialized nature of biotechnology risks requires insurers to develop sophisticated risk assessment capabilities and specialized coverage products.

**Clinical Research Organizations (CROs).** Contract Research Organizations provide clinical trial and testing services for new drugs and medical devices, serving as essential intermediaries between biotechnology companies and regulatory agencies. IQVIA represents one of the world's leading CRO companies with 2023 revenue of $14.4 billion [23]. This sector plays crucial roles in bringing biotechnology products to market and possesses a distinctive legal status combining service provider and regulatory compliance responsibilities.

Charles River Laboratories specializes in preclinical and clinical research services, supporting biotechnology products throughout their entire development cycles. The company provides animal testing, safety assessment, and regulatory consulting services essential for biotechnology product development.

CRO companies operate within complex regulatory environments requiring compliance with Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and other quality standards. These organizations must maintain accreditation from multiple regulatory agencies while managing complex relationships with sponsors, investigators, and regulatory authorities.

**Table 3**

**Major CRO Companies and Their Specializations**

| Company | 2023 Revenue | Primary Services | Geographic Focus |
|---|---|---|---|
| IQVIA | $14.4 billion | Full-service CRO, Data Analytics | Global |
| Charles River | $3.9 billion | Pre-clinical, Safety Testing | Global |
| PPD (Thermo Fisher) | $7.1 billion | Clinical Development | Global |
| ICON | $3.2 billion | Clinical Research, Consulting | Global |

**Regulatory and Control Subjects System.** Biotechnology sector safety and effectiveness require complex, multi-level regulatory systems operating at national and international levels. These systems include various organs and institutions with regulatory subjects not only performing control functions but also determining biotechnology sector development directions.

**United States Regulatory Framework.** The Coordinated Framework for Regulation of Biotechnology (CFRB), established in 1986, operates through three primary federal agencies representing one of the world's most comprehensive and influential biotechnology regulation systems [24]. According to 2024 updates, the framework operates based on four fundamental principles.

**Product-based regulation** emphasizes product characteristics rather than production processes as primary evaluation criteria. This approach enables biotechnology products created through genetic engineering to be evaluated using the same criteria as products produced through traditional methods. For example, genetically engineered insulin receives evaluation using the same safety criteria as traditionally produced insulin.

**Existing legislation framework** applies current legal foundations to biotechnology products rather than creating entirely new regulatory structures. This approach provides flexibility for rapidly evolving technologies while occasionally creating regulatory gaps requiring case-by-case interpretation.

**Risk-based approaches** provide differential regulation based on potential risk levels, with high-risk products receiving stricter oversight while low-risk products undergo simplified procedures. This approach enables regulatory resources to focus on products posing greatest potential risks.

**Science-based decision-making** requires regulatory decisions based on empirical data and peer-reviewed research rather than political or economic considerations. This principle aims to ensure objective evaluation processes independent of external pressures [25].

**FDA (Food and Drug Administration)** possesses the broadest authority in biotechnology regulation, covering food, feed, human drugs, and animal drugs. The agency operates multiple specialized centers including the Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Food Safety and Applied Nutrition (CFSAN).

**EPA (Environmental Protection Agency)** regulates pesticides and toxic substances including biotechnology products' ecological impacts. The agency evaluates environmental releases of genetically modified organisms and establishes requirements for environmental safety testing.

**USDA (U.S. Department of Agriculture)** operates in agricultural biotechnology with authority covering the entire agricultural

product cycle from research and development through commercial release [26]. The agency's Animal and Plant Health Inspection Service (APHIS) evaluates genetically modified crops and animals for agricultural use.

**European Union Regulatory System.** The European Commission's biotechnology policy undergoes fundamental changes in 2024-2025, with the European Biotech Act planned for presentation in the third quarter of 2026 [27]. This legislation aims to enhance European biotechnology sector global competitiveness while improving regulatory effectiveness.

The European approach emphasizes precautionary principles more strongly than American frameworks, often requiring more extensive safety data before approving new biotechnology products. This approach reflects European political culture's emphasis on risk aversion and public participation in technology assessment.

**European Medicines Agency (EMA)** serves as the primary regulatory body for biotechnology products in European Union markets. The agency coordinates evaluation processes across member states while ensuring consistent application of European regulations.

**European Food Safety Authority (EFSA)** evaluates genetically modified foods and feeds, providing scientific opinions supporting regulatory decisions by member states and European Commission. EFSA's role demonstrates European emphasis on scientific expertise in regulatory decision making.

**Japanese Regulatory System**

Japan's Pharmaceuticals and Medical Devices Agency (PMDA) serves as the primary biotechnology regulatory body with distinctive characteristics setting it apart from American and European counterparts. Singh observes that "PMDA's strict Chemistry, Manufacturing and Controls (CMC) data requirements make Japan unique" [28]. This uniqueness reflects Japanese regulatory system's emphasis on high quality standards and thorough documentation requirements [29].

Japanese regulatory approaches often emphasize consensus building and extensive consultation with industry stakeholders before implementing new regulations. This approach can slow regulatory processes but often results in regulations with broad industry support and effective implementation.

**International Regulatory Coordination**

International organizations play increasingly important roles in biotechnology regulation through harmonizing standards and facilitating cooperation between national regulatory agencies. The International Council for Harmonisation (ICH) coordinates drug development standards globally, enabling companies to develop products meeting multiple national requirements simultaneously.

The World Health Organization (WHO) shapes biotechnology policy from global health perspectives, particularly regarding access to essential medicines and pandemic preparedness [30]. WHO's guidelines influence national regulatory decisions and international cooperation agreements.

**OECD biotechnology guidelines** establish standards for economically developed countries, providing frameworks for biotechnology policy development and international cooperation [31]. These guidelines facilitate technology transfer and investment flows between member countries while ensuring appropriate safety standards.

**Table 4**

**Comparison of Major Regulatory Systems**

| Aspect | United States | European Union | Japan |
|---|---|---|---|
| Primary Principle | Product-based, Risk-based | Precautionary, Process-aware | Quality-focused, Consensus |
| Key Agencies | FDA, EPA, USDA | EMA, EFSA, National Agencies | PMDA, MAFF |
| Decision Timeline | 6-12 months | 12-24 months | 12-18 months |
| Public Participation | Limited | Extensive | Moderate |
| International Influence | High | High | Moderate |

**Sectoral Specialization and Color-Code Classification.** Another classification criterion for determining the legal nature of biotechnology subjects involves specialization by biotechnology sectors based on color-code systems. This classification system provides an intuitive framework for understanding different biotechnology applications and their associated regulatory requirements.

Red Biotechnology encompasses medical and pharmaceutical subjects, including drug development companies, medical device manufacturers, gene therapy companies, and diagnostic firms. This sector represents the largest biotechnology market segment with the highest regulatory complexity due to direct human health implications.

Major red biotechnology companies include Amgen, Genentech, Moderna, and BioNTech, each specializing in different therapeutic areas. The regulatory requirements for red biotechnology products typically involve extensive clinical testing, safety monitoring, and post-market surveillance.

Green Biotechnology involves agricultural biotechnology subjects, including GMO seed producers, biopesticide manufacturers, and agricultural technology firms. This sector addresses global food security challenges while raising environmental and ethical concerns about genetic modification.

Leading green biotechnology companies include Monsanto (now part of Bayer), Syngenta, and DowDuPont Agriculture Division. These companies develop genetically modified crops with enhanced characteristics, including pest resistance, herbicide tolerance, and improved nutritional content.

White Biotechnology covers industrial biotechnology subjects, including biofuel producers, industrial fermentation companies, and biomaterials manufacturers. This sector focuses on replacing traditional chemical processes with biological alternatives, often emphasizing environmental sustainability.

Major white biotechnology applications include the production of biofuels, biodegradable plastics, industrial enzymes, and specialty chemicals. Companies such as Novozymes, DSM, and Genencor (now part of DuPont) lead this sector through developing biological solutions for industrial applications.

Blue Biotechnology relates to marine biotechnology subjects, including aquaculture companies, marine organism biological compound extraction firms, and ocean biotechnology companies. This emerging sector exploits marine biodiversity for pharmaceutical, industrial, and food applications.

Blue biotechnology represents significant untapped potential, as marine environments contain vast numbers of unexplored species with potential applications in medicine, materials science, and energy production.

**Digital Transformation and Emerging Technologies.** Contemporary biotechnology witnesses artificial intelligence-based drug discovery companies serving as primary drivers of digital transformation [32]. AI-powered drug discovery companies fundamentally transform the traditional pharmaceutical industry by creating new business models and accelerating development timelines [33].This transformation creates new subject categories in biotechnology ecosystems while eliminating traditional boundaries between technology sectors [34]. Companies such as DeepMind, Recursion Pharmaceuticals, and Atomwise represent hybrid entities combining artificial intelligence capabilities with biological expertise.

Synthetic biology combines engineering principles with biology through designing and constructing biological systems. This field represents a paradigm shift from traditional biotechnology approaches by enabling systematic design of biological systems rather than relying on natural processes.

NBIC convergent technologies (nanotechnology, biotechnology, information technologies, and cognitive sciences) create new interdisciplinary solutions transcending traditional sector boundaries [35]. This convergence enables the development of sophisticated medical devices, diagnostic systems, and therapeutic approaches impossible within single technology domains.

Quantum biotechnology opens new possibilities for molecular process simulation and biosensor development [36]. Quantum computing applications in biotechnology include drug discovery acceleration, protein folding prediction, and complex biological system modeling.

These technological convergences result in hybrid subjects emerging through collaboration between pharmaceutical giants and technology startups. Future biotechnology sector subject systems will become increasingly complex, requiring new legal and ethical relationship frameworks.

**Analysis of the research results**

**Theoretical Framework Implications.** The analysis reveals that traditional civil law subject classifications prove inadequate for addressing biotechnology sector complexity. The multi-helix innovation models provide more appropriate theoretical frameworks for understanding biotechnology subject interactions, but these models require adaptation to address legal relationship specificities.

The primary challenge involves reconciling dynamic innovation requirements with legal certainty needs. Biotechnology subjects operate in rapidly changing environments where technological capabilities, market conditions, and regulatory requirements evolve continuously. Legal frameworks must provide sufficient flexibility to accommodate innovation while maintaining predictability and fairness.

The interdisciplinary nature of biotechnology creates additional challenges for subject classification. Many biotechnology entities simultaneously function as research institutions, commercial enterprises, and regulatory compliance organizations. This multi-functionality complicates legal status determination and creates potential conflicts between different operational roles.

**Regulatory Effectiveness Analysis.** Comparative analysis of different regulatory systems reveals trade-offs between innovation promotion and risk management. The American system emphasizes innovation promotion through product-based regulation and risk-based approaches, potentially accelerating technology development while creating some safety concerns.

The European system prioritizes risk management through precautionary approaches and extensive public participation, potentially ensuring higher safety standards while slowing

innovation adoption. The Japanese system emphasizes quality and consensus, creating thorough but sometimes lengthy approval processes.

The effectiveness of different regulatory approaches depends partly on broader institutional contexts, including legal systems, political cultures, and economic development levels. Successful biotechnology regulation requires alignment between regulatory approaches and broader institutional environments.

**International Cooperation Challenges.** Biotechnology's global nature creates needs for international regulatory coordination, but different regulatory philosophies and national interests sometimes impede cooperation. Patent rights, data exclusivity periods, and safety standards vary significantly between jurisdictions, creating barriers to international technology transfer and market access.

The emergence of new biotechnology applications, including gene editing, synthetic biology, and AI drug discovery, creates additional coordination challenges as regulatory agencies struggle to develop appropriate oversight frameworks for rapidly evolving technologies.

**Future Development Implications.** Digital transformation and technological convergence will continue reshaping biotechnology subject systems, requiring continuous adaptation of legal and regulatory frameworks. The integration of artificial intelligence, nanotechnology, and biotechnology will create new hybrid entities requiring novel legal approaches.

The increasing importance of data and algorithms in biotechnology will raise new intellectual property and privacy issues requiring specialized legal frameworks. Biotechnology companies will need to navigate complex data protection requirements while maintaining innovation capabilities.

Environmental and social concerns will increasingly influence biotechnology regulation, requiring subjects to address sustainability and ethical considerations more comprehensively. ESG (Environmental, Social, and Governance) criteria will become increasingly important in biotechnology investment and regulatory decisions.

**Conclusion**

The multi-level system of civil law relations subjects in biotechnology represents one of the most complex and dynamic elements of the contemporary innovation economy. Deep analysis reveals that biotechnology sector success depends not only on scientific achievements but also on creating effective legal-institutional environments that can accommodate innovation while protecting public interests. Primary research conclusions include:

*First,* biotechnology subject systems fundamentally differ from traditional legal classifications. This sector requires complex interactions between primary (research and production), secondary (service and financial), and regulatory subjects. Triple and Quadruple Helix models provide theoretical foundations for understanding this complexity, but legal frameworks must adapt to address the distinctive characteristics of biotechnology innovation ecosystems.

*Second,* digital transformation in contemporary biotechnology creates new subject categories requiring novel legal approaches. AI-powered drug discovery companies, bioinformatics platforms, and blockchain-based solutions fundamentally alter traditional biotechnology ecosystems while creating new forms of legal relationships that existing frameworks struggle to address adequately.

*Third,* international experience demonstrates that successful biotechnology systems rely on balanced regulatory approaches, multi-sectoral cooperation, and continuous adaptability principles. United States, European Union, and Japanese experiences reveal distinctive

advantages and disadvantages of different regulatory philosophies, suggesting that optimal approaches may require combining elements from multiple systems.

*Fourth,* biotechnology subject legal status and obligations continuously expand, reflecting new technological capabilities and social demands. ESG criteria, bioethics requirements, and digital transformation create new responsibility areas that biotechnology subjects must navigate while maintaining innovation capabilities and commercial viability.

*Fifth,* future biotechnology subject systems will become increasingly complex with emerging synthetic biology, convergent technologies, and quantum biotechnology directions requiring unprecedented levels of interdisciplinary cooperation and regulatory innovation.

**Recommendations for Developing Nations**

Developing nations seeking to build effective biotechnology sectors should consider several key recommendations based on international experience and theoretical insights: Gradual development strategies prove more effective than attempting comprehensive biotechnology systems immediately. Countries should focus initially on building educational and research capabilities before developing complex regulatory frameworks and commercial sectors.

International cooperation provides essential learning opportunities and resource access. Developing nations should actively participate in international biotechnology organizations, regulatory harmonization efforts, and technology transfer programs.

Balanced regulatory approaches should emphasize both innovation promotion and risk management without creating unnecessary barriers to legitimate research and development activities. Regulatory frameworks should incorporate learning mechanisms enabling adaptation as experience accumulates.

Multi-sectoral collaboration between government, academia, and industry requires institutional frameworks encouraging cooperation while maintaining appropriate independence and accountability. Public-private partnerships can provide valuable mechanisms for sharing risks and resources.

Intellectual property protection must balance innovation incentives with access considerations, particularly regarding essential medicines and agricultural technologies. Developing nations should consider flexible intellectual property approaches that encourage innovation while ensuring reasonable access to essential biotechnology products.

The biotechnology sector's continued evolution will require ongoing adaptation of legal and regulatory frameworks. Successful navigation of these challenges will depend on maintaining dialogue between all stakeholders while preserving flexibility for continued innovation and adaptation.

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# TSUL LEGAL REPORT

INTERNATIONAL ELECTRONIC SCIENTIFIC JOURNAL

VOLUME 6
ISSUE 3
SEPTEMBER 2025