Journal Website: https://www.icjn.net/cl ISSN: 3106-5058 | EISSN: 3106-5066

ICJN Press

Cytotherapy and Longevity (CL)

Volume. 01 | Issue. 01 | Aug. 2026 DOI: 10.66729/cl202607001

REVIEW

Regulatory Evolution and Transformation of China's Cell and Gene Therapy Industry

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Abstract

Cell and gene therapy (CGT) products have driven a global transformation in medicine, opening new avenues for the diagnosis and treatment of major diseases, while also posing new challenges to regulatory agencies worldwide. In the context of the current global CGT industry landscape, this article systematically reviews the evolution of China's CGT regulatory framework over the past three decades, delves into the stages of regulatory development, and analyzes the profound impact of regulatory policies in different periods on the industry landscape, biopharmaceutical research and development (R&D) activities, and clinical translational application. At present, China ranks among the global leaders in the number of CGT pipelines under development, demonstrating strong momentum for industrial growth. However, under the conventional regulatory paradigm, challenges such as long R&D cycles, inefficient translational application pathways, and unclear delineation of authorities and responsibilities have long constrained the development of the industry. On this basis, this article interprets the *Regulation on the Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies*, which entered into force in 2026, with a particular focus on its new dual-track regulatory framework that comprises a drug registration pathway and a new biomedical technology pathway, and its transformative impact on regulatory approval procedures, clinical translational application, and full lifecycle risk management.

Keywords

Cell and gene therapy (CGT); Stem cell clinical research filing; New biomedical technologies; Clinical translational application

Citation: Wei Li, Zhen Qin Xiujuan Wang, *et al*. Regulatory Evolution and Transformation of China's Cell and Gene Therapy Industry. *Cytotherapy and Longevity*, 2026, 01 (1): 1-12. doi: 10.66729/cl202607001.

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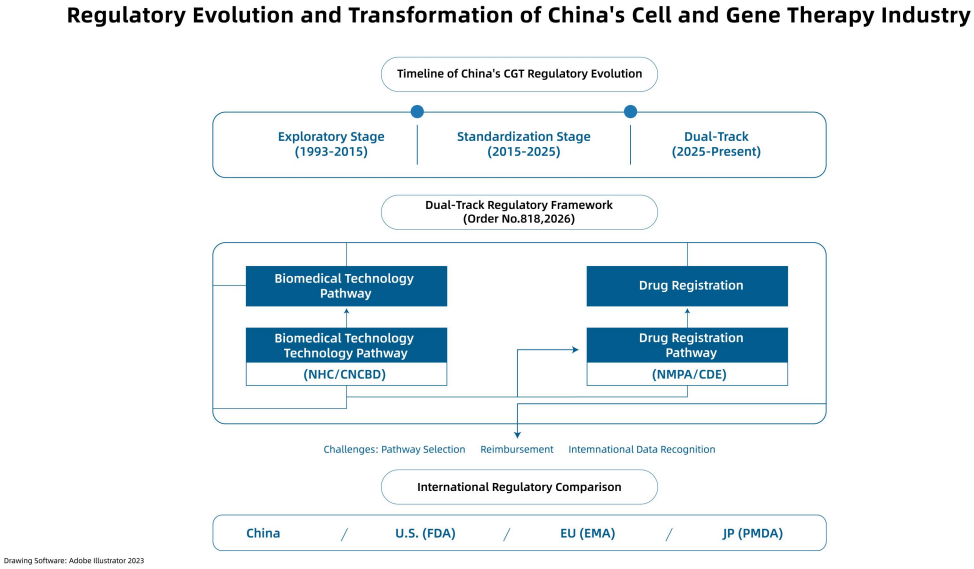
Received 2 July 2026; Revised 24 July 2026; Accepted 20 August 2026; Available online 26 August 2026.

Graphical Abstract



Highlights

- This review systematically traces China's 30-year CGT regulatory evolution from early exploration (1993) to dual-track reform (2025–present).
- Order No. 818 establishes a novel dual-track framework with separate drug registration and new biomedical technology pathways.
- A comprehensive four-jurisdiction comparison (China, U.S., EU, Japan) of CGT regulatory frameworks is provided.
- Critical challenges including pathway selection, reimbursement mechanisms, and international data recognition are analyzed.
- The review offers practical guidance for compliant CGT development and evidence-based regulatory policy optimization.

1. Introduction

Cell and gene therapy (CGT) products, following large-molecule drugs and antibody therapies, represent the core driving force in the third medical revolution[1,2] and have fundamentally changed the diagnostic and therapeutic landscapes for a wide range of serious diseases, including cancer, genetic diseases, and autoimmune diseases. Owing to the novel mechanisms of action and manufacturing technologies of CGT products, existing regulatory frameworks for chemical drugs and conventional biologics are no longer fully applicable. Consequently, establishing a novel regulatory framework for CGT has emerged as a new challenge for regulatory authorities worldwide.

In March 2026, the *Outline of the 15th Five-Year Plan for National Economic and Social Development*[3] incorporated, for the first time, CGT technologies into China's strategic emerging industries, explicitly calling for the "accelerated R&D and application of CGT products and antibody therapeutics". In addition, the implementation of the *Regulation on the Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies* (Order No. 818 of the State Council)[4] on May 1, 2026 represents a major regulatory initiative by the Chinese regulatory authorities to align with the aforementioned national strategy, aiming to address regulatory bottlenecks in industrial development, identify a China-specific regulatory pathway for the development of the CGT industry, and further enhance China's participation in the global biopharmaceutical field.

This review is based on a systematic search of regulatory documents, policy documents, and academic literature related to China's CGT industry. Inclusion criteria encompassed formally promulgated laws, administrative regulations, departmental rules, normative documents, and technical guidelines directly related to CGT product development, clinical research, translational application, and marketing authorization. Official regulatory documents were retrieved from the websites of the National Health Commission (NHC) and the National Medical Products Administration (NMPA). Academic literature was searched through PubMed, Web of Science, and CNKI databases using the search terms "cell and gene therapy," "CGT regulation," "stem cell," "new biomedical technology," and "China" (in both English and Chinese), covering the period from January 1993 to May 2026. Industry reports from authoritative consulting firms and peer-reviewed academic publications providing critical analysis of regulatory reforms were also included. Comparative regulatory information for the United States (Food and Drug Administration, FDA), the European Union (European Medicines Agency, EMA), and Japan (Pharmaceuticals and Medical Devices Agency, PMDA) was obtained from the respective official regulatory websites.

2. "Development" and "Dilemmas" of the Global CGT Industry

According to a 2025 Q3 report, a total of 38 gene therapies, 35 RNA therapies, and 71 non-genetically modified cell therapies have been approved worldwide[5]. Another report indicated that, by the end of 2025, a total of 139 CGT products had obtained

marketing authorization, over 57% of which were approved within the preceding five years[6].

Globally, there are more than 6,000 CGT pipelines currently in different stages of development[7]. Among them, hemato-oncology represents the most mature therapeutic area, with promising advances made in solid tumors, autoimmune diseases, rare genetic diseases, neurodegenerative diseases, tissue repair and regeneration, and aging intervention. Notably, China's CGT pipelines have faster growth, with domestic pipelines under development accounting for over 40% of the global total[8,9].

CGT products exert therapeutic effects through completely different mechanisms from those of conventional drugs. The dynamic nature and heterogeneity of CGT products fundamentally challenge the essential quality requirements for homogeneity and stability that underpin conventional drugs[10,11]. The development process and quality control of CGT products are complex and challenging, such as high individualization, technological complexity, and a lack of harmonized standards. Therefore, the regulatory rules for conventional drugs are inevitably not applicable to CGT-related technologies.

Currently, both the U.S. FDA[12] and the EMA[13] regulate CGT products within the conventional pharmaceutical regulatory framework. To better accommodate the unique characteristics of CGT products, both agencies have introduced adaptive regulatory mechanisms, including the FDA's expedited programs, such as the Regenerative Medicine Advanced Therapy (RMAT) and Breakthrough Therapy designations[14-16], as well as the EMA's regulatory framework for Advanced Therapy Medicinal Products (ATMPs)[17]. While these initiatives are intended to facilitate the development of innovative CGT products, they do not fundamentally depart from the conventional pharmaceutical regulatory paradigm. Consequently, the current regulatory system has hindered the translation of research outputs into marketable products, leading to an imbalance between substantial R&D investment, prolonged development time, and limited commercial returns, thereby significantly limiting the clinical application prospects of CGT products.

3. Evolution of CGT Regulatory Framework in China

3.1 Early Exploratory Stage (1993-2015)

CGT regulations in China date back to 1993, when the former Ministry of Health first incorporated human somatic cell therapy and gene therapy into the regulatory scope and issued the *Key Points for Quality Control of Clinical Research on Human Somatic Cell Therapy and Gene Therapy*[18]. In 2009, the former Ministry of Health issued the *Administrative Specifications for Autologous Immune Cell (T Cell and NK Cell) Therapy Technologies (Draft for Comments)*[19], classifying autologous immune cells (T cells and NK cells) and allogeneic stem cell transplantation as Class III medical technologies[20] and permitting their clinical application and fee-based provision. This policy led to the rapid development of biotherapy departments and stem cell centers in hospitals. In addition, many provinces incorporated such therapies into their medical insurance reimbursement schemes, thus substantially reducing patients' financial burden. At that time, immune cell therapy became a preferred treatment option for many cancer patients. However, unlike hematopoietic stem cell transplantation, which only involves centrifugation and cryopreservation of samples, the preparation of stem cells and immune cells requires cell culture, expansion, cryopreservation, and multiple quality testing procedures before infusion. Except for a few leading Class A tertiary hospitals and military hospitals, most hospitals relied on third-party enterprises for cell culture and drug product preparation. Meanwhile, China's CGT regulatory framework was still in its infancy, and regulatory oversight as well as qualification and certification mechanisms for cell manufacturing enterprises had yet to be established. Consequently, limited emphasis was placed on technical capabilities and product quality in cell manufacturing enterprises, resulting in poorly qualified manufacturers and substandard products, which not only compromised patient interests but also hindered the development of the CGT industry. In 2013, Bosheng Excellence and the 307th Hospital of the Chinese People's Liberation Army (the Affiliated Hospital of the Academy of Military Medical Sciences) jointly submitted an investigational new drug (IND) application for a mesenchymal stem cell (MSC)-based product, marking the beginning of drug registration for MSC-based products in China. However, in the absence of an established evaluation framework for such products, the application did not progress to marketing authorization.

3.2 Standardized Filing and Drug-Registration Stage (2015-2025)

In 2015, the former National Health and Family Planning Commission issued a notice abolishing the approval requirements for clinical application of Class III medical technologies, including hematopoietic stem cell and immune cell therapies[21]. In the same year, the National Health Commission (NHC) issued the *Administrative Measures for Stem Cell Clinical Research (Trial)*[22], which designated medical institutions conducting stem cell clinical research as the entities responsible for the quality management of stem cell preparations and clinical research, including review, filing, and oversight. In 2016, the research project "standardized evaluation system for clinical-grade stem cells" was included in the first batch of National Key R&D Programs on "Stem Cell and Translational Research", thereby setting the benchmark for subsequent quality research on stem cell products. During the same period, China's pharmaceutical regulatory framework began to evolve more comprehensively and standardizedly, with regulatory policies, technical guidelines, and review procedures. In May 2016, the Standing Committee of the National People's Congress issued the *Pilot Program for the Drug Marketing Authorization Holder System*, marking the beginning of China's efforts to deepen the reform of drug review and approval processes[23]. In January 2026, the Center for Drug Evaluation issued the *Technical Guidelines for Pharmaceutical Change Research and Evaluation of Cell Therapy Products (Trial)*[24], which specifies the technical requirements for pharmaceutical comparability studies of cell therapy products. Over the past decade, China's drug regulatory authorities have established a comprehensive regulatory framework encompassing pharmaceutical, nonclinical, and clinical research through the issuance of regulatory policies, technical guidelines, and supporting documents, thereby facilitating the addressing of unmet medical needs.

Regulatory policy shifts reshaped the landscape of the CGT industry. In 2016, hospital-based biotherapy departments were closed, and many low-quality enterprises exited the market. However, this industry-wide restructuring also triggered a decade of accelerated development in China's CGT industry. CGT enterprises refocused on product quality research and process

development, leading to the emergence of several outstanding domestic enterprises with independent intellectual property rights, which have gradually expanded into European and American markets[25].

Under the stem cell clinical research filing pathway, as of January 2026, approximately 185 stem cell clinical research projects had been approved in China, with indications covering hematological diseases, autoimmune diseases, neurological diseases, cardiovascular diseases, and musculoskeletal system diseases. Among them, more than 60% focused on chronic diseases, such as decompensated cirrhosis, spinal cord injury, and Parkinson's disease. Under the drug registration pathway, multiple domestically developed chimeric antigen receptor T (CAR-T) cell products have been approved for marketing[26,27]. In 2025, China's first MSC-based product, Amimatoside Injection, also received marketing approval[28], marking a milestone in the decade-long rise of China's CGT enterprises. Over this period, not only have CGT companies grown rapidly, but upstream suppliers of raw materials and equipment have also significantly improved in quality. A large number of high-quality domestic manufacturers of culture reagents, cytokines, and automated equipment, as well as professional contract development and manufacturing organizations (CDMOs), have emerged, enabling a qualitative leap across the entire CGT industry chain in China[29,30].

However, the regulatory system at this stage also faced several limitations. The stem cell clinical research filing system introduced in 2015 required dual-filing with the national health administrative authority. Specifically, clinical research files were subjected to NHC review, with a focus on evaluating the clinical protocols, the product manufacturing processes, preclinical safety data, and risk control strategies. Clinical research could only be conducted after approval. In principle, the stem cell clinical research filing system is broadly aligned with the investigator-initiated trial (IIT) framework, with only the additional review procedures by provincial and national health commissions. However, neither provincial nor national health commissions had established qualified supporting systems. As a result, enterprises were unable to accurately conduct effective studies, particularly for new technologies and new indications, and often failed to properly complete early-stage pharmaceutical and nonclinical research. Furthermore, no dedicated functional departments, expert reviewers, or standardized review workflow had been established by the health commissions for stem cell filing, resulting in significant variability in data requirements across provinces and time periods. Applications often underwent multiple rounds of revision, with approval time averaging 2 years–3 years, significantly reducing industry incentives for participation.

In addition, although clinical research may be conducted under the filing pathway, subsequent marketing authorization still requires submission under the new drug process. However, the regulatory authorities have generally adopted a cautious attitude toward research data from filing projects, and the industry continued to face long development cycles and substantial capital investment. Overall, these measures have drifted from the original intent of the filing pathway for encouraging innovation and new technologies in cell products.

3.3 Dual-Track Regulatory Stage (2025-Present)

During the standardized filing and drug-registration stage, an increasing number of enterprises shifted away from stem cell clinical research filing and instead pursued IND applications for biologics. However, compared with IITs, IND applications require the establishment of a professional and well-developed organizational structure, higher labor costs, longer research cycles, and substantially greater R&D investment, which is not conducive to early-stage clinical research by research-oriented enterprises and technical personnel lacking commercial teams, thereby constraining the innovation capacity of the industry.

To promote differentiated regulation, standardize and guide enterprises in R&D and clinical application, regulatory authorities have undertaken a series of policy initiatives and issued the *Regulation on the Administration of Clinical Application of New Biomedical Technologies (Draft for Comments*[31]) as early as 2019. However, due to the absence of various supporting systems and other factors, its formal promulgation was significantly delayed.

The promulgation and implementation of Order No. 818[4] and a series of supporting regulations (**Table 1**) represent not merely an adjustment to existing rules, but a systematic transformation of China's CGT regulatory strategy, marking a strategic divergence from the conventional drug regulatory system (**Table 2**, **Figure. 1**).

Table 1. Hierarchical framework of Order No. 818 and supporting regulations

Level	Document Name	File No.	Core Functions	Effective Date
Administrative Regulations	Regulation on the Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies[4]	State Council Order No. 818[4]	Top-level legislation, consisting of 7 chapters and 58 articles	2026.05.01
Rules and Regulations	Working Specifications for the Approval of Clinical Translational Application of New Biomedical Technologies (Trial)[32]	NHC Science and Education Letter [2026] No.13	Full-process operational procedures for regulatory approval	2026.05.01
	Guiding Principles for the Definition of New Biomedical Technologies, Drugs, and Medical Devices (Interim)[33]	NHC Science and Education Letter [2026] No.12	Delineating the boundary between the new biomedical technology pathway and the drug registration pathway	2026.05.01
Normative Document	Guidance List for Filing Clinical Research of New Biomedical Technologies (Version 1)[4]	Annex to Order No.12	Technology classification list covering 5 major categories and over 20 subcategories	/
	Guidelines for Risk Classification of New Biomedical Technologies[4]	NHC Science and Education Letter	Defining high-risk, medium-risk, and low-risk levels	2026.05.01
Announcement	Announcement on Matters Concerning Implementation[4]	No.4 of 2026	Six implementation guidelines	/

NOTE: NHC: National Health Commission. Sources: https://www.cncbd.org.cn/Index/

Table 2. Comparison between the new biomedical technology pathway and the drug registration pathway

Item	New Biomedical Technology	Drug Registration
Legal Basis	State Council Order No. 818	Drug Administration Law + Regulations for the Implementation of the Drug Administration Law
Regulatory Authorities	NHC + China National Center for Biotechnology Development (CNCBD)	NMPA + Center for Drug Evaluation
Product Characteristics	Highly individualized, difficult to standardize production	Standardized and scalable production
Clinical Trial Authorization	Class A tertiary hospital filing system (Filing within 5 working days after academic and ethical review)	IND application
Applicant	Clinical research initiating institution (Legal person) + clinical research institution (Class A tertiary hospital)	Marketing authorization holder
Approval Timeline	Transferred for evaluation within 5 working days after acceptance, with a decision made within 15 working days after receipt of the evaluation opinion	60 working days for IND review and 200 working days for NDA review (Standard)
Commercialization Model	In-hospital translational application with service charging	Nationwide sales
Charging Restrictions	Charging strictly prohibited during the clinical research stage	Charging strictly prohibited during the clinical research stage
Data Management Requirements	≥ 30 years (Permanent retention for offspring-related data)	Managed in accordance with the Good Pharmacovigilance Practice (GVP)
Risk Management Approach	Limited application period of 5 years for high-risk technologies, 3 years for medium-risk technologies, and 1 year for low-risk technologies	Post-marketing phase IV clinical trial + adverse reaction monitoring
R&D Cost	Relatively low	High (Hundreds of millions to billions)

NOTE: NMPA: National Medical Products Administration; IND: Investigational New Drug; NDA: New Drug Application.

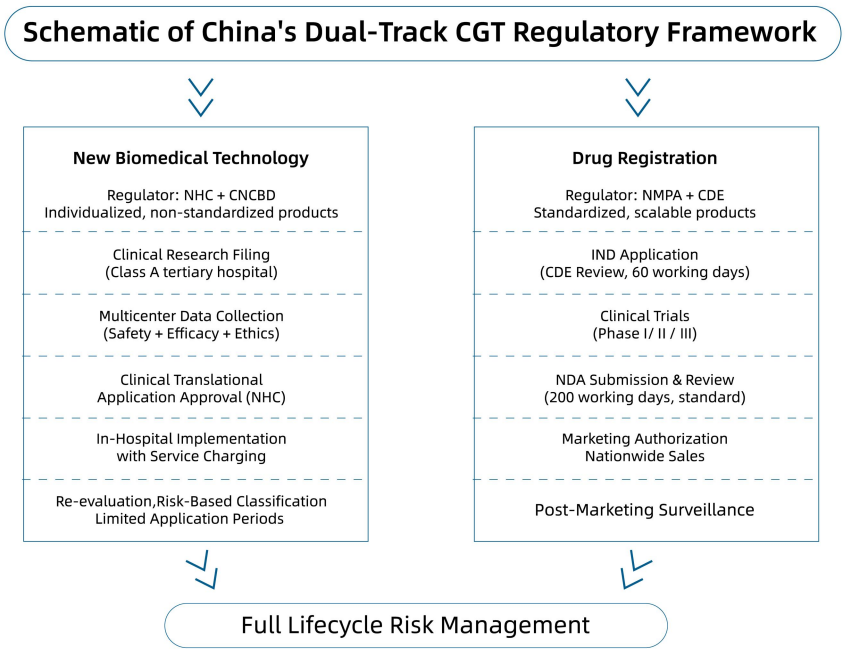


Figure. 1 Schematic of China's dual-track CGT regulatory framework. **NOTE:** CDE: Center for Drug Evaluation. Copyright: Drawing Software: Adobe Illustrator 2023.

This reform has established a hierarchical regulatory architecture spanning top-level administrative regulations, departmental rules and normative documents, technical guidelines, and detailed implementation rules. Within this dual-track framework, the NHC oversees the new biomedical technology pathway for individualized and non-standardized products, while the NMPA regulates the drug registration pathway for standardized and scalable products.

The new regulatory pathway is led by the NHC, with operational implementation carried out by the CNCBD, which is mainly responsible for managing the filing and review of new biomedical technology projects, evaluating applications for

clinical translational application, and re-evaluating translational projects. The National Center for Medical Service Administration of the NHC undertakes the re-evaluation following clinical translational application and implementation, and assists in completing evaluation matters concerning institution and personnel qualifications and operation specifications for clinical application, thereby fulfilling the full-chain management requirements from “clinical research filing” to “clinical application approval”[34].

The above provides a comprehensive discussion on the development history of China's CGT industry over the past 30 years, with a summary of the content shown in **Figure. 2**.

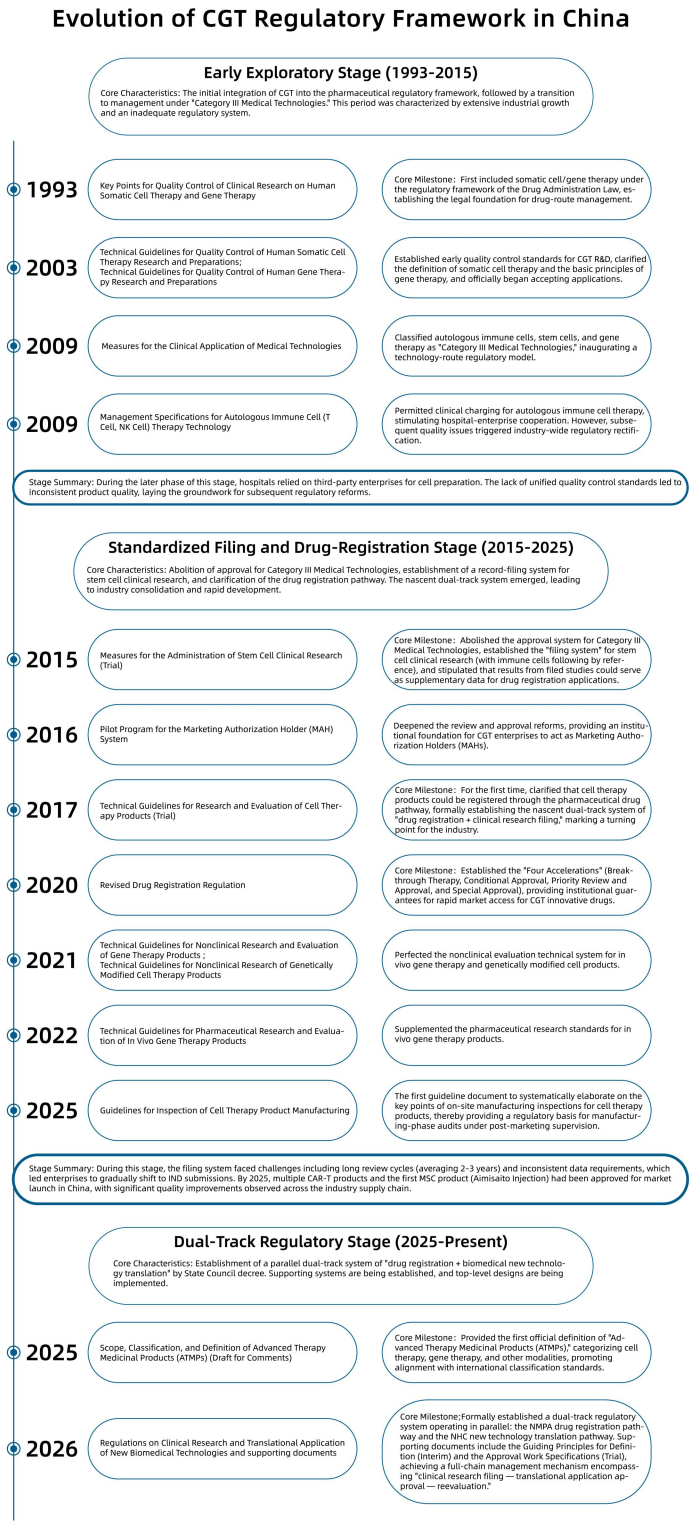


Figure. 2 Evolution of CGT Regulatory Framework in China. Copyright: Drawing Software: Adobe Illustrator 2023

Compared to the USA, the FDA's RMAT designation, established under the 21st Century Cures Act, expedites the development and review of regenerative medicine therapies through mechanisms such as early interaction with the FDA, priority review, and accelerated approval pathways. However, RMAT-designated products still follow the traditional biologics license application (BLA) framework and must meet the same safety and efficacy standards as conventional biologics. In the European Union, ATMPs are regulated under Regulation (European Commission, EC) No. 1394/2007[35] and the Committee for Advanced Therapies (CAT), which provide centralized scientific expertise. The EU framework also includes the Hospital Exemption (HE) mechanism under Article 28, which allows member states to authorize the use of ATMPs on a non-routine, individualized basis within hospitals, a concept that shares certain similarities with China's new biomedical technology pathway.

In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) administers the Sakigake (pioneering) designation and the conditional and time-limited approval system under the Act on Safety of Regenerative Medicine[36,37], which allows conditional marketing authorization based on early-phase clinical data for products targeting serious diseases. The Japanese model also permits medical institutions to provide unlicensed regenerative medicine treatments under a notification-based system, representing another dual-track approach.

Compared with these international frameworks, China's dual-track system under Order No. 818[4] is distinctive that it may establish a separate, non-drug regulatory pathway with its own clinical translational application approval mechanism, which is more institutionalized than the EU Hospital Exemption and more structured than Japan's notification-based system (**Table 3**). However, the Chinese framework may face challenges in areas such as international data recognition, post-marketing surveillance infrastructure, and coordination between the NHC and NMPA, which will require ongoing refinement.

Table 3. Comparison of CGT regulatory frameworks across major jurisdictions

Feature	**China (**NMPA**)**	**United States (FDA)**	**European Union (EMA)**	**Japan (PMDA)**
Legal Basis / Enabling Legislation	Regulation on the Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies (Order No. 818, 2025)[4]; Drug Administration Law (2019)[38]	21st Century Cures Act (2016)[14]; Public Health Service Act (PHS Act); 21 CFR Parts 600, 1271[39]	Regulation (EC) No. 1394/2007 (ATMP Regulation)[35]; Directive 2001/83/EC[40]; Regulation (EC) No. 726/2004[41]; Regulation (EU) No. 536/2014 (CTR)[42]	Act on Safety of Regenerative Medicine (ASRM, 2014)[37]; Pharmaceutical and Medical Device Act (PMD Act, 2014)[43]
Regulatory Framework	Dual-track: Drug registration pathway (NMPA) + New biomedical technology pathway (NHC)[4]	Single-track: Biologics license framework with adaptive designations (RMAT, Breakthrough, Fast Track)[12]	Centralized marketing authorization under ATMP framework[44]; Hospital Exemption (Art. 28) for non-routine individualized use[13]	Dual-track: Marketing authorization pathway + Regenerative medicine provision pathway (notification-based)[36]
Key Regulatory Authority	NHC/CNCBD[34] (new biomedical technology); NMPA/CDE (drug registration)[45]	FDA/CBER — Office of Cellular, Tissue, and Gene Therapies (OCTGT)[46]	EMA/CAT (Committee for Advanced Therapies[13]); National competent authorities for hospital exemption[47]	PMDA/MHLW; certified regenerative medicine review committees[37] for provision pathway
Accelerated / Expedited Pathway	Clinical translational application approval (5–15 working days); priority review for innovative CGT drugs[4,32]; special review procedure for urgently needed clinical needs	RMAT designation (early interaction, priority review, accelerated approval); Breakthrough Therapy; Fast Track; Accelerated Approval (21 CFR 314 Subpart H)[12]	PRIME (Priority Medicines)[48]; conditional marketing authorization (Art. 14-a of Reg. 507/2006)[49]; accelerated assessment (150 days)[13]	Sakigake (pioneering) designation[50]; conditional and time-limited approval (up to 7 years) based on early-phase data[36]
Non-drug / Hospital-Level Pathway	Yes: New biomedical technology pathway for individualized therapies in Class A tertiary hospitals; clinical translational application approval required[4]	No explicit non-drug pathway; expanded access/compassionate use under 21 CFR 312 Subpart I[51]; Right-to-Try Act (2018) for investigational products[52]	Hospital Exemption (Art. 28 of Reg. 1394/2007[35]): member states may authorize non-routine, individualized ATMP use within hospitals under national law	Regenerative medicine provision: three-class risk-based system (Class 1–3)[53]; medical institutions provide treatments under notification to MHLW[37]
Clinical Trial Framework	Class A tertiary hospital filing system (new biomedical technology); IND application for drug pathway (60-day review[4])	IND application (21 CFR 312); 30-day default review period[51]; clinical holds for safety concerns	Clinical Trial Application under CTR (Reg. 536/2014[42]); single submission via CTIS; coordinated assessment by member states	Clinical trial notification under PMD Act[43]; PMDA consultation available; clinical trial certification by certified review board

Table 3. Comparison of CGT regulatory frameworks across major jurisdictions (continued)

Feature	China (NMPA)	United States (FDA)	European Union (EMA)	Japan (PMDA)
Manufacturing Requirements	GMP compliance for drug pathway; quality management system for new biomedical technology; CNCBD inspects manufacturing facilities[23]	GMP per 21 CFR Parts 210/211 and 600 series[54]; FDA pre-approval inspections; comparability protocols for process changes	GMP per Eudralex Volume 4; Annex 1 (sterile products) [55] and Annex 2 (biological medicines)[56]; EMA manufacturing authorization required	GMP per MHLW Ordinance No. 179 (2014)[57]; PMDA GMP inspection; regenerative medicine product-specific standards
Risk Classification System	Three-tier risk classification for new biomedical technologies (low/medium/high) with differentiated review procedures[4,33] and application periods	Risk-based tiered approach: 361 products (PHS Act 361, minimal manipulation) vs. 351 products (full biologics regulation)[39]	ATMP subclassification: gene therapy, somatic cell therapy, and tissue engineering products; combined ATMPs assessed by CAT[35]	Three-class system for regenerative medicine: Class 1 (high risk, committee review), Class 2 (medium risk), Class 3 (low risk, notification only)[37]
Post-Marketing Surveillance	Risk-based classification with limited application periods (1–5 years for new biomedical technology); phase IV studies for drug pathway; mandatory adverse event reporting[4]	Post-marketing phase IV studies; REMS (Risk Evaluation and Mitigation Strategy); postmarketing safety reporting under 21 CFR 600.80[58]	Pharmacovigilance (GVP) per Directive 2010/84/EU[59]; additional monitoring for ATMPs (black triangle); risk management plan required	Post-marketing surveillance and re-examination (4–8 years for regenerative products); mandatory safety reporting[60]; periodic safety update reports
Reimbursement / Market Access	Not yet covered by national basic medical insurance; pilot programs in selected regions; local medical insurance exploratory coverage	Medicare coverage for FDA-approved CAR-T therapies; CMS National Coverage Determination (NCD) process[61]; commercial insurance varies by plan	Member state-level reimbursement decisions; no EU-wide pricing; Health Technology Assessment (HTA) under Directive 2011/24/EU[62]; Joint Clinical Assessment under HTAR (2025+)	National Health Insurance (NHI) coverage; conditional pricing for conditional/term-limited approvals; cost-effectiveness evaluation by Chuikyo
Data Retention Requirements	≥30 years (permanent for offspring-related data); comprehensive clinical research data archiving	Per 21 CFR requirements[51]; retention of study records for at least 2 years after marketing application approval or formal discontinuation	Per EMA guidelines and EU GMP Annex 11 (computerized systems)[63]; retention periods set by national law (typically 10–25 years for ATMPs)	Per MHLW regulations; retention for at least the re-examination period; long-term safety data collection mandated
International Harmonization	ICH member since 2017; active participation in ICH guidelines (E6, Q5A, S6)[64]; bilateral agreements with FDA and EMA for inspection cooperation[65]	Founding ICH member; FDA participates in IPRP (International Pharmaceutical Regulators Programme)[66]; bilateral mutual recognition agreements with EU, Japan, and Canada	Founding ICH member; EMA leads EU participation in IPRP and IPRP-Cell Therapy Working Group; mutual recognition agreement with FDA and Japan	ICH founding member; PMDA participates in IPRP; APEC Regulatory Harmonization Steering Committee; bilateral agreements with FDA and EMA

NOTE: RMAT: Regenerative Medicine Advanced Therapy; ATMP: Advanced Therapy Medicinal Product; CAT: Committee for Advanced Therapies; PRIME: Priority Medicines; CBER: Center for Biologics Evaluation and Research; MHLW: Ministry of Health, Labour and Welfare; REMS: Risk Evaluation and Mitigation Strategy; BLA: Biologics License Application; OCTGT: Office of Cellular, Tissue, and Gene Therapies; CTIS: Clinical Trials Information System; CTR: Clinical Trials Regulation; ASRM: Act on Safety of Regenerative Medicine; PMD Act: Pharmaceutical and Medical Device Act; NHI: National Health Insurance; HTAR: Health Technology Assessment Regulation; HTA: Health Technology Assessment; CMS: Centers for Medicare & Medicaid Services; NCD: National Coverage Determination; Chuikyo: Central Social Insurance Medical Council; IPRP: International Pharmaceutical Regulators Programme; CTIS: Clinical Trials Information System; GVP: Good Pharmacovigilance Practice; GMP: Good Manufacturing Practice; EMA: European Medicines Agency.

4. Will the Regulation on the Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies Lead the CGT Industry Into a New Era?

The Regulation under Order No. 818[4] clarifies the translational application requirements, procedures, and review timelines, and establishes a clear set of operating procedures. It aims to achieve scientific regulation by prioritizing regulatory resources for high-risk areas and stimulating industrial innovation while maintaining high safety standards.

Under the new regulatory system, once a filed clinical research project has been completed, the project initiating institution may submit an application for clinical use to the NHC, provided that multicenter data demonstrate the technology's safety, efficacy, and ethical compliance. Once the application is approved, the technology may be implemented as an established medical technology within

qualified medical institutions, with clinical use and service charges permitted. This may enable the translation of research outcomes into clinical services, address the previous limitation of "termination upon research completion" in stem cell clinical research filing, and establish a virtuous cycle.

Applications for clinical translation are subject to two eligibility criteria. First, the technology must exhibit a high degree of individualization, and no drug with the same mechanism of action has obtained marketing authorization or entered confirmatory clinical trials in China. Second, the technology must target rare diseases, and no drug with the same mechanism of action for the same indication has obtained marketing authorization or entered confirmatory clinical trials in China. Notably, classification is determined primarily based on the target and mechanism of action rather than product modality. For example, regardless of differences in product modality (e.g., autologous cell therapies versus off-the-shelf products), CD19-targeted CAR-T therapies are directed to the drug registration pathway because nine such products have already been approved. Enterprises are therefore required to conduct prior comparative assessments against databases of marketed and investigational drugs, as inappropriate pathway selection may lead to development delays and redundant investment.

For technologies that have obtained approval for clinical use, the Implementation Regulation establishes complete post-marketing regulatory rules, addressing the previous institutional imbalance favoring pre-approval review over post-approval oversight. Projects with clinical approval must be managed in accordance with rules on risk-based classification and limited application periods. Specifically, high-risk technologies are permitted for use only within five years of authorization, medium-risk technologies within three years, and low-risk technologies within one year. During these periods, clinical application is restricted to qualified medical institutions participating in the corresponding clinical research.

The Regulation further establishes a long-term evaluation framework for translated technologies that require technology re-evaluation based on updates in scientific understanding, the occurrence of adverse reactions in clinical practice, and the availability of relevant real-world data. During the re-evaluation stage, the use of the corresponding technology must be suspended. If the evaluation concludes that the technology's safety and efficacy cannot be assured, it should be withdrawn from clinical use, and such decisions should be made publicly available.

In summary, the regulatory framework established under Order No. 818 intends to construct a virtuous cycle encompassing clinical need-driven development, validation of R&D innovation, clinical translational application, and feedback-informed optimization, thereby promoting the deep integration of industry, academia, research, and application. It is also expected to address the long-standing problems in CGT industry regulation, including overlapping authorities and responsibilities and unclear regulatory boundaries.

However, despite the establishment of explicit classification principles, certain emerging technologies that lie at the interface between the new biomedical technology and drug registration pathways, such as certain standardized exosome therapies[67] and engineered red blood cell therapies, still require consensus among regulators, academia, and industry regarding the most appropriate regulatory pathways. Therefore, maintaining and refining the "principle of new biomedical technology pathway exclusivity" in a dynamic and scientific manner is a long-term task. Regulatory authorities may adjust pathway boundaries in response to technological evolution to ensure system adaptability.

Furthermore, it is important to distinguish between the intended objectives of the Regulation and its actual implementation outcomes. While the dual-track framework is designed to streamline regulatory approval and facilitate clinical translational application, potential unintended consequences may arise. For instance, the coexistence of two parallel pathways may create regulatory uncertainty for enterprises at the boundary between the two tracks, potentially leading to increased compliance costs and delayed decision-making. Additionally, the in-hospital translational application model under the new biomedical technology pathway may face challenges in scaling beyond individual institutions, potentially limiting broader patient access. The effectiveness of the risk-based classification and limited application period mechanisms also depends on robust post-approval surveillance infrastructure, the adequacy of which remains to be verified in practice. Therefore, the conclusions presented in this review are based on policy design and stated objectives rather than empirical implementation evidence, and should be interpreted with appropriate caution.

The most pressing challenge following translational application approval lies in establishing an appropriate payment mechanism. Critical issues remain regarding how therapies based on individualized medical technologies should be priced and appropriately integrated into national basic medical insurance, critical illness insurance, or commercial health insurance schemes. These issues are central to determining whether such innovative technologies can benefit the broader patient population and deliver public health value. Addressing these challenges requires coordinated policy development across medical insurance, healthcare, and pricing authorities to establish a payment model tailored to CGT technologies[68].

Globally, significant uncertainty remains regarding whether clinical data generated under the new biomedical technology pathway following translational approval will be recognized by overseas regulatory authorities, including the U.S. FDA and the EMA, in support of overseas marketing authorization applications for CGT products. Chinese CGT developers continue to face regulatory barriers arising from differences in regulatory standards and evaluation paradigms across jurisdictions in overseas markets. Therefore, it is essential for Chinese regulatory authorities to actively engage in global regulatory dialogue and harmonization initiatives and promote international mutual recognition of data standards to facilitate global development of domestically developed CGT products.

5. Conclusions

The Regulation on the Administration of Clinical Research and Clinical Translational Application of New Biomedical Technologies[4] may establish a unified top-level regulatory framework for China's CGT industry and serve as a reference for global CGT governance. The Regulation is expected to substantially address the long-standing industry challenges in translation, regulation, and quality control, thereby establishing a regulatory paradigm that balances safety and innovation.

From an industry perspective, the Regulation could clarify the specific direction for compliant development, provide a stable institutional framework for translating innovative research into clinical applications, and reduce uncertainties in R&D and regulatory compliance. At the regulatory level, its implementation also intends to impose new requirements on governance capacity, necessitate the progressive development of supporting detailed

rules, enhance professional review capabilities, strengthen full lifecycle oversight, and actively participates in global regulatory dialogue.

The formal implementation of this system is expected to drive China's CGT industry from a relatively uncoordinated stage of development toward a more standardized and quality-oriented trajectory. However, its long-term impact on the industry, as well as its value in informing global regulatory governance, remains to be established in practice.

The authors emphasize that the analysis presented herein is based on the regulatory design and stated policy objectives, and that empirical evidence regarding the actual implementation outcomes of the dual-track framework will require continuous monitoring and rigorous evaluation in the coming years.

Author Contributions

Wei Li: investigation, methodology, writing-original draft preparation, validation; Zhen Qin: investigation, writing-original draft preparation; Xiujuan Wang: validation, writing-review and editing; Xiu'e Wang.: investigation; methodology; Jing Wen: visualization; Yichen Shi: visualization; Chunlin Mou: Conception and design of the study, writing-review and editing, funding acquisition. All authors have read and approved the final manuscript and agree to be accountable for all aspects of this work.

Ethics Approval

Not applicable.

Artificial Intelligence (AI) Statements

This work used artificial intelligence tools to writing assistance, language refinement and polishing of the figures.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Informed Consent Statement

Not applicable.

Conflicts of Interest

The authors declare no competing financial interests.

Funding

This work was supported by Tianjin Science and Technology Plan Project (No.25YFKFYS00150), Tianjin Biomedical Major Special Program (24ZXYXSY00010).

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