IPRP
International Pharmaceutical Regulators Programme

July 2025

International Regulatory Frameworks for Cell and Gene Therapies

Introduction

Cell and gene therapy products are rapidly entering the global market. These products pose unique regulatory challenges for product developers with respect to meeting regulatory requirements for many regions. In this document the IPRP Cell Therapy and Gene Therapy Working Groups present regulatory frameworks that apply to cell therapies, cell and tissue-based therapies, gene therapies, and tissue engineered products. To assist product developers in accessing global regulatory requirements for cell and gene therapies. This document will be revised as regulatory frameworks evolve. The information contained here is current as of July 2025.

Disclaimer

This document reflects the views of subject matter experts participating in the IPRP Cell Therapy and Gene Therapy Working Group and should not be construed to represent the official views of any given regulatory authority participating in the IPRP.

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Argentina National Administration of Drugs, Food, and Medical Technology (ANMAT, Argentina)	Disposition 179/2018: Advanced Therapy Medicines - Requirements, Demands and Classification.	This law, Provision 179/2018 of the Presidency of the Nation in Argentina, establishes regulations regarding the production, registration, authorization, and surveillance of advanced therapy medicines. It defines advanced therapy medicines as including gene therapy medications, somatic cell therapy medications, and tissue engineering products. The law outlines specific technical requirements and demands for the production and registration of these medicines, including quality, preclinical, and clinical aspects to demonstrate their safety and efficacy. It also addresses issues such as donation of human cells or tissues, clinical research studies, manufacturing practices, labeling requirements, and risk	Disposición 179/2018 | Argentina.gob.ar

		management plans. The law emphasizes the importance of traceability systems to monitor the safety of these medicines and outlines penalties for non-compliance.	
	Official communication: International Reference Guides for Advanced Therapy Medicines	This Appendix lists other existing laws and guidances that will also come into force in Argentina following the notice's publication.	https://www.boletinoficial.gob.ar/detalleAviso/primera/223014/20191205

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Australia Therapeutic Goods Administration (TGA, Australia)	Therapeutic Goods Act Therapeutic Goods Regulations	Biologics- cell and gene-modified cells	Legislation and legislative instruments | Therapeutic Goods Administration (TGA)
	Standards for Human Cell and Tissue Products	Donor screening Therapeutic Goods Order (TGO 108)	https://ichportal.sharepoint.com/sites/IPRPCGTWG/Shared Documents/5_Projects/Biological Standardshttps://www.tga.gov.au/resources/guidance/understanding-donor-screening-rules-human-cell-or-tissue-products
	Unapproved Supply Pathways	Patient access pathway for drugs that have not been included in the Australian Register of Therapeutic Goods (ARTG)	https://www.tga.gov.au/products/unapproved-therapeutic-goods/supply-unapproved-therapeutic-good-sponsors

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Brazil Agência Nacional de Vigilância Sanitária (ANVISA, Brazil)	RDC 836/2023 - Good Cell Practices	Requirements for Good Cell Practices	https://anvisalegis.datalegis.net/action/UrlPublicasAction.php?acao=abrirAtoPublico&num_ato=00000836&sgl_tipo=RDC&sgl_orgao=RDC/DC/ANVISA/MS&vlr_ano=2023&seq_ato=000&cod_modulo=134&cod_menu=1696
	RDC 506/2021 – Clinical Trials with ATMP	Requirements for conducting clinical trials with investigational ATMP	https://anvisalegis.datalegis.net/action/UrlPublicasAction.php?acao=abrirAtoPublico&num_ato=00000506&sgl_tipo=RDC&sgl_orgao=RDC/DC/ANVISA/MS&vlr_ano=2021&seq_ato=000&cod_modulo=134&cod_menu=1696
	RDC 505/2021 – Marketing authorization for ATMP	Requirements for ATMP marketing authorization	https://anvisalegis.datalegis.net/action/UrlPublicasAction.php?acao=abrirAtoPublico&num_ato=00000505&sgl_tipo=RDC&sgl_orgao=RDC/DC/ANVISA/MS&vlr_ano=2021&seq_ato=000&cod_modulo=134&cod_menu=1696

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Canada **Health Canada (Health Canada, Canada)**	Food and Drugs Act R.S.C., 1985, C. F-27	General requirements for therapeutic products including cell and gene therapies. There are three sets of regulations under the Act relevant to cell and gene therapies: (1) the Food and Drug Regulations (2) the Safety of Human Cells, Tissues and Organs for Transplantation Regulations (3) the Medical Device Regulations Legislative provisions introduced in 2019 created a new framework to authorize Advanced Therapeutic Products (ATPs). ATPs are drugs or devices, or any combination of drugs and devices, that our current regulations were not designed to handle because they're so complex or distinct. This framework allows Health Canada to customize regulatory requirements for these products.	https://laws-lois.justice.gc.ca/eng/acts/f-27/
	(1) Food and Drug Regulations C.R.C., c. 870	Requirements for clinical investigation and authorization of drugs.	https://laws.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html
	(2) Safety of Cells, Tissues and Organs for Transplantation Regulations (CTO Regulations)	The CTO Regulations apply to all individuals and establishments that handle, process, distribute or import human organs, or minimally manipulated cells and tissues for homologous use, for transplantation in another individual in Canada.	https://laws-lois.justice.gc.ca/eng/regulations/sor-2007-118/index.html
	(3) Medical Devices Regulations (MDR)	These regulations are relevant as novel processing/manufacturing technologies are increasingly being used to process cells and to manufacture gene and cell therapy products close to the bedside by physicians. Some of these	https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/

		manufacturing technologies have been classified as devices. In addition, some cell and tissue-based products may be classified as drug-device combination products or fall at the drug-medical device interface.	

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Chile – Public Health Institute Chili (ISPCH, Chile)		Left Blank Intentionally	

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Chinese Taipei - Taiwan Food and Drug Administration (TFDA, Chinese Taipei)	Regenerative Medicine Act	Define Regenerative Medicine, including Regenerative medicinal products and Regenerative medicine techniques. Also include the establishment of Review Board, policy development, ensuring patient rights and medical ethics, and regulation of cell banks.	Regenerative Medicine Act
	Regenerative Medicinal Products Act	Define categories of regenerative products and the requirement for approval and post approval managements. Allowing conditional approval for certain products.	Regenerative Medicinal Products Act
	Regulation Governing the Application of Specific Medical	Includes the regulation for	Regulation Governing the Application of Specific Medical Examination Technique and Medical Device (Chinese version only)

	Examination Technique and Medical Device	conducting listed cell therapies at authorized medical institutes (Chapter 2 Section 1, and Table 3; Chinese version only).	

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Egypt - Egyptian Drug Authority (EDA, Egypt)	Decree No. (343)/2021pt	Rules and procedures for registering biological products, serums, vaccines and blood products; this was published in the Official Gazette No. (168 Annex/ 2021)	https://www.ela.law/firms/ibrachy-dermarkar/articles/the-egyptian-drug-authority-eda-has-issued-decree-no-343-2021pt

Country Regulatory Authority	Law/Regulation	Details	Weblinks
European Commission-European Union European Medicines Agency (EMA/EC, Europe)	Regulation 1394/2007 on ATMPs	'Lex specialis' (only describing what is specific for ATMP)	https://eur-lex.europa.eu/eli/reg/2007/1394/oj/eng
	Directive 2001/83/EC	Main pharmaceutical legislation	https://eur-lex.europa.eu/eli/dir/2001/83/oj/eng
	Regulation (EC) 726/2004	Regulation on the centralized evaluation procedure and EMA	https://health.ec.europa.eu/system/files/2016-11/reg_2004_726_en_0.pdf
	Directive 2009/120/EC	Scientific and technical requirements for ATMPs (dossier requirements)	https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:242:0003:0012:EN:PDF

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Israel - Enforcement and Pharmaceutical Division, Ministry of Health (CPED, Israel)	Public Health Regulations (clinical trials in human subjects) (1980)	General provision, includes definitions of clinical trials, dedicated committees (including superior committee responsible for genetic issues)	https://www.ema.europa.eu/en/human-regulatory-overview/research-development/clinical-trials-human-medicines/clinical-trials-regulationhttps://www.health.gov.il/LegislationLibrary/Briut18.pdf
	Pharmacists Ordinance [New Version], 1981	General provision, includes definition of medicinal product to include Advanced Therapies	https://www.health.gov.il/legislationlibrary/rokhut23.pdf
	The Pharmacists Regulations (Medicinal products) 1986	General provision, for licensing, registering and renewal of medicinal products Marketing Authorizations	https://www.health.gov.il/LegislationLibrary/Rokhut04.pdf
	Pharmacist Regulations (Good Manufacturing Practice for Medicinal Products) 2008	General provision, GMP regulation (in accordance with EU GMP legislation)	https://www.health.gov.il/LegislationLibrary/Rokhut27.pdf
	Cord Blood -Law and Regulation (2012)	For control and licensing of public and private Cord Blood Banks	https://www.health.gov.il/LegislationLibrary/Dam01.pdf https://www.health.gov.il/LegislationLibrary/Dam01.pdf https://ichportal.sharepoint.com/sites/IPRPCGTWG/Shared Documents/5_Projects/Cord Blood (02)
	Notice on the approval of general director according to pharmacist regulation (2016)	For use of Unlicensed medicines, to include Hospital Exemption	https://www.health.gov.il/LegislationLibrary/Rokhut31.pdf

Country	Law/Regulation	Details	Weblinks

Regulatory Authority			
Japan Ministry of Health, Labor and Welfare/Pharmaceutical Medical Devices Agency (MHLW/PMDA, Japan)	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceuticals and Medical Device Act)	Defines" Regenerative Medical Products" and allows "conditional and time-limited" approval for some of the products.	PMDA Quality, Efficacy, and Safety
	Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Protocol Domestic Law, Cartagena Law)	Regulates manufacture and use of gene-modified organisms (before marketing authorization).	Cartagena Protocol, Domestic
	Act on the Safety of Regenerative Medicine (regulated by MHLW, and PMDA's role is limited to inspection of the structure and equipment of contract CPC facilities)	Regulates regenerative medicine and cell therapy in medical practice and CPCs outside of PMD Act (i.e. without intention of product registration for marketing).	Safety - Products not intended to be marketed Tobita, et al. Regenerative Therapy. 4 (2016) 78e81 (https://doi.org/10.1016/j.reth.2016.04.001)
	Standards for Biological Raw Materials (Ministerial Ordinance to supplement PMD Act)		Standards for Biological Raw Materials

Country Regulatory Authority	Law/Regulation	Details	Weblinks

Malaysia - National Pharmaceutical Regulatory Agency (NPRA, Malaysia)	Sale of Drugs Act 1952: Control of Drugs and Cosmetic Regulations (CDCR) 1984 Peraturan-Peraturan Kawalan Dadah & Dadah & Kosmetik 1984	As Cell and Gene Therapy Products (CGTPs) are presented as having properties for medical purposes – treating or preventing diseases in human beings, or that they may be used in or administered to human beings with a view of restoring, correcting, or modifying physiological functions by exerting principally pharmacological, immunological, or metabolic action, they are classified as medicinal products. CGTPs fit within the meaning of medicinal products under the Sale of Drugs Act 1952: Control of Drugs and Cosmetic Regulations 1984 [P.U.(A) 223/84]. And in accordance to the statutory provisions CGTPs would be classified as biological products.	https://pharmacy.moh.gov.my/en/documents/sale-drugs-act-1952-and-regulations.html https://pharmacy.moh.gov.my/sites/default/files/document-upload/control-drugs-and-cosmetics-regulation-1984.pdf
	Direktif Berkenaan Peluasan Skop Produk Kajian Klinikal First-In-Human (FIH) Untuk Permohonan Lesen Import	Directive regarding expanding the IP scope of First-In-Human Clinical Trials to Cell & Gene Therapy Products (CGTP) (effective 1 April 2025).	https://www.npra.gov.my/index.php/en/directive-general/1527703-direktif-berkenaan-peluasan-skop-produk-kajian-klinikal-first-in-human-fih-untuk-permohonan-lesen-import-percubaan-klinikal-ctil-dan-kebenaran-untuk-mengilang-produk-tidak-berdaftar-untuk-tujuan-percubaan-klinikal-ctx-kepada-cell-and-gene-therapy-product-cgtp.html

	Percubaan Klinikal (CTIL) dan Kebenaran Untuk Mengilang Produk Tidak Berdaftar Untuk Tujuan Percubaan Klinikal (CTX) kepada Cell and Gene Therapy Product (CGTP)		
	Surat Pekeliling Ketua Pengarah Kesihatan Malaysia Bil. 4/2015. KKM87/P1/26/10 jld.18 (41). Tatacara Prosedur Permohonan Berkaitan Penyelidikan Sel Stem dan Cell-Based Therapies.	Circular Letter of the Director General of Health Malaysia No. 4/2015.KKM87/P1/26/10vol.18(41) detailing about the procedures related to stem cell research and cell-based therapies.	https://clinicalresearch.my/wp-content/uploads/2020/11/Surat-Pekeliling-KPK-Bil.4-2015.pdf
	Guidance document issued by the Director of Pharmaceutical Services under Regulation 29, CDCR 1984: • Drug Registrati	Regulatory framework and registration requirements of CGTPs	https://www.npra.gov.my/index.php/en/component/sppagebuilder/925-drug-registration-guidance-document-drgd.html https://www.npra.gov.my/easyarticles/images/users/1153/drgd_appendices/APPENDIX-4-Guideline-on-Registration-of-Biologics.pdf https://www.npra.gov.my/easyarticles/images/users/1051/CGTP_guidelinesbio.pdf

	on Guidance Document (DRGD), 3rd Edition, Ninth Revision January 2025 - Appendix 4: Guideline on Registration of Biologics • Guidance Document and Guidelines for Registration of Cell and Gene Therapy Products (CGTPs) in Malaysia		

	Guidance document issued by the Director of Pharmaceutical Services under Regulation 29, CDCR 1984: • Malaysian Guideline for Application of Clinical Trial Import License and Clinical Trial Exemption, 8.1th Edition	Applications of Clinical Trial Import Licence/Clinical Trial Exemption (CTIL/CTX) for the purpose of conducting clinical trials, involving various product categories including CGTPs	https://www.npra.gov.my/index.php/en/biologics-main-page.html

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Mexico **Comision Federal Para La Proteccion Contra Riesgos Sanitarios (COFEPRIS, Mexico)**	General Health Law, Title fourteenth (All title) Main regulation: Art. 314 Definitions Art. 315 Establishment that require license to operate	For quality specifications and review procedures for drug substance, drug product and excipients, COFEPRIS can use information from Pharmacopeia from other	https://www.olivares.mx/product-regulation-and-liability-in-mexico/http://www.diputados.gob.mx/LeyesBiblio/pdf_mov/Ley_General_de_Salud.pdf Note: The General Health Law and Regulation for Health products are undergoing many changes during this administration.

	Art.316 Bis 1: Blood and components Art. 318: Embryo and germ cells 321 bis: stem cell donation CHAPTER III BIS Disposition of blood, blood components, human blood products and stem cells. Art. 342 Bis 3. National registry for Blood Stem cells	countries (Regulation for Health products, article 8). COFEPRIS can wield the sanitary control for health products under the terms of the Law, the international instruments and other applicable provisions (Regulation for the Federal Commission for protection against sanitary risk).	Sometimes the updates are only available in the Official Journal of the Federation: https://www.dof.gob.mx/ COFEPRIS website also provides a specific link for the legal framework: https://www.gob.mx/cofepris/acciones-y-programas/marco-juridico-de-la-cofepris?state=published *This link is an unofficial website, COFEPRIS is not responsible for the content:* *https://www.olivares.mx/product-regulation-and-liability-in-mexico/*
	Regulation for Health Products Chapter III Registry	General requirements for the marketing authorization for medicinal products For quality specifications and review procedures for drug substance, drug product and excipients, COFEPRIS can use information from Pharmacopeia from other	COFEPRIS website also provides an specific link for the legal framework: https://www.gob.mx/cofepris/acciones-y-programas/marco-juridico-de-la-cofepris?state=published

		countries (Regulation for Health products, article 8). COFEPRIS can wield the sanitary control for health products under the terms of the Law, the international instruments and other applicable provisions (Regulation for the Federal Commission for protection against sanitary risk).	
	Official Mexican Standard NOM-059-SSA1-2015, Good manufacturing practices for medicinal products	GMP for medicinal products	https://mexicanlaws.com/SALUD/NOM-059-SSA1-2015.htm

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Republic of Korea Ministry of Food and Drug Safety (MFDS, Republic of Korea)	Pharmaceutical Affairs Act	To prescribe matters necessary to deal with pharmaceutical affairs	http://law.go.kr/LSW/eng/engMain.do
	Act on the Safety of and Support for Advanced Regenerative Medicine and Advanced Biopharmaceuticals	To prepare concrete procedure and details for the implementation of whole life-cycle safety management for advanced biopharmaceuticals and clinical research on advanced regenerative medicine	http://law.go.kr (English version is not yet available.)

	Enforcement Decree of the Safety of and Support for Advanced Regenerative Medicine and Advanced Biopharmaceuticals	To prescribe the matters mandated by the safety of and support for advanced regenerative medicine and advanced biopharmaceuticals Act and those necessary for enforcing said Act affairs.	http://law.go.kr/LSW/eng/engMain.do http://law.go.kr (English version is not yet available.)
	Regulation on the Safety of and Support for Advanced Biopharmaceuticals	To prescribe matters delegated by the safety of and support for advanced biopharmaceuticals Act and the Enforcement Decree of the safety of and support for advanced biopharmaceuticals Act and matters necessary for their enforcement.	http://law.go.kr (English version is not yet available.)
	Regulation on Approval and Review of Advanced Biopharmaceuticals	For improvement the efficiency of review and approval processes and promote the advanced biopharmaceutical products that have been developed using new technologies.	http://law.go.kr (English version is not yet available.)
	Enforcement Decree on the Standards of Facilities of Manufacturers and Importers of Medicinal Products etc.	To prescribe requirements for facilities of manufacturers and importers of medicinal products etc.	http://www.mfds.go.kr (Language: English version) Bio&Cosmetics → Regulation → Find #15
	Enforcement Regulation of the Enforcement Decree on the Standards of Facilities of Manufacturers and Importers of Medicinal Products etc.	To prescribe requirements and procedures delegated by the Enforcement Decree on Standards of Facilities of Manufacturers and Importers of Medicinal Products, etc.	http://www.mfds.go.kr (Language: English version) Bio&Cosmetics → Regulation → Find #16
	Regulation on Safety of Medicinal Products, etc.	To prescribe matters delegated by the Pharmaceutical Affairs Act and the Enforcement Decree of the Pharmaceutical Affairs Act and matters necessary for their enforcement.	http://www.mfds.go.kr (Language: English version) Bio&Cosmetics → Regulation → Find #14
	Regulation on Pharmaceutical GMP	To assure appropriate Pharmaceutical GMP by specifying detailed requirements for enforcement of Regulation on Safety of	http://www.mfds.go.kr (Language: English version)

		Medicinal Products, etc., and detailed requirements for expiry period of certificate of GMP compliance of a manufacturer for medicinal products under application for product approval.	Bio&Cosmetics → Regulation → Find #18
	Regulation on Approval for Investigational New Drug Application of Drugs	To set force the detailed matters regarding the preparation tip, scope, requirement, and exemption scope of data necessary for IND application, approval procedure, and standard, and to ensure that appropriate measures are used in conjunction with the Investigational new drug (IND) approval processes.	http://www.mfds.go.kr (Language: English version) Bio&Cosmetics → Regulation → Find #22
	Regulation on Fees for Pharmaceutical Approval etc.		http://www.mfds.go.kr (Language: English version) Bio&Cosmetics → Regulation → Find #28
	Regulation on Approval and Review of Biological Products	For improvement the efficiency of review and approval processes and promote the biological products that have been developed using new technologies.	http://www.mfds.go.kr (Language: English version) Bio&Cosmetics → Regulation → Find #32
	Korean Pharmacopeia		https://www.mfds.go.kr/eng/brd/m_18/view.do?seq=71538

Country	Law/Regulation	Details	Weblinks

Regulatory Authority			
Saudi Food and Drug authority (SFDA)	Notification and documentation of proposed clinical trial /Submission of declaration that no enrichment or culturing is used during this procedure.	This regulation is applied for well established procedures. Clinical trial applications for Hematopoietic Progenitor Stem Cell (HPC) Transplantation, and Non-Myeloablative Conditioning and Transplantation of Partially HLA-Mismatched and HLA-Matched Bone Marrow followed this regulation.	www.sfda.gov.sa
	Notification and documentation of proposed clinical trial /Submission of procedural steps	This regulation is applied for clinical trial applications regarding aamniotic membrane harvested from placenta of healthy women delivered by elective cesarean section.	https://www.sfda.gov.sa/sites/default/files/2025-02/ConductingClinicalTrialsDrugE.pdf
	Requirements for Importation of Minimally Manipulated Biological Products Intended for Human Application		https://www.sfda.gov.sa/en/forms/80910
	SFDA Guideline on Classification of Advanced Therapy Medicinal Products	06 November 2023	ClassificationAdvancedTherapyGV01.pdf (sfda.gov.sa)
	Guidance on Submission of Chemistry, Manufacturing, and Control (CMC) Information for Cell-based Clinical Trial Applications	04 April 2023	CMC-cell-based-IND_V01_1.pdf (sfda.gov.sa)
	Clinical Considerations for efficacy and safety assessment	09 July 2023	https://www.sfda.gov.sa/en/regulations/88546

	SFDA is working on draft Guidance on Submission of Chemistry, Manufacturing, and Control (CMC) Information for Gene therapy Clinical Trial Applications	Expected 2025	N. A
	Good Manufacturing Practice for Blood Establishments Guide to Good Manufacturing Practice for Medicinal Products		https://www.sfda.gov.sa/sites/default/files/2024-01/DrugGMPBloodEstablishments-AR_0.pdf https://www.sfda.gov.sa/sites/default/files/2023-01/SFDA-GMP-Guideline%20_0.pdf - Annex 2A - Manufacture of Advanced Therapy medicinal for Human Use - Annex 14 manufacture of medicinal products derived from human blood or plasma
	Requirements for Importation of Minimally Manipulated Biological Products Intended for Human Application		https://www.sfda.gov.sa/en/regulations/65999
	Guidance for Combination Products Classification		FINAL_for_implementation.pdf (sfda.gov.sa)
	Genome editing technologies		Internal review guidance

Country	Law/Regulation	Details	Weblinks

Regulatory Authority			
Singapore Health Sciences Authority (HSA, Singapore)	Health Products Act Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021	The regulations cover both lower risk (minimally manipulated for homologous use that are not combined with therapeutic product or medical devices) and higher risk CTGTPs, from clinical trials, registration, manufacture, import, supply to post-market duties and obligations.	https://www.hsa.gov.sg/ctgtphttps://www.hsa.gov.sg/ctgtp

Country Regulatory Authority	Law/Regulation	Details	Weblinks
South Africa – SAHPRA (SAHPRA, South Africa)		Left Blank Intentionally	

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Switzerland Swissmedic (Swissmedic, Switzerland)	Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; SR 812.21)	The purpose of this Act is to protect human and animal health and to guarantee that only high quality, safe and effective therapeutic products are placed on the market. Applicable to all biologics including cell therapy, gene therapy, tissue engineered products.	https://www.fedlex.admin.ch/eli/cc/2001/422/en

	Ordinance on Licensing in the Medicinal Products Sector (Medicinal Products Licensing Ordinance, MPLO; SR 812.212.1)	This Ordinance regulates the manufacture and trading of medicinal products. Applicable to all biologics including cell therapy, gene therapy, tissue engineered products.	https://www.fedlex.admin.ch/eli/cc/2018/786/en
	Verordnung über die Arzneimittel (Arzneimittelverordnung, VAM; SR 812.212.21)	This regulation governs, among other things, the approval of ready-to-use medicinal products and the approval of procedures. Applicable to all biologics including cell therapy, gene therapy, tissue engineered products. (DE, FR, IT languages only)	https://www.fedlex.admin.ch/eli/cc/2018/588/de
	Verordnung des Schweizerischen Heilmittelinstituts über die Anforderungen an die Zulassung von Arzneimitteln (Arzneimittel-Zulassungsverordnung, AMZV; SR 812.212.22)	This regulation lays down the requirements for the marketing authorization of a ready-to-use medicinal product. Applicable to all biologics including cell therapy, gene therapy, tissue engineered products. (DE, FR, IT languages only)	https://www.fedlex.admin.ch/eli/cc/2001/517/de
	Clinical Trials Ordinance (ClinO; SR 810.305)	Ordinance on Clinical Trials with the exception of Clinical Trials of Medical Devices	https://www.fedlex.admin.ch/eli/cc/2013/643/en
	Transplantation Act (SR 810.21)	Federal Act on the Transplantation of Organs, Tissues and Cells. This Act sets out the requirements for the use of organs, tissues or cells for transplantation purposes.	https://www.fedlex.admin.ch/eli/cc/2007/279/en
	Ordinance on the Transplantation of Human Organs, Tissues and Cells (Transplantationsverordnung; SR 810.211)	Verordnung über die Transplantation von menschlichen Organen, Geweben und Zellen. This ordinance regulates the handling of human organs, tissues and cells.	https://www.fedlex.admin.ch/eli/cc/2007/280/de

		(DE, FR, IT languages only)	
	Ordinance on the Handling of Organisms in the Environment (Release Ordinance, RO; SR 814.911)	This Ordinance is intended to protect human beings, animals and the environment, as well as biological diversity and its sustainable use, from hazards or harm caused by handling organisms, their metabolic products and wastes. It also aims, during the handling of genetically modified organisms, their metabolic products and wastes, to guarantee consumers' freedom of choice and protect production that does not use genetically modified organisms. Applicable to biologics such as GMO and gene therapy products.	https://www.fedlex.admin.ch/eli/cc/2008/614/en
	Ordinance of 9 May 2012 on Handling Organisms in Contained Systems (Containment Ordinance, ContainO; SR 814.912)	This Ordinance regulates the handling of organisms, in particular genetically modified, pathogenic or alien organisms, in contained systems. Applicable to all biologics such as GMO and gene therapy products.	https://www.fedlex.admin.ch/eli/cc/2012/329/en

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Türkiye - Turkish Medicines and Medical Devices (TITCK, Türkiye)	Regulation on the Marketing Authorization of Advanced Therapy Products	Requirements for marketing authorization.	https://www.resmigazete.gov.tr/eskiler/2023/05/20230527-7.htm
	Regulation on the Quality and Safety of Human Tissues, Cells, and related Centers	Requirements for human tissues donations and procurement.	https://www.resmigazete.gov.tr/eskiler/2010/10/20101027-6.htm

Country Regulatory Authority	Law/Regulation	Details	Weblinks
United Kingdom – Medicines and Healthcare products Regulatory Agency (MHRA)	The Human Medicines Regulations 2012	Regulations governing ATMPs	The Human Medicines Regulations 2012 (legislation.gov.uk)
	The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019		The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (legislation.gov.uk)
	The Medicines for Human Use (Clinical Trials) Regulations 2004		The Medicines for Human Use (Clinical Trials) Regulations 2004 (legislation.gov.uk)
	The Human Tissue (Quality and Safety for Human Application) Regulations 2007	Regulations governing the collection of starting material	The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (legislation.gov.uk)
	The Blood Safety and Quality Regulations 2005		The Blood Safety and Quality Regulations 2005 (legislation.gov.uk)

	The Medical Devices Regulations 2002	Regulations governing combination products where the ATMPs includes an integrated medical device	The Medical Devices Regulations 2002 (legislation.gov.uk)
	Medicines and Medical Devices Act 2021		Medicines and Medical Devices Act 2021 (legislation.gov.uk)
	The Windsor Framework (Regulation of medicinal products in Northern Ireland)	Allowances are made to the EU Directives. From 2025 the Windsor Framework will take effect for medicines.	The Windsor Framework - further detail and publications - GOV.UK (www.gov.uk)

Country Regulatory Authority	Law/Regulation	Details	Weblinks
United States Food and Drug Administration (US FDA)	21 CFR 1271 Tissue Regulations	Tissue Rules intended to prevent the spread of infectious disease (Donor eligibility) Applicable to cell therapy, gene therapy, tissue engineered products	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271
	21 CFR 600 -690 Biological License Applications (BLA) Requirements	Applicable to all biologics including cell therapy, gene therapy, tissue engineered products	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-600

	21 CFR 312 Investigation New Drug (IND) Requirements	Applicable to all biologics including cell therapy, gene therapy, tissue engineered products	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312
	21 CFR 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs	Applicable to all biologics including cell therapy, gene therapy, tissue engineered products	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210
	21 CFR 211 Current Good Manufacturing Practices for finished pharmaceuticals	Applicable to all biologics including cell therapy, gene therapy, tissue engineered products	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211
	21 CFR 314.126 Clinical Trial Standards	Applicable to all biologics including cell therapy, gene therapy, tissue engineered products	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-314/subpart-D/section-314.126
	21 CFR 812 Investigational Device Exemption (IDE) Requirements	Applicable to devices	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-812
	21 CFR 814 Pre-market approval (PMA)/Humanitarian Device Exemption (HDE) Regulations	Applicable to devices	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-814

	21 CFR 820 Quality Systems Regulation/Good Manufacturing Practices	Applicable to devices	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820
	21 CFR 807(e) Premarket Notification Procedures	Applicable to devices	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-E

Country Regulatory Authority	Law/Regulation	Details	Weblinks
Uzbekistan – Center for Pharmaceutical Product Safety (CPPS, Uzbekistan)		Left Blank Intentionally	