



Global partner in innovative drug R&D

Assisting in the whole go-to-market process from drug R&D



HYQURE

Compliant and Impartial·Integrity

One-Stop Biosafety Solution

Uphold Biosafety, Accelerate Biotech Innovation

HyQure BioTech Company Brochure

2026 Edition



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Multi-Site Efficiency for Reliable Delivery

HyQure BioTech, established by a top-notch team of technical and quality professionals, is an international platform dedicated to offering comprehensive biosafety testing solutions to global pharmaceutical innovators. It provides high-quality services that meet regulatory requirements in China, the US, and Europe, including virus clearance validation, cell bank testing, replication-competent virus detection, batch release testing, CGT bioanalysis, and process impurity detection, covering the full lifecycle of biopharmaceuticals from R&D to market launch.

HyQure BioTech has completed four funding rounds, has over **170** staff, and operates nearly **8,000** sqm of lab space across various locations. With verified facilities, a data-integrityfocused IT system, extensive project expertise, dependable testing data, and considerate service, it ensures the successful market entry and global expansion of innovative biopharmaceuticals.



Testing Center

4500m² BSL-2/ BSL-2 Plus
CNAS, GLP, cGMP
>400/Year IND projects
>30 /Year BLA projects
>1000 /Year batches of LRT



R&D Center

500m² BSL-2
Customized method development and verification for Virus Testing, Process Residue Detection, and other assay development of biosafety testing



Innovation Center

1500m² BSL-2\ABSL-2
CNAS, GLP, cGMP
>60/Year IND projects,
>10/Year BLA projects,
>300 /Year batches of LRT



Europe Lab (Basel Stücker Park)

This milestone signifies the successful deployment of HYQURE's Dual-Core Strategy (China-Europe) and the extension of its global service network, reinforcing its commitment to supporting worldwide biopharmaceutical companies in one-stop biosafety solutions.



Complete Range of Application Types

- ✓ Antibodies-VC-CDE/FDA
- ✓ Antibodies-CLC-CDE/FDA
- ✓ CGT-VC-CDE/FDA
- ✓ CGT-CLC-CDE/FDA
- ✓ RCL CDE/FDA
- ✓ rcAAV CDE/FDA



Diverse Cell Types

- ✓ CHO
- ✓ HEK293
- ✓ HEK293T
- ✓ SF9
- ✓ PG13
- ✓ TIL
- ✓ iPSC



Comprehensive Pipeline Categories

- ✓ ADC drugs
- ✓ Monoclonal/Bispecific/
Trispecific antibodies
- ✓ Recombinant proteins
- ✓ CAR-T/CAR-NK
- ✓ iPSC
- ✓ Gene editing
- ✓ AAV gene therapy

8000+ m² BSL2/BSL2+ Laboratory facilities

170+ Technical and quality team

130+ Successful approved cases

60+ Global(FDA/EMA/TGA/PMDA, etc.) approved cases

10+ Successfully licensed out to global MNCs

400+ Biopharmaceutical clients

700+ Confirmed and validated instruments and equipment

Compliant with NMPA, FDA, EMA, PMDA requirements

Paper and electronic data comply with the ALCOA+ principle

LIMS, EMS systems compliant with ISPE GAMP5

**Holds QP, CNAS, and ISO 9001 certification,
Adherence of GLP & GMP**

The Founding Team of HYQURE

The founding team of HYQURE consists of recognized virologists, process experts, molecular biology specialists, and regulatory experts in the pharmaceutical industry. Our Subject Matter Experts(SMEs), Platform Technology Team and Project Managers come from global CROs and bring deep hands-on experience in Viral Clearance Studies(VCS), Cell Bank Testing, Broader Viral Safety Programs, etc. More importantly, we provide comprehensive support for global authority communications to response to any comments, enabling seamless collaboration with you to facilitate the approval of your biologic and advanced therapy medicinal product (ATMP) projects.



Seamless Cooperation



Our Vision

To be an innovative industry leader in biological and pharmaceutical testing
Supporting the innovative R&D journey of our global partners

Our Mission

Committed to biological testing,
Safeguarding life and health

Our Values

Integrity
Collaboration
Rigorous and scientific
Customer orientation
Accountability
Internally-driven growth

Quality System

Starting with high standards and global compliance

Strict adherence to GLP, GMP systems;

Meet audit requirements from multiple regulatory bodies such as CDE, NMPA, FDA, EMA, PMDA;

Independent third-party inspection and testing institution.

BSL-2 +

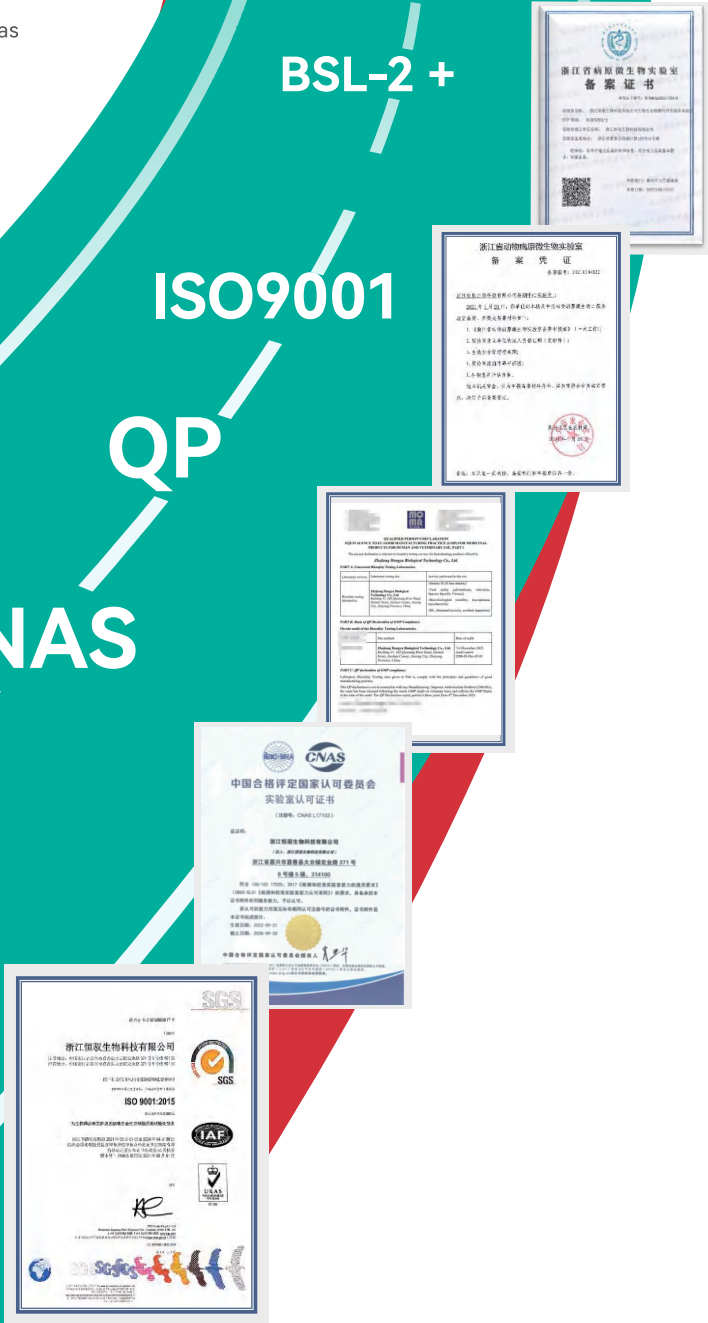
ISO9001

QP

CNAS

GLP

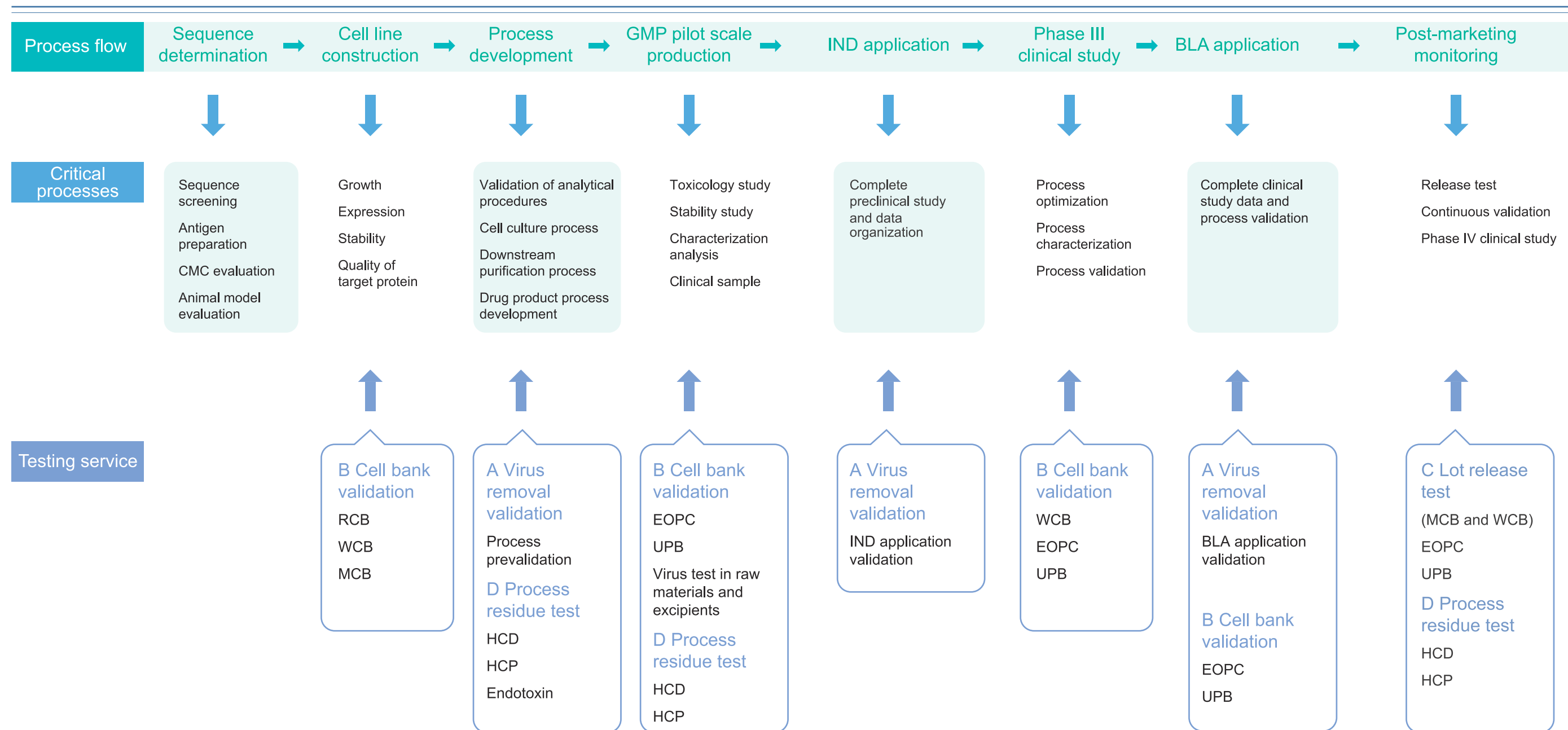
GMP



Biosafety Testing Type

Testing service type	Application service stage	Recombinant proteins and antibodies	Mesenchymal stem cells	CART cells	Gene therapy	Vaccines
A. Viral Clearance Studies	Process development IND BLA Process change	Downstream purification process validation	N/A	N/A	Downstream purification process validation	N/A
B. Cell Line Characterization	(IIT) IND BLA	CHO cell bank validation (PCB/MCB/WCB)	Cell assay Virus contamination test in raw materials and excipients	Cell assay Virus contamination test in raw materials and excipients	HEK 293/SF9, etc. Cell bank validation (PCB/MCB/WCB) Virus contamination test in raw materials and excipients	VERO, etc. Cell bank validation (PCB/MCB/WCB) Virus contamination test in raw materials and excipients
C. Lot Release Testing	Clinical stage Commercialization stage	UPB lot release test EOPC lot release test	Lot release test	LV lot release test (RCL) CART lot release test	AAV lot release test (rcAAV) UPB lot release test EOPC lot release test	Lot release test
D. Process Residuals Testing	IND BLA	HCD, HCP, endotoxin, etc.	BSA, endotoxin, etc.	HCP, HCD, endotoxin, BSA, etc.	HCD, HCP, endotoxin, etc.	HCD, HCP, endotoxin, etc.

Recombinant Proteins and Antibodies (Including Recombinant Protein Vaccines) Biosafety Testing



Virus Removal Process Validation

Regulatory requirements and cases		IND			BLA		
		China	Overseas	Dual application in China and US	China	Overseas	Dual application in China and US
Sample batch		1 batch twice	1 batch twice	1 batch twice	1 batch twice	1 batch twice	1 batch twice
Indicator virus	Low pH treatment	X-MuLv PRV	X-MuLv (PRV)	X-MuLv PRV	X-MuLv PRV	X-MuLv PRV	X-MuLv PRV
	Nanofiltration	MVM Reo-3	MVM X-MuLv	MVM Reo-3 X-MuLv	MVM Reo-3 X-MuLv PRV	MVM Reo-3 X-MuLv PRV	MVM Reo-3 X-MuLv PRV
	Chromatography	MVM X-MuLv	MVM X-MuLv	MVM X-MuLv	MVM Reo-3 X-MuLv PRV New and old resins	MVM Reo-3 X-MuLv PRV New and old resins	MVM Reo-3 X-MuLv PRV New and old resins
Harvesting and clarification → Protein A → Low PH → CEX → AEX → Nanofilter → Drug product							

Cell Bank Validation

CHO Cells - Characterization for global application RCB/MCB/WCB

Lot Release Test

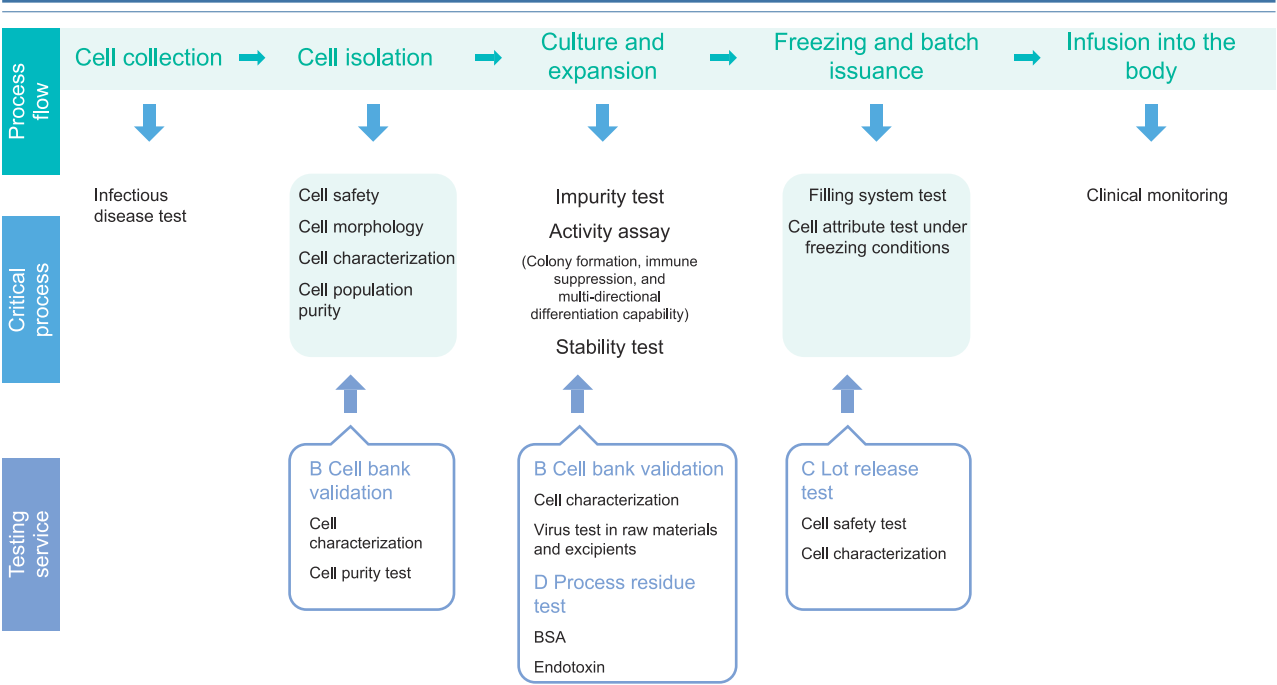
EOPC/UPB

List of cell bank validation items - animal cells (CHO cells)

Test item	Test method	(MCB)	(WCB)	EOPC ⁽¹⁾	UPB1	UPB2
TAT	N/A	3-4 months	3-4 months	3-4 months	3-4 months	1.5-2.5 months
Sample Preparation	Cell Culture and Sample Preparation	(+)	(+)	(+)	-	-
Cell Identification	Cytochrome P450 CO1 Detection	+	+	+	-	-
Bacteria, Fungi	Film Filtration Method - Method Suitability	+	(+)	+	+	(+)
	Film Filtration	+	+	+	+	+
Mycoplasma (CHP & USP)	Direct Culture Method - Method Suitability	+	(+)	+	+	(+)
	Direct Culture Method	+	+	+	+	+
	Indicator Cell Culture Method - Method Suitability	+	(+)	+	+	(+)
	Indicator Cell Culture Method	+	+	+	+	+
Mycobacterium(CHP)	Inclination Method - Method Suitability	+	(+)	+	-	-
	Inclination Method	+	+	+	-	-
Exogenous and endogenous virus contamination tests	Cell Morphology Observation	+	+	+	-	-
	In Vitro Different Indicator Cell Culture Method	+	+	+	+	+
	Animal Inoculation Method	+	-	+	-	-
	Reverse Transcriptase Activity Check	+	-	+	-	-
	Ultra-thin Section Transmission Electron Microscopy Check	+	-	+	-	-
	Negative Staining Transmission Electron Microscopy Quantitative	-	-	-	+	+
	Infectious Experiment	+	-	+	+	+
	Mouse Parvovirus Test	+	-	+	+	+
	Species-specific Human Virus Check	+	-	-	-	-
	Other Specific Virus Tests	+	-	-	-	-
Exogenous and endogenous virus contamination tests	Reverse Transcriptase Virus	+	-	+	-	-
	Mouse Parvovirus Test	+	-	+	+	+
	Species-specific Human Virus Check	+	-	-	-	-
	Other Specific Virus Tests	+	-	-	-	-
	Bovine Source Virus (8 types)	+	-	-	-	-
	Bovine Papillomavirus Test	+	-	-	-	-
	Feline Calicivirus 2117 Test	(+)	-	-	-	-
	Porcine Source Virus (7 types)	+	-	-	-	-
	Porcine Source Virus (5types)	+	-	-	-	-
	Porcine Source Virus (5types)	+	-	-	-	-

Note: (1) is the end of production cells, which refer to the cells harvested at or beyond the end of production.
The end of production cells at the production scale should be taken whenever possible.
"+" indicates a mandatory test item, and "-" indicates a non-mandatory test item.

Mesenchymal Stem Cell Therapy Biosafety Testing



Cell Bank Validation

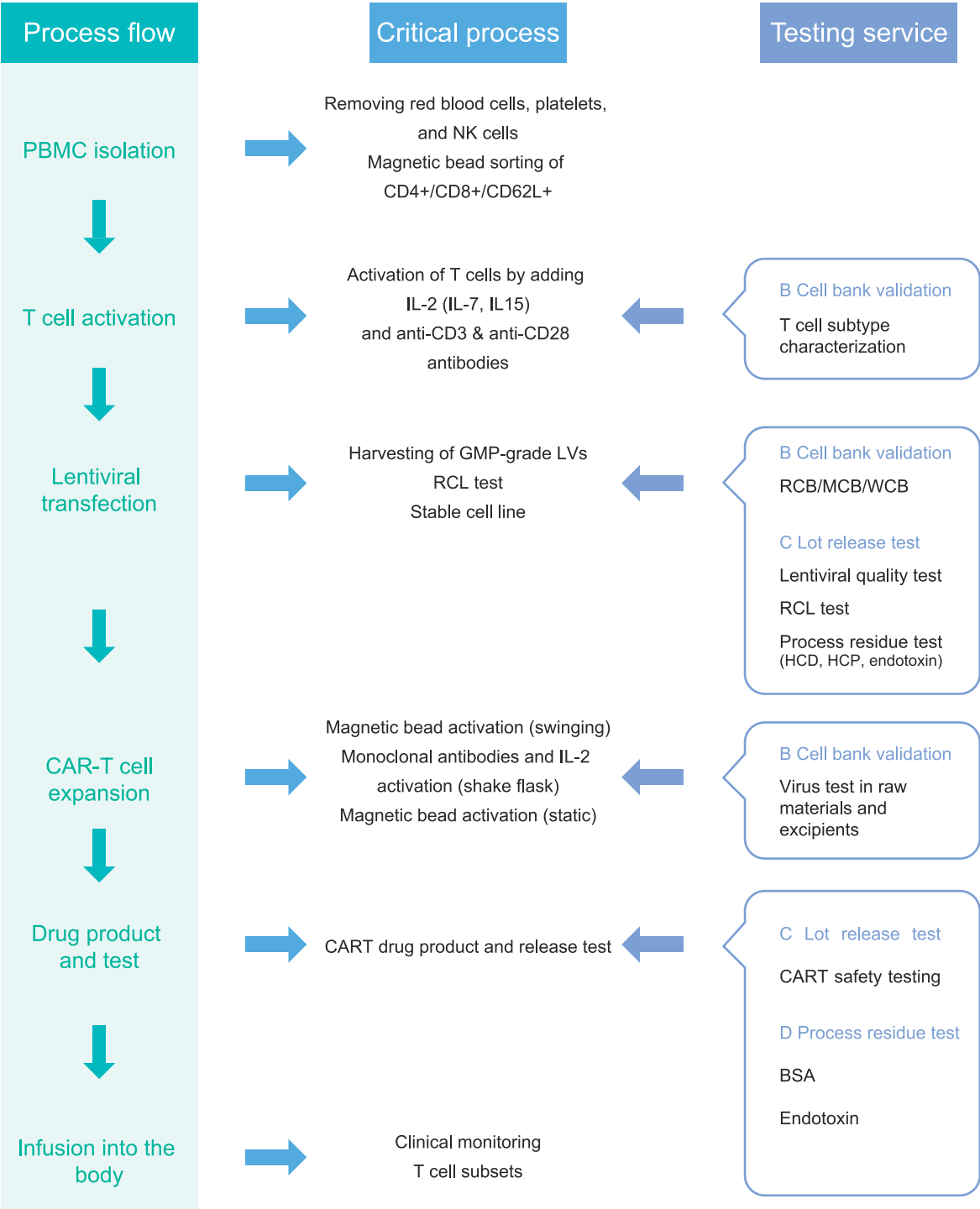
Stem Cell Safety Testing

Lot Release Test Stem Cell Safety Testing

List of stem cell safety testing items

Test item	Test method	RCB	MCB(P3)	WCB(P5)	DP(P10)
Cell Identification	Cell Morphology Examination	✓	✓	✓	✓
	Cytochrome C Oxidase 1 (CO1) Detection	✓	✓	✓	✓
Bacteria and Fungi Check	Flow Cytometry for Cell Surface Markers	✓	✓	✓	✓
	Short Tandem Repeat (STR) Analysis	✓	✓	✓	✓
Mycobacteria Check	Chromosome Karyotype Analysis	✓	✓	✓	✓
	Membrane Filtration Method (Method Suitability Test)	✓	✓	✓	✓
Mycoplasma Check	Membrane Filtration Method	✓	✓	✓	✓
	Direct Inoculation Method (Method Suitability Test)	✓	✓	✓	✓
Endogenous and Exogenous Virus Factor Check	Direct Inoculation Method	✓	✓	✓	✓
	Pour Plate Method (Method Suitability Test)	✓	✓	✓	✓
Immunological Response Detection	Pour Plate Method	✓	✓	✓	✓
	Culture Method (Method Suitability Test) - For China Submission	✓	✓	✓	✓
Biological Efficacy Evaluation	Culture Method - For China Submission	✓	✓	✓	✓
	Indicator Cell Culture Method (Method Suitability Test) - For China Submission	✓	✓	✓	✓
Cell Viability Check	Indicator Cell Culture Method - For China Submission	✓	✓	✓	✓
	Culture Method - For US Submission	✓	✓	✓	✓
Secreted Cytokines	Indicator Cell Culture Method (Method Suitability Test) - For US Submission	✓	✓	✓	✓
	Observation of Cytopathic Effect and Hemadsorption	✓	✓	✓	✓
Tumorigenesis Check	In Vitro Inoculation of Different Indicator Cells (28 days - MRC-5, HeLa, and Vero)	✓	✓	✓	✓
	In Vivo Inoculation in Animals (Suckling Mice, Adult Mice, Guinea Pigs, and Rabbits)	✓	✓	✓	✓
Residual Check	Fertile Egg Inoculation Method - For China Submission	✓	✓	✓	✓
	Fertile Egg Inoculation Method - For US Submission	✓	✓	✓	✓
Residual Check	Retrovirus Check (Reverse Transcriptase Activity Assay)	✓	✓	✓	✓
	Retrovirus Check (Ultra-thin Section Transmission Electron Microscopy)	✓	✓	✓	✓
Residual Check	Bovine Viral Diagnostics - qPCR	✓	✓	✓	✓
	Porcine Papillomavirus Check (Fluorescent Quantitative PCR Method)	✓	✓	✓	✓
Residual Check	Porcine Parvovirus Check (Fluorescent Quantitative PCR Method)	✓	✓	✓	✓
	Porcine Circovirus Type 1 Check (qPCR Method)	✓	✓	✓	✓
Residual Check	Porcine Circovirus Type 2 Check (qPCR Method)	✓	✓	✓	✓
	Porcine Torque teno Virus Type 1 Check (qPCR Method)	✓	✓	✓	✓
Residual Check	Porcine Torque teno Virus Type 2 Check (qPCR Method)	✓	✓	✓	✓
	Species-Specific Human Virus Check (qPCR Method)	✓	✓	✓	✓
Residual Check	Lymphocyte Proliferation Suppression Test	✓	✓	✓	✓
	Detection of Specific Lymphocyte Subpopulations	✓	✓	✓	✓
Residual Check	Lymphocyte TNF-α Secretion Inhibition Test	✓	✓	✓	✓
	Osteoblast Differentiation	✓	✓	✓	✓
Residual Check	Chondrocyte Differentiation	✓	✓	✓	✓
	Adipocyte Differentiation	✓	✓	✓	✓
Residual Check	Cell Count and Survival Rate	✓	✓	✓	✓
	Cell Growth Curve	✓	✓	✓	✓
Residual Check	Cell Cycle Determination	✓	✓	✓	✓
	TGF-β Secretion Level	✓	✓	✓	✓
Residual Check	VEGF Secretion Level	✓	✓	✓	✓
	Nude Mouse Inoculation Test	✓	✓	✓	✓
Residual Check	Soft Agar Clonal Formation Test	✓	✓	✓	✓
	Telomerase Activity Assay	✓	✓	✓	✓
Residual Check	Bovine Serum Albumin Residual Check	✓	✓	✓	✓
	Antibiotic Residual Check	✓	✓	✓	✓
Residual Check	Trypsin	✓	✓	✓	✓
	Bacterial Endotoxin Check (Gel Clot Limitation Method)	✓	✓	✓	✓

CAR-T Cell Therapy Biosafety Testing



CAR-T Cell Therapy Biosafety Testing

Cell Bank Validation 293T Cells - Characterization for global application

List of cell bank validation items - human-derived cells (293T cells)						
Test item	Test method	MCB	WCB	EOPC ⁽¹⁾	UPB1	UPB2、3
TAT	N/A	3-4 months	3-4 months	3-4 months	3-4 months	1.5-2.5 months
Sample Preparation	Cell Culture and Sample Preparation	(+)	(+)	(+)	-	-
Cell Identification	Cytochrome P450 C01 Detection					
	STR Typing	+	+	+	-	-
	5 Type Adenovirus E1A Insertion Gene Identification					
	SV40 Large T Antigen Nucleic Acid Sequence Determination					
Bacteria, Fungi	Film Filtration Method - Method Suitability	+	(+)	+	+	(+)
	Film Filtration	+	+	+	+	+
Mycoplasma (CHP & USP)	Direct Culture Method - Method Suitability	+	(+)	+	+	(+)
	Direct Culture Method	+	+	+	+	+
	Indicator Cell Culture Method - Method Suitability	+	(+)	+	+	(+)
	Indicator Cell Culture Method	+	+	+	+	+
Mycobacterium	Incubation Method - Method Suitability	+	(+)	+	-	-
	Incubation Method	+	+	+	-	-
Exogenous and endogenous virus contamination tests	Cell Morphology Observation and Hemadsorption Test	+	+	+	-	-
	In Vitro Different Indicator Cell Culture Method	+	+	+	+	+
	Animal Inoculation Method	+	-	+	(+)	-
	Reverse Transcriptase Activity Check	+	-	+	-	-
	Ultra-thin Section Transmission Electron Microscopy Check	+	-	+	-	-
	Negative Staining Transmission Electron Microscopy Quantitative	-	-	-	-	-
	Infectious Experiment	+	-	+	-	-
	qPCR Method	+	-	-	-	-
	Species-specific Human Virus Check (22 types)	+	-	-	-	-
	Cell Pathology Observation	+	-	-	-	-
	Hemadsorption	+	-	-	-	-
	Bovine Source Virus (8 types)	+	-	-	-	-
	Fluorescent Antibody Detection	(+)	-	-	-	-
	qPCR Method	+	-	-	-	-
	Cell Pathology Observation	+	-	-	-	-
	Hemadsorption	+	-	-	-	-
Porcine Source Virus (7 types)	Fluorescent Antibody Detection	+	-	-	-	-
	Porcine Parvovirus Check - qPCR Method	+	-	-	-	-
	Porcine Circovirus (Type 1) Virus Check - qPCR Method	+	-	-	-	-
	Porcine Circovirus (Type 2) Virus Check - qPCR Method	+	-	-	-	-
	Porcine Kobuvirus (Type 1) Virus Check - qPCR Method	(+)	-	-	-	-
	Porcine Kobuvirus (Type 2) Virus Check - qPCR Method	(+)	-	-	-	-
Porcine Source Virus (5types)	Replication-Competent Virus (RCA) - Including Method Suitability	+	-	-	-	-
	Replication-Competent Virus (RCL/RCR) - Including Method Suitability	+	-	-	-	-
Replication-Competent Virus (RCA) - Including Method Suitability	qPCR Method, Infection Method	-	-	+	+	+
	qPCR Method, Infection Method	-	-	+	+	+

Note: (1) is the end of production cells, which refer to the cells harvested at or beyond the end of production. The end of production cells at the production scale should be taken whenever possible. "+" indicates a mandatory test item, and "-" indicates a non-mandatory test item.



CAR-T Cell Therapy Biosafety Testing

Lot Release Test
CAR-T Cell Safety Testing

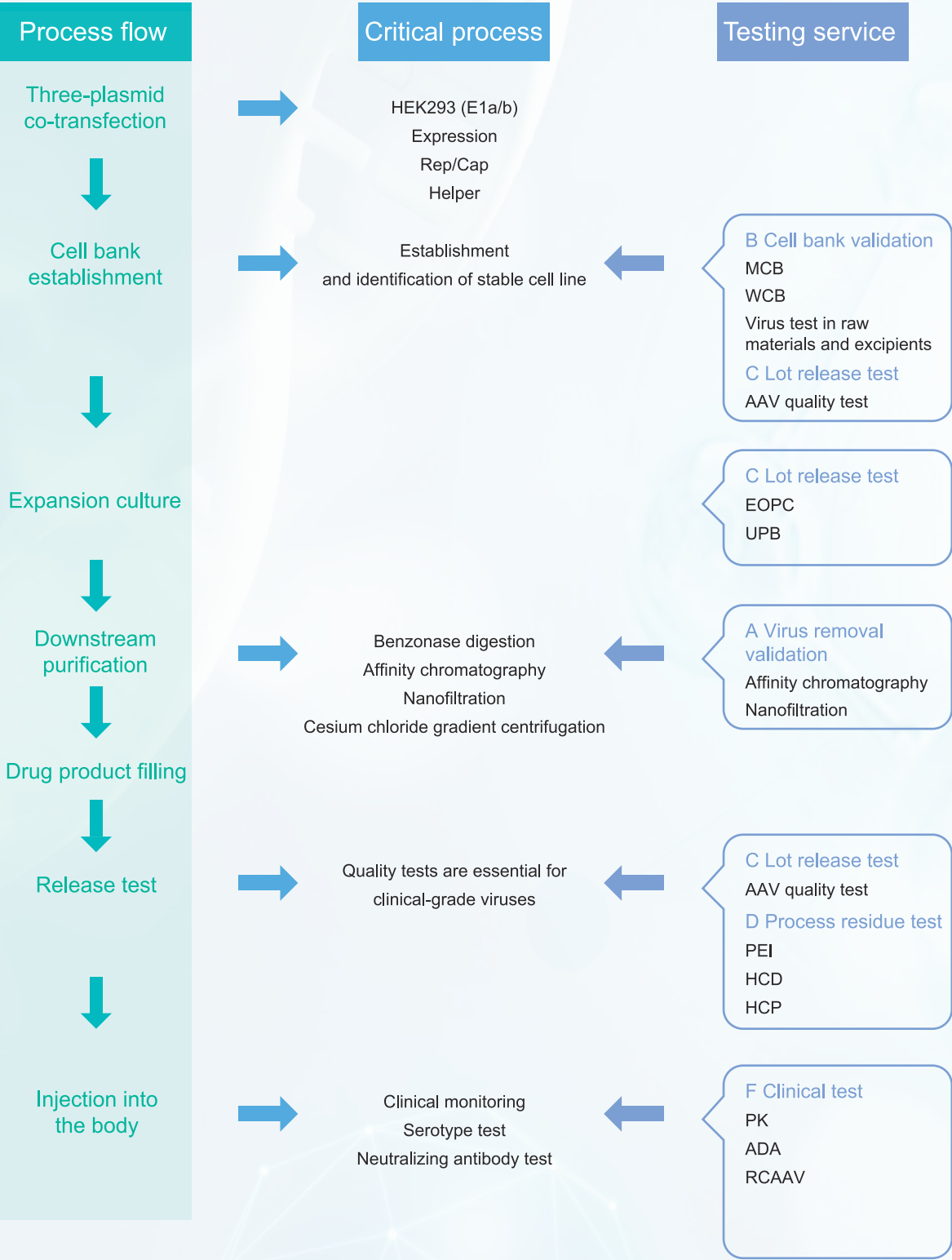
CAR-T Cells: list of safety testing items			
Test item	Test method	CART cells	Cell culture supernatant
Cell identification	STR	+	-
Bacterial and fungal tests	Membrane filtration method	+	+
Mycoplasma test	Direct culture method, indicator cell culture method	+	+
RCL	qPCR, culture method	+	+
Endotoxin	LAL test	+	+
Exogenous and endogenous virus contamination tests	Cell morphology observation and hemadsorption test	+	-
	In vitro inoculation and culture of different indicator cells	+	+
	In vivo inoculation in animals and chicken embryos	+	+
	Retrovirus test	+	+
	Human virus test	+	+
	Bovine virus test	+	-
	Porcine virus test	+	-
	Chromosome test (human diploid cell strain)	+	-
	Oncogenicity test*	+	-
	Tumorigenicity test*	+	-

CAR-T Cell Therapy Biosafety Testing

Lot release test
Lentiviral quality test

Testing service type	LV test item	Test method	Quality requirements
General examinations	Appearance test	Gross observation	Colorless, clear, and transparent solution
	PH value	PH meter	PH 7.0–8.5
	Physical titer	ELISA	Compliant with the requirements
	Infection titer	qPCR	Compliant with the requirements
Purity tests	Restriction digestion map	AGE	Consistent with the reference standard
	Full sequence determination	Sanger	Consistent with theory
	HCP	ELISA	≤ 0.1%
	HCD	Q-PCR	≤ 0.1%
	HCR	Q-PCR	≤ 0.1%
Safety examinations	Sterility test	Sterility test method	Negative
	Mycoplasma test	qPCR	Not detected
	Endotoxin test	LAL test	< 10 EU/mL
	RCL	qPCR, culture method	Not detected
	Exogenous virus	Reference regulations	Not detected

Viral Vector-Based (AAV) Gene Therapy Biosafety Testing



Viral vector-based (AAV) gene therapy Biosafety Testing

Virus Removal Process Validation - Characterization for global application

Regulatory requirements and cases		IND Indicative Virus Recommendation	BLA Indicative Virus Recommendation
Indicator virus	Low pH Incubation Method	PRV* MLV	PRV MLV
	S/D Organic Solvent	PRV* MLV	PRV MLV
	Nano-membrane Filtration Method	MVM MLV Reo3* Production Helper Virus (e.g., AD5)	PRV MVM MLV Reo3 Production Helper Virus (e.g., AD5)
	Chromatography Method	MVM MLV Production Helper Virus (e.g., AD5) - -	PRV MVM MLV Reo3 Production Helper Virus (e.g., AD5)

Lying cells to release viruses → Nucleic acid digestion → Centrifugation and filtration → Affinity chromatography → Cesium chloride gradient centrifugation → Sterile filtration → Drug product

Cell bank validation HEK 293 cells - Characterization for global application

List of cell bank validation items - human-derived cells (HEK 293 cells)						
Test item	Test method	MCB	WCB	EOPC ⁽¹⁾	UPB1	UPB2、 3
TAT	N/A	3-4 months	3-4 months	3-4 months	3-4 months	1.5-2.5 months
Sample Preparation	Cell Culture and Sample Preparation Cytochrome P450 CO1 Detection STR Typing	(+)	(+)	(+)	-	-
Cell Identification	5 Type Adenovirus E1A Insertion Gene Identification SV40 Large T Antigen Nucleic Acid Sequence Determination	+	+	+	-	-
Bacteria, Fungi	Film Filtration Method - Method Suitability Film Filtration	+	(+)	+	+	(+)
Mycoplasma (CHP & USP)	Direct Culture Method - Method Suitability Direct Culture Method Indicator Cell Culture Method - Method Suitability Indicator Cell Culture Method	+	(+)	+	+	(+)
Mycobacterium	Inclination Method - Method Suitability Inclination Method	+	(+)	+	-	-
Exogenous and endogenous virus contamination tests	Cell Morphology Observation and Hemadsorption Test	+	+	+	-	-
	In Vitro Different Indicator Cell Culture Method	+	+	+	+	+
	Animal Inoculation Method	+	-	+	(+)	-
	Reverse Transcriptase Virus	+	-	+	-	-
	Species-specific Human Virus Check (22 types)	+	-	-	-	-
	Bovine Source Virus (8 types)	+	-	-	-	-
	Bovine Papillomavirus	(+)	-	-	-	-
	Porcine Source Virus (7 types)	+	-	-	-	-
	Porcine Parvovirus Check - qPCR Method	+	-	-	-	-
	Porcine Circovirus (Type 1) Virus Check - qPCR Method	+	-	-	-	-
	Porcine Circovirus (Type 2) Virus Check - qPCR Method	+	-	-	-	-
	Porcine Kobuvirus (Type 1) Virus Check - qPCR Method	(+)	-	-	-	-
	Porcine Kobuvirus (Type 2) Virus Check - qPCR Method	(+)	-	-	-	-
	Replication-Competent Virus (RCA) - Including Method Suitability	+	-	-	-	-
	Replication-Competent Virus (RCL/RCR) - Including Method Suitability	-	-	+	+	+

Note: (1) is the end of production cells, which refer to the cells harvested at or beyond the end of production. The end of production cells at the production scale should be taken whenever possible. "+" indicates a mandatory test item, and "-" indicates a non-mandatory test item.

Viral Vector-Based (AAV) Gene Therapy Biosafety Testing

Lot release test

AAV (type 2/5/8/9) virus quality tests

Test category	AAV test item	Test method	Raw materials & harvest	Batch purification	Product & classification	Quality requirements
General examinations	Appearance test	Gross observation	✓	✓	✓	Colorless, clear & transparent solution
	Osmolality	Osmometer			✓	300–400 mOsm/kg
	PH value	PH meter			✓	PH 6.5–8.0
Safety examinations	Sterility test	Sterility test method (EP2.6.1, USP71)	✓	✓	✓	Negative
	Mycoplasma test	qPCR	✓	✓		Negative
	Endotoxin test	LAL test, C-reactive protein		✓	✓	≤ 2.5 EU/mL
	In vivo adenovirus contamination	qPCR		✓		Negative
	rcAAV	Sensitive cell assay/rep, cap qPCR		✓		Not detected
Activity test	Infection titer	TCID50 (Cell culture + qPCR/ddPCR)		✓	✓	N/A
	Genome titer VG	qPCR/ddPCR		✓	✓	10E11-10E15/mL
	Particle titer	ELISA			✓	10E11-10E15/mL
Purity test	General purity	SDS-PAGE/silver staining			✓	Identifying proteins other than vp
	Protein	SDS-PAGE/Coomassie brilliant blue		✓	✓	≥ 95%
	Residual host cell DNA	qPCR, HTS		✓		≤ 10 ng/injection
	Residual original plasmid DNA	qPCR, HTS		✓		100 pg/10(9) vg
	Residual BSA	ELISA		✓		≤ 10 ng/mL
	Residual host cell protein	ELISA, MS				—
	Residual benzonase	ELISA		✓		≤ 1 ng/vial
	Residual raw material reagents	HPLC, MS, ELISA		✓	✓	—
Others	Empty capsid/intermediate particle	vq (qPCR)/vp (ELISA)	✓	✓	✓	≥ 95%
	Total protein	Electron microscopy, AUC method	✓	✓	✓	
		BCA			✓	—
	Aggregation	DLS, SEC-HPLC			✓	—
	Integrity of gene	Southern Blotting	✓		✓	Intact
	Integrity of capsid	Western Blotting	✓		✓	Intact
	Serotype identification	Differential scanning fluorimetry			✓	Qualitative
	Serum neutralizing antibody	Measurement of absorbance after serum binding incubation				None

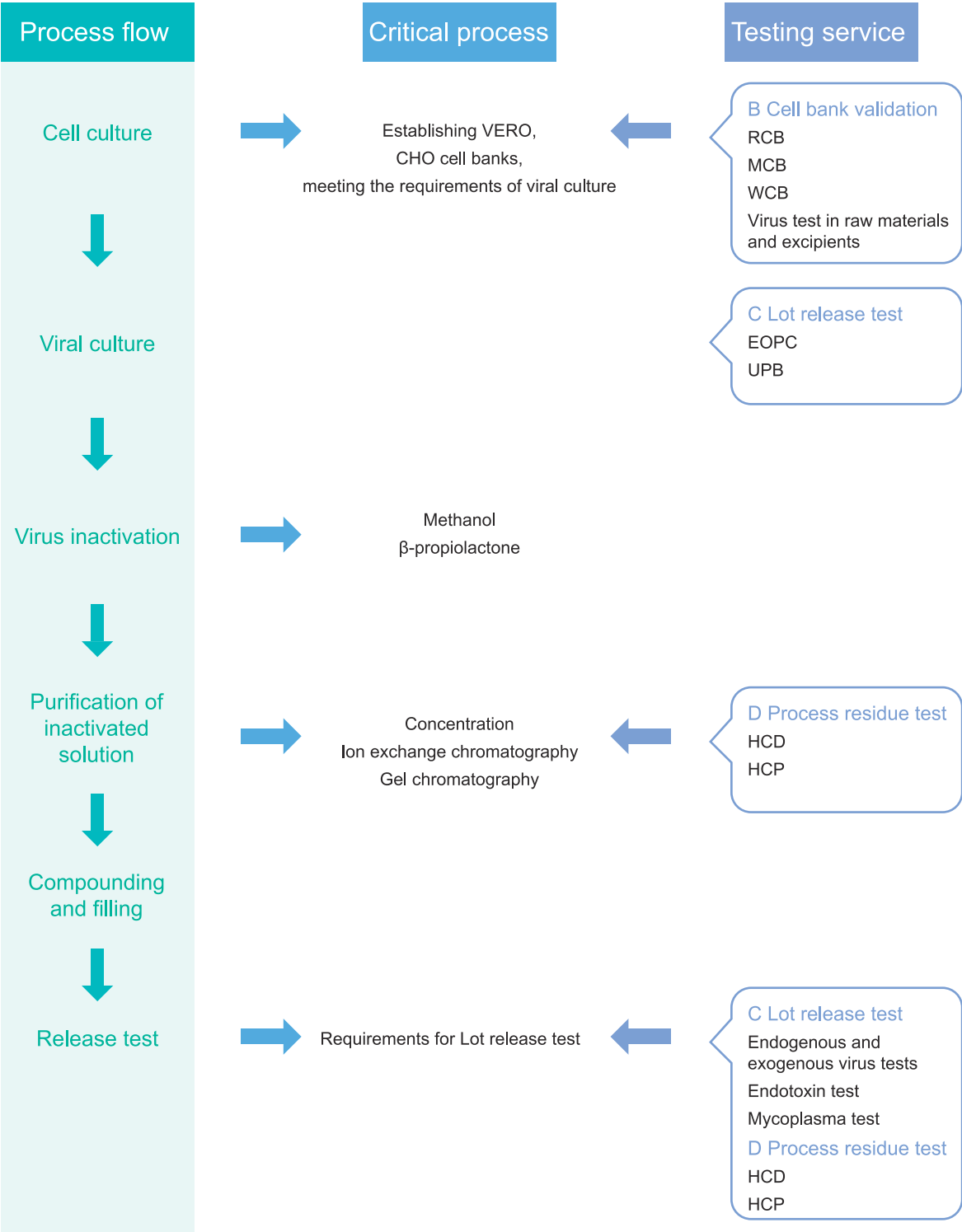
Literature source:

[1] Wright, J.F. (2021), Quality Control Testing, Characterization and Critical Quality Attributes of Adeno-Associated Virus Vectors Used for Human Gene Therapy. Biotechnol. J., 16: 2000022. <https://doi.org/10.1002/biot.202000022>

[2] Wright, John & Zeleniaia, Olga. (2011). Vector Characterization Methods for Quality Control Testing of Recombinant Adeno-Associated Viruses. Methods in Molecular Biology (Clifton, N.J.), 737. 247-78. 10.1007/978-1-61779-095-9_11.

[3] Magalie Penaud-Budloo, Achille François, Nathalie Clément, Eduard Ayuso, Pharmacology of Recombinant Adeno-associated Virus Production, Molecular Therapy - Methods & Clinical Development, Volume 8, 2018, Pages 166-180, ISSN 2329-0501, <https://doi.org/10.1016/j.omtm.2018.01.002>.

Vaccines (Recombinant Eukaryotic Expression Vaccines) Biosafety Testing



Other Biosafety Testing

01

Biochemical drugs: virus removal process validation

Tissue sampling

Tissue pulverization

Extraction

Heating

Salting out

Precipitation

Ultrafiltration

Desalination

Drying

02

Blood products: virus removal process validation

Plasma collection

Registration for testing

Frozen storage

Pre-plasma dissolution

Separation of plasma protein fraction

Virus inactivation

Sterile dispensing

Virus removal

Refinement

03

Animal-derived medical devices: virus removal process validation

Tissue acquisition

Decellularization

S/D treatment

Heat treatment

Denaturation

Filtration

Irradiation sterilization

04

Raw material testing

Suppliers of fetal bovine serum, collagen, trypsin, etc. (quality test);

05

Testing services

Suppliers of nanofiltration membranes, purification columns, resins, etc. (performance validation);

Common Indicator Viruses

Indicator virus	Genome	With or without envelope	Application
Pseudorabies virus (PrV)	DNA	With envelope	Applicable to various products Validation of various virus inactivation/removal processes such as low pH, S/D, nanofiltration, and chromatography
X-MuLV Xenotropic murine leukemia virus	RNA, retrovirus	With envelope	Applicable to mouse-derived cell expression products (antibodies, etc.) Validation of various virus inactivation/removal processes such as low pH, S/D, nanofiltration, and chromatography
Minute virus of mice (MVM)	DNA	Without envelope	Applicable to mouse-derived cell expression products (antibodies, etc.) Validation of various virus inactivation/removal processes such as nanofiltration and chromatography
Reovirus 3 (Reo3)	RNA	Without envelope	Applicable to mouse-derived cell expression products (antibodies, etc.) Validation of various virus inactivation/removal processes such as nanofiltration and chromatography
Sindbis virus (Sindbis)	RNA	With envelope	Applicable to validation of blood products and others Low pH, S/D, etc.
Vesicular stomatitis virus (VSV)	RNA	With envelope	Applicable to validation of blood products and others Low pH, etc.
Porcine parvovirus (PPV)	DNA	Without envelope	Applicable to validation of blood products and others Nanofiltration, dry heat, etc.
Encephalomyocarditis virus (EMCV)	RNA	Without envelope	Applicable to validation of blood products and others Nanofiltration, dry heat, etc.

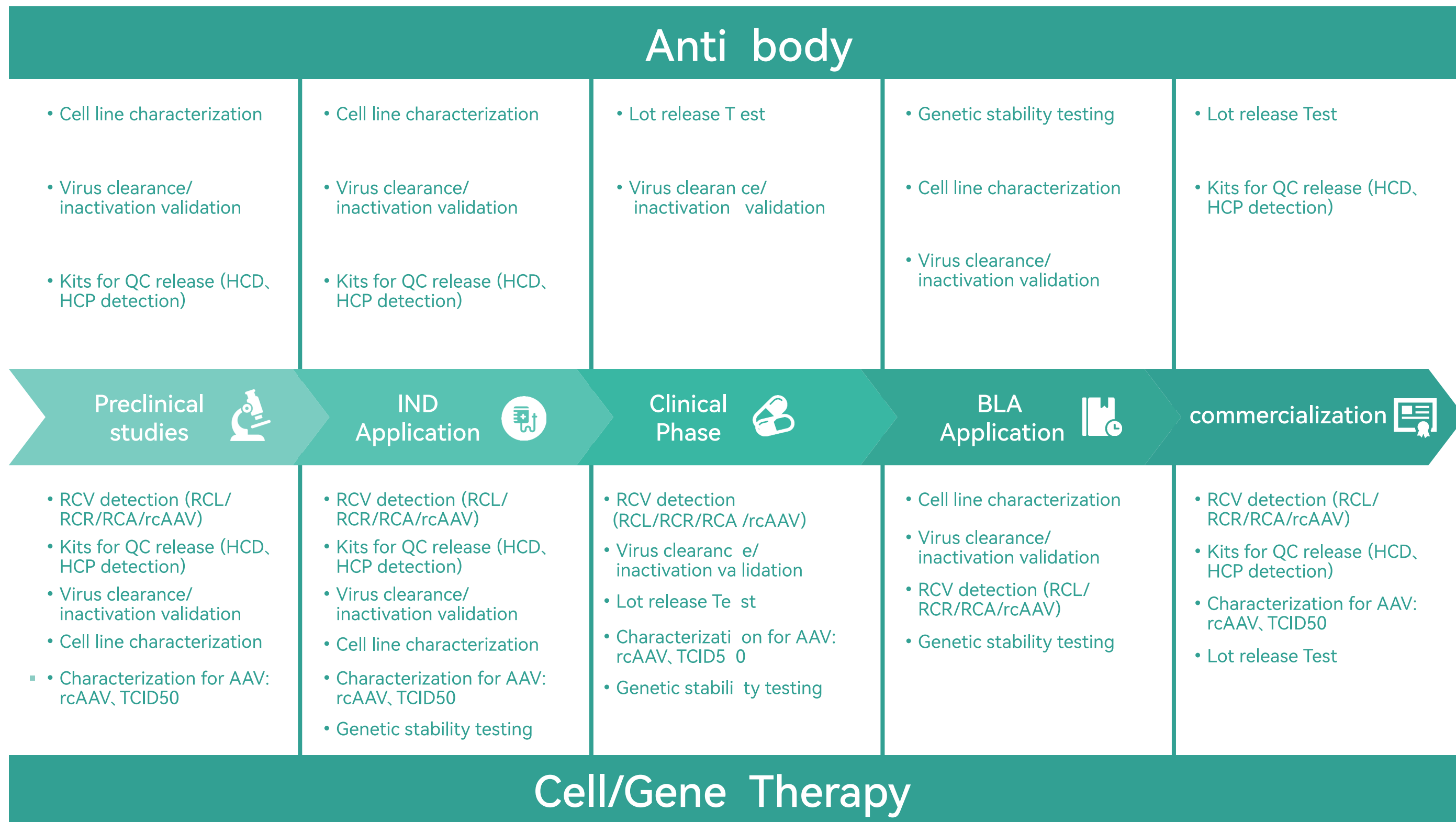
Virus Removal Validation Reference Regulations

1	General Rules for Technical Review of Virus Safety Evaluation for Biological Tissue Extract Products and Eukaryotic Expression Products	[S] GPH3-1. 2005
2	General Principals of Technical Evaluation of Quality Control for Mammalian Cells for Recombinant Products	Center for Drug Evaluation, October 2006
3	Technical Guidelines for Blood Product Virus Removal/Inactivation Method and Validation	NMPA [2002] No. 160
4	Viral Safety Control of Biological Products	Chinese Pharmacopeia (2025 Edition, Volume IV)
5	Guidelines for Validation of Virus Inactivation/Removal Effectiveness of Animal-Derived Medical Devices, Notice on the Issuance of Technical Guidelines for Animal-Derived Medical Device Registration (2017 Revised Edition) by State Food and Drug Administration (now NMPA)	(No. 224, 2017)
6	VIRAL SAFETY EVALUATION OF BIOTECHNOLOGY PRODUCTS DERIVED FROM CELL LINES OF HUMAN OR ANIMAL ORIGIN	FDA & ICH Q5A (R2)
7	Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use, 1997	FDA
8	Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals	FDA
9	Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products	EMA/CHMP/BWP/398498/2005
10	Note for Guidance on Viral Validation Studies: The Design, Contribution and Interpretation of Studies Validating the Inactivation and Removal of Viruses	CPMP/BWP 1996
11	Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products	(ICH Q5D)
12	Technology Guidelines for Cell-Based Therapy Product Research and Evaluation (Trial)	Center for Drug Evaluation, December 2017
13	General Rules for Research Review of Cell Substrate for Vaccine Production	Center for Drug Evaluation, August 2007
14	Guidance for Bovine Serum Production and Quality Control for Cell Culture	Center for Drug Evaluation, March 2003

Cell Bank Validation Reference Regulations

1	Chinese Pharmacopeia (2025 Edition, Volume IV)
2	National Medical Products Administration. General Rules for Technical Review of Virus Safety Evaluation for Biological Tissue Extract Products and Eukaryotic Expression Products [S]. 2005
3	National Medical Products Administration. General Principals of Technical Evaluation of Quality Control for Mammalian Cells for Recombinant Products [S]. 2007
4	ICH Q2(R2) Validation Of Analytical Procedures (November 2023)
5	ICH Q5A (R2) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin (November 2023)
6	ICH Q5B Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used For Production of r-DNA Derived Protein Products (November 1995)
7	ICH Q5D: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products (July 1997)
8	United States Pharmacopeia (USP)
9	Code of Federal Regulations Title 9 Animals and Animal Products
10	FDA Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (July 1993)
11	FDA Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products For Human Use (February 1997)
12	FDA Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products (January 2011)
13	European Pharmacopeia (Ph. Eur.)
14	EMA Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products, EMA/CHMP/BWP/398498/2005 (July 2008)

One-Stop Biosafety Services





Global Compliance

- Meet the requirements of global regulatory agencies such as **FDA, EMA, PMDA, TGA, CDE**, etc.
- Adherence of **GLP & GMP**
- Holds **CNAS and QP** certification
- Has FDA facility registration
- **Capability Verified** by official and Third-Party testing agency



Approved Cases of Multiple Modality

- ADC drugs
- Monoclonal/Bispecific/Trispecific antibodies
- Recombinant proteins
- CAR-T/CAR-NK/TCRT
- AAV gene therapy
- iPSC/MSC
- Gene editing



Extensive Experience in Global Application

- Professional project management personnel with PMP certification
- Over **130 IND or BLA** Approved Cases
- Over **60 global approval cases.**
- Collaborated over **400 Drugs** of over 300
- biopharmaceutical clients.
- Over **100 RCV** projects



Commercial Capability

- Over **60 BLA** and Commercial projects
- Over **10 drugs'** Commercial UPB lot release testing
- Full ability of **PSQ**
- Efficient **Time Cycle**
- **Global Compliance & Quality Assurance**

Investors and Representative Clients

> 60M USD in 4 financing rounds

GP 金浦健康基金
Healthcare Capital

2020.12

承樹投資
CS Capital

2021.08

海邦投資 growth
国方创新

2022.07

招銀國際
CMB INTERNATIONAL

HED@和达

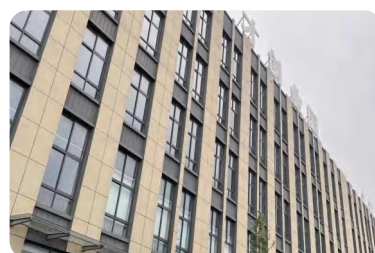
物产中大
WZ GROUP

浙江股权服务集团
Zhejiang Equity Service Group

金浦投资
GP Capital

2024.03 30M Series B funding

Capacity Establishment



2020

Market Exploration



2021

Accelerated Expansion



2022

Top Domestic Clients



2023

Top Global Clients



2024

130+
IND&BLA
Approved Cases

60+
Global Approved Cases
by FDA, EMA, TGA etc

10+
Successfully Licensed
Out to Global MNCs