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

WeChat Official Account

LinkedIn official Account

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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 Stücki 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.

Committed to biological testing, safeguarding life and health

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+ Laboratorr 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+ Conffrmed and validated instruments and equipment

Compliant with NMPA、FDA、EMA、PMDA requirements

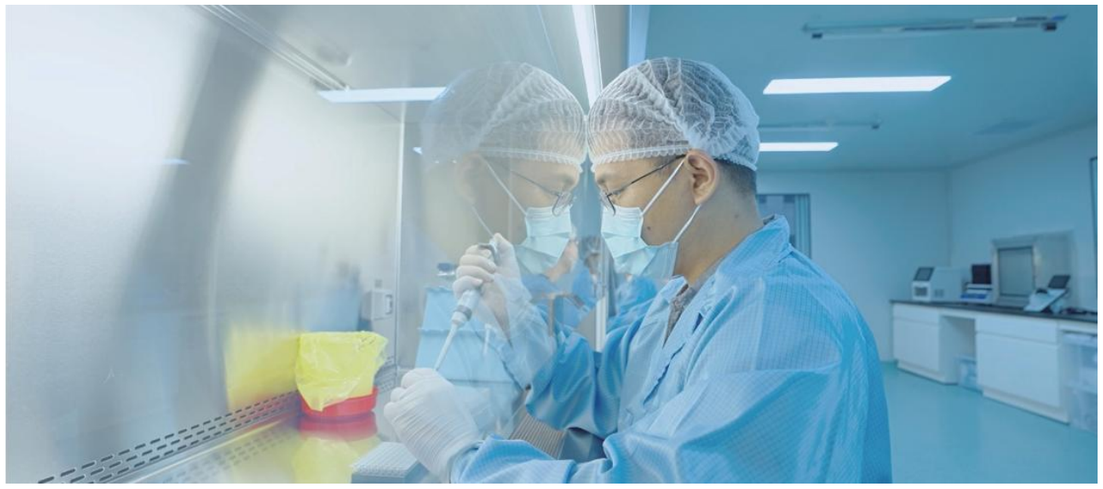
Paper and electronic data comply with the ALCOA+ principle

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

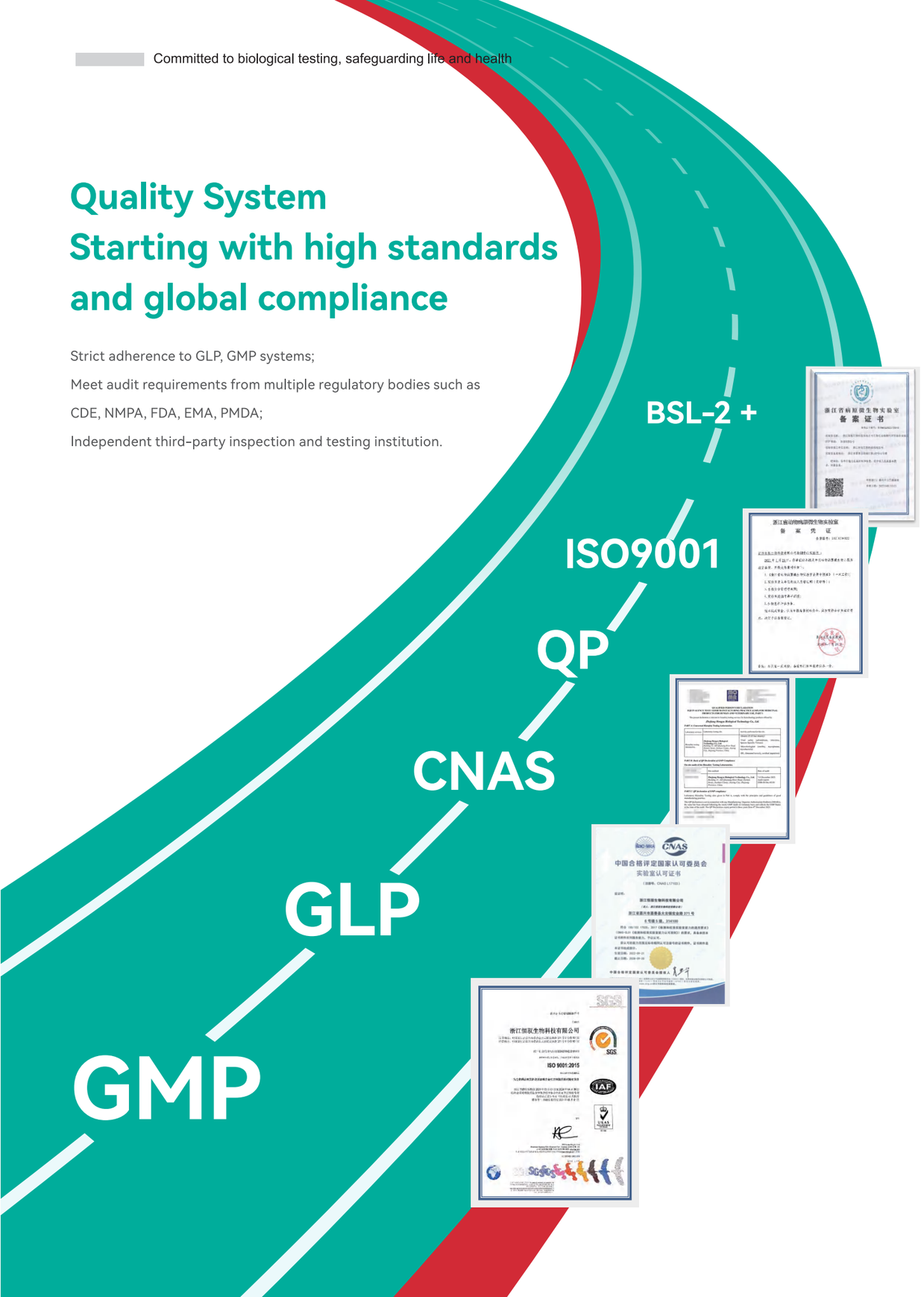
Integrity
Collaboration
Rigorous and scientific
Customer orientation
Accountability
Internally-driven growth

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.



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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.

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

Process flow	Sequence determination	Cell line construction	Process development	GMP pilot scale production	IND application	Phase III clinical study	BLA application	Post-marketing monitoring
Critical processes	Sequence screening Antigen preparation CMC evaluation Animal model evaluation	Growth Expression Stability Quality of target protein	Validation of analytical procedures Cell culture process Downstream purification process Drug product process development	Toxicology study Stability study Characterization analysis Clinical sample	Complete preclinical study and data organization	Process optimization Process characterization Process validation	Complete clinical study data and process validation	Release test Continuous validation Phase IV clinical study
Testing service		B Cell bank validation RCB WCB MCB	A Virus removal validation Process prevalidation D Process residue test HCD HCP Endotoxin	B Cell bank validation EOPC UPB Virus test in raw materials and excipients D Process residue test HCD HCP	A Virus removal validation IND application validation	B Cell bank validation WCB EOPC UPB	A Virus removal validation BLA application validation B Cell bank validation EOPC UPB	C Lot release test (MCB and WCB) EOPC UPB D Process residue test HCD HCP

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

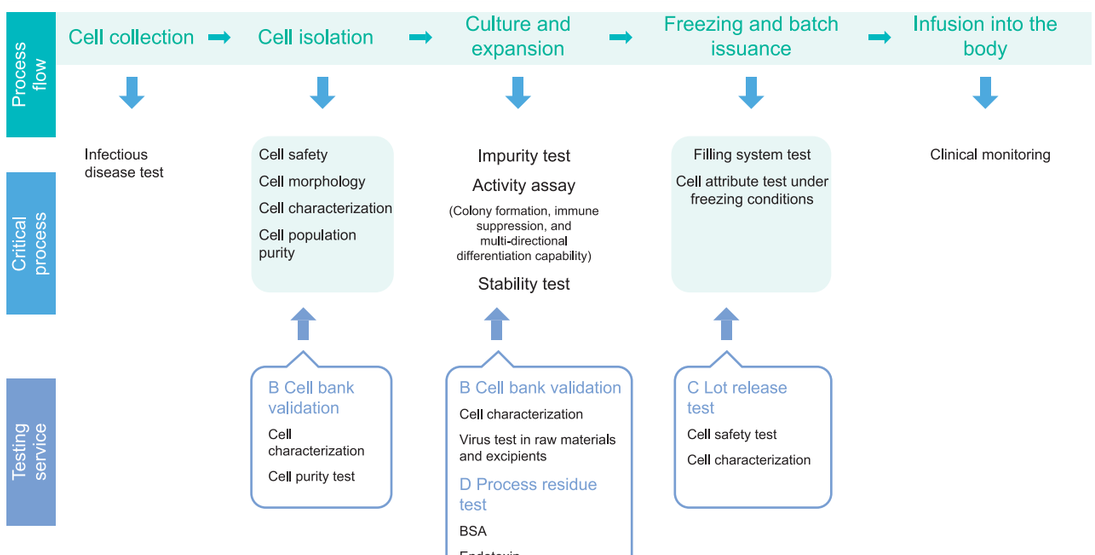
EOPC/UPB

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	Cell Pathology Observation (CPE)	+	+	+	-	-
	In Vitro Different Indicator Cell Culture Method	(MRC-5, 293T, and Vero) -28 days	+	+	+	+	+
	Animal Inoculation Method	Pups, Adult Rats, Chicken Embryos (CHP & USP)	+	-	+	-	-
	Reverse Transcriptase Virus	Reverse Transcriptase Activity Check	+	-	+	-	-
		Ultra-thin Section Transmission Electron Microscopy Check	+	-	+	-	-
		Negative Staining Transmission Electron Microscopy Quantitative	-	-	-	+	+
		Infectious Experiment	+	-	+	+	+
	Mouse Parvovirus Test	Cytopathic Effect Observation Method (NB324K)	+	-	+	+	+
		qPCR Method					
	Species-specific Human Virus Check	Mouse Antibody Production Test (MAP)	+	-	-	-	-
		Hamster Antibody Production Test (HAP)	+	-	-	-	-
	Other Specific Virus Tests	qPCR Method-Feline Calicivirus 2117、Bovine Polyomavirus BPyV	+	-	-	-	-
	Bovine Source Virus (8 types)	Cell Pathology Observation					
		Hemadsorption	+	-	-	-	-
		Fluorescent Antibody Detection					
	Bovine Papillomavirus Test	qPCR Method	(+)	-	-	-	-
	Feline Calicivirus 2117 Test						
	Porcine Source Virus (7 types)	Cell Pathology Observation					
		Hemadsorption	+				
		Fluorescent Antibody Detection					
	Porcine Source Virus (5types)	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	(+)	-	-	-	-

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	√	√	√	√
	Flow Cytometry for Cell Surface Markers	√	√	√	√
	Short Tandem Repeat (STR) Analysis	√	√	√	√
	Chromosome Karyotype Analysis	√	√	√	√
Bacteria and Fungi Check	Membrane Filtration Method (Method Suitability Test)	√	√	√	√
	Membrane Filtration Method	√	√	√	√
	Direct Inoculation Method (Method Suitability Test)	√	√	√	√
	Direct Inoculation Method	√	√	√	√
Mycobacteria Check	Pour Plate Method (Method Suitability Test)	√	√	√	
	Pour Plate Method	√	√	√	
Mycoplasma Check	Culture Method (Method Suitability Test) - For China Submission	√	√	√	√
	Culture Method - For China Submission	√	√	√	√
	Indicator Cell Culture Method (Method Suitability Test) - For China Submission	√	√	√	√
	Indicator Cell Culture Method - For China Submission	√	√	√	√
	Culture Method (Method Suitability Test) - For US Submission	√	√	√	√
	Culture Method - For US Submission	√	√	√	√
	Indicator Cell Culture Method (Method Suitability Test) - For US Submission	√	√	√	√
	Indicator Cell Culture Method - For US Submission	√	√	√	√
Endogenous and Exogenous Virus Factor Check	Observation of Cytopathic Effect and Hemadsorption		√	√	
	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)		√		
	Fertile Egg Inoculation Method - For China Submission		√		
	Fertile Egg Inoculation Method - For US Submission		√		
	Retrovirus Check (Reverse Transcriptase Activity Assay)		√		
	Retrovirus Check (Ultrathin Section Transmission Electron Microscopy)		√		
	Retrovirus Check (Infectivity Assay)		√		
	Bovine Viral Diagnostics - 9CFR		√		
	Porcine Viral Diagnostics - 9CFR		√		
	Bovine Papillomavirus Check (Fluorescent Quantitative PCR Method)		√		
	Porcine Parvovirus Check (Fluorescent Quantitative PCR Method)		√		
	Porcine Circovirus Type 1 Check (qPCR Method)		√		
	Porcine Circovirus Type 2 Check (qPCR Method)		√		
	Porcine Torque teno Virus Type 1 Check (qPCR Method)		√		
	Porcine Torque teno Virus Type 2 Check (qPCR Method)		√		
	Species-Specific Human Virus Check (qPCR Method)		√		
Immunological Response Detection	Lymphocyte Proliferation Suppression Test	√	√	√	√
	Detection of Specific Lymphocyte Subpopulations	√	√	√	√
	Lymphocyte TNF-α Secretion Inhibition Test	√	√	√	√
Biological Efficacy Evaluation	Osteoblast Differentiation	√	√	√	√
	Chondrocyte Differentiation	√	√	√	√
	Adipocyte Differentiation	√	√	√	√
Cell Viability Check	Cell Count and Survival Rate		√	√	√
	Cell Growth Curve		√	√	√
	Cell Cycle Determination		√	√	√
Secreted Cytokines	TGF-β Secretion Level	√	√	√	√
	VEGF Secretion Level	√	√	√	√
Tumorigenesis Check	Nude Mouse Inoculation Test				√
	Soft Agar Clonal Formation Test		√	√	√
	Telomerase Activity Assay		√	√	√
Residual Check	Bovine Serum Albumin Residual Check				√
	Antibiotic Residual Check				√
	Trypsin				√
	Bacterial Endotoxin Check (Gel Clot Limitation Method)				√

CAR-T Cell Therapy Biosafety Testing

Process flow	Critical process	Testing service
PBMC isolation	Removing red blood cells, platelets, and NK cells Magnetic bead sorting of CD4+/CD8+/CD62L+	
T cell activation	Activation of T cells by adding IL-2 (IL-7, IL15) and anti-CD3 & anti-CD28 antibodies	B Cell bank validation T cell subtype characterization
Lentiviral transfection	Harvesting of GMP-grade LVs RCL test Stable cell line	B Cell bank validation RCB/MCB/WCB C Lot release test Lentiviral quality test RCL test Process residue test (HCD, HCP, endotoxin)
CAR-T cell expansion	Magnetic bead activation (swinging) Monoclonal antibodies and IL-2 activation (shake flask) Magnetic bead activation (static)	B Cell bank validation Virus test in raw materials and excipients
Drug product and test	CART drug product and release test	C Lot release test CART safety testing D Process residue test BSA Endotoxin
Infusion into the body	Clinical monitoring T cell subsets	

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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 CO1 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	Inclination Method - Method Suitability	+	(+)	+	-	-
		Inclination Method	+	+	+	-	-
Exogenous and endogenous virus contamination tests	Cell Morphology Observation and Hemadsorption Test	Cell Pathology Observation (CPE) Hemadsorption Test	+	+	+	-	-
	In Vitro Different Indicator Cell Culture Method	(MRC-5, 293T, and Vero) -28 days	+	+	+	+	+
	Animal Inoculation Method	Pups, Adult Rats, Chicken Embryos (CHP & USP)	+	-	+	(+)	-
	Reverse Transcriptase Virus	Reverse Transcriptase Activity Check	+	-	+	-	-
		Ultra-thin Section Transmission Electron Microscopy Check	+	-	+	-	-
		Negative Staining Transmission Electron Microscopy Quantitative	-	-	-	-	-
	Species-specific Human Virus Check (22 types)	Infectious Experiment	+	-	+	-	-
		qPCR Method	+	-	-	-	-
	Bovine Source Virus (8 types)	Cell Pathology Observation Hemadsorption	+	-	-	-	-
	Bovine Papillomavirus	Fluorescent Antibody Detection qPCR Method	(+)	-	-	-	-
	Porcine Source Virus (7 types)	Cell Pathology Observation Hemadsorption Fluorescent Antibody Detection	+	-	-	-	-
	Porcine Source Virus (5types)	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	qPCR Method, Infection Method	+	-	-	-	-
	Replication-Competent Virus (RCL/RCR) - Including Method Suitability	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

HYQURE

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	Cytopathy observation (CPE), hemadsorption test	+	-
	In vitro inoculation and culture of different indicator cells	Cytopathy observation (CPE), hemadsorption test, hemagglutination test	+	+
	In vivo inoculation in animals and chicken embryos	In vivo inoculation	+	+
	Retrovirus test	Reverse transcriptase activity test, electron microscopy, infection method	+	+
	Human virus test	Cytopathy assay, qPCR	+	+
	Bovine virus test	Cytopathy assay, hemadsorption, fluorescent antibody assay	+	-
	Porcine virus test	Porcine parvovirus test (quantitative fluorescence method), cytopathy assay	+	-
	Chromosome test (human diploid cell strain)	Chromosome karyotyping	+	-
	Oncogenicity test*	Animal test	+	-
	Tumorgenicity test*	Animal test	+	-

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CAR-T Cell Therapy Biosafety Testing

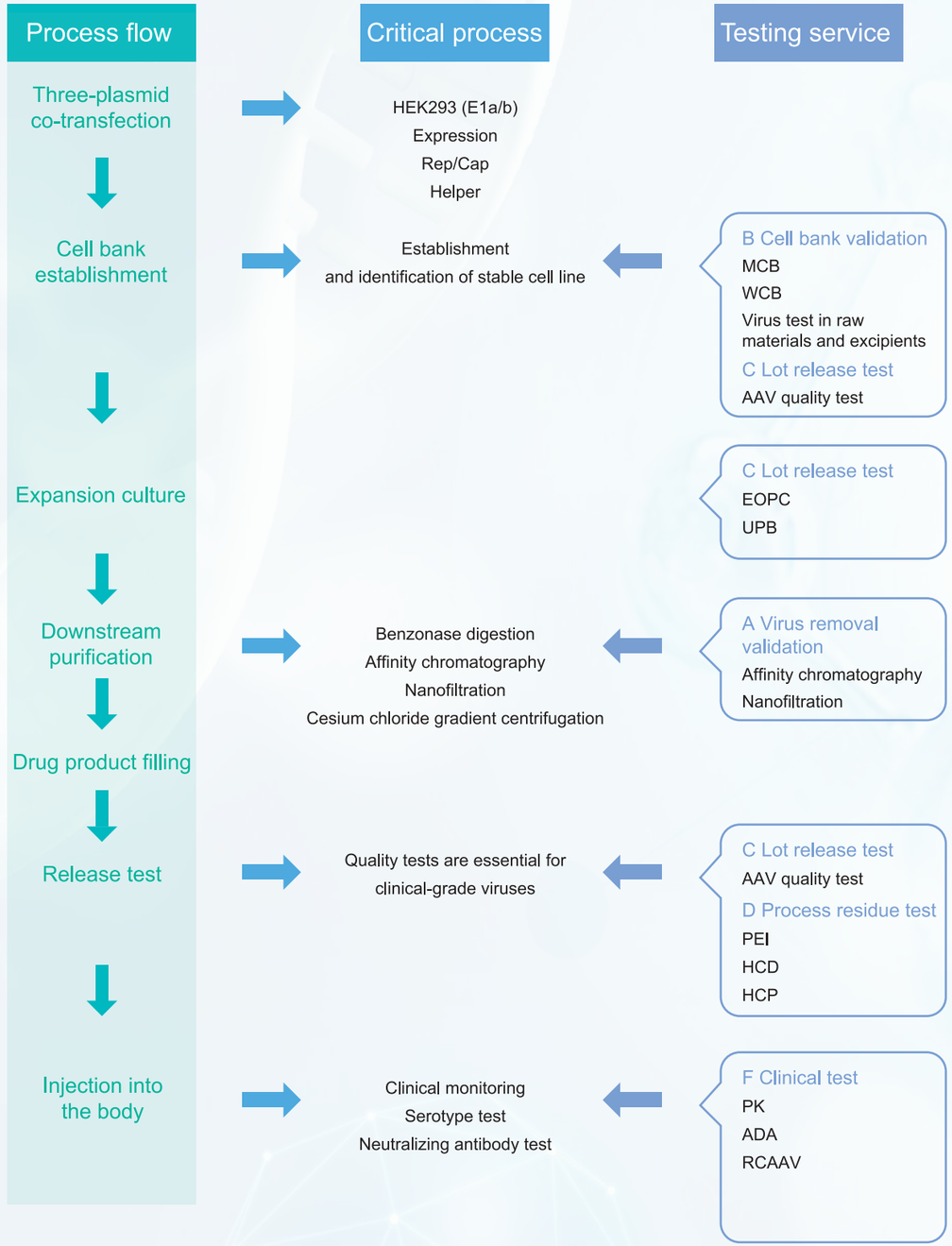
Lot release test

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

BIOTECH

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	(+)	(+)	(+)	-	-
	Cell Identification	Cytochrome P450 CO1 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	Inclination Method - Method Suitability Inclination Method	+ +	(+) +	+ +	- -	- -
Exogenous and endogenous virus contamination tests	Cell Morphology Observation and Hemadsorption Test	Cell Pathology Observation (CPE) Hemadsorption Test	+	+	+	-	-
	In Vitro Different Indicator Cell Culture Method	(MRC-5, 293T, and Vero) -28 days	+	+	+	+	+
	Animal Inoculation Method	Pups, Adult Rats, Chicken Embryos (CHP & USP)	+	-	+	(+)	-
	Reverse Transcriptase Virus	Reverse Transcriptase Activity Check Ultra-thin Section Transmission Electron Microscopy Check Negative Staining Transmission Electron Microscopy Quantitative Infectious Experiment	+ + - +	- - - -	+ + - +	- - - -	- - - -
	Species-specific Human Virus Check (22 types)	qPCR Method	+	-	-	-	-
	Bovine Source Virus (8 types)	Cell Pathology Observation Hemadsorption Fluorescent Antibody Detection	+	-	-	-	-
	Bovine Papillomavirus	qPCR Method	(+)	-	-	-	-
	Porcine Source Virus (7 types)	Cell Pathology Observation Hemadsorption Fluorescent Antibody Detection	+	-	-	-	-
	Porcine Source Virus (5types)	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	qPCR Method, Infection Method	+	-	-	-	-
	Replication-Competent Virus (RCL/RCR) - Including Method Suitability	qPCR Method, Infection Method	-	-	+	+	+

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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 & classificaiton	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 Bloting	✓		✓	Intact
	Integrity of capsid	Western Bloting	✓		✓	Intact
	Serotype identification	Differential scanning fluorimetry			✓	Qualitative
	Serum neutralizing antibody	Measurement of absorbance after serum binding incubation				None

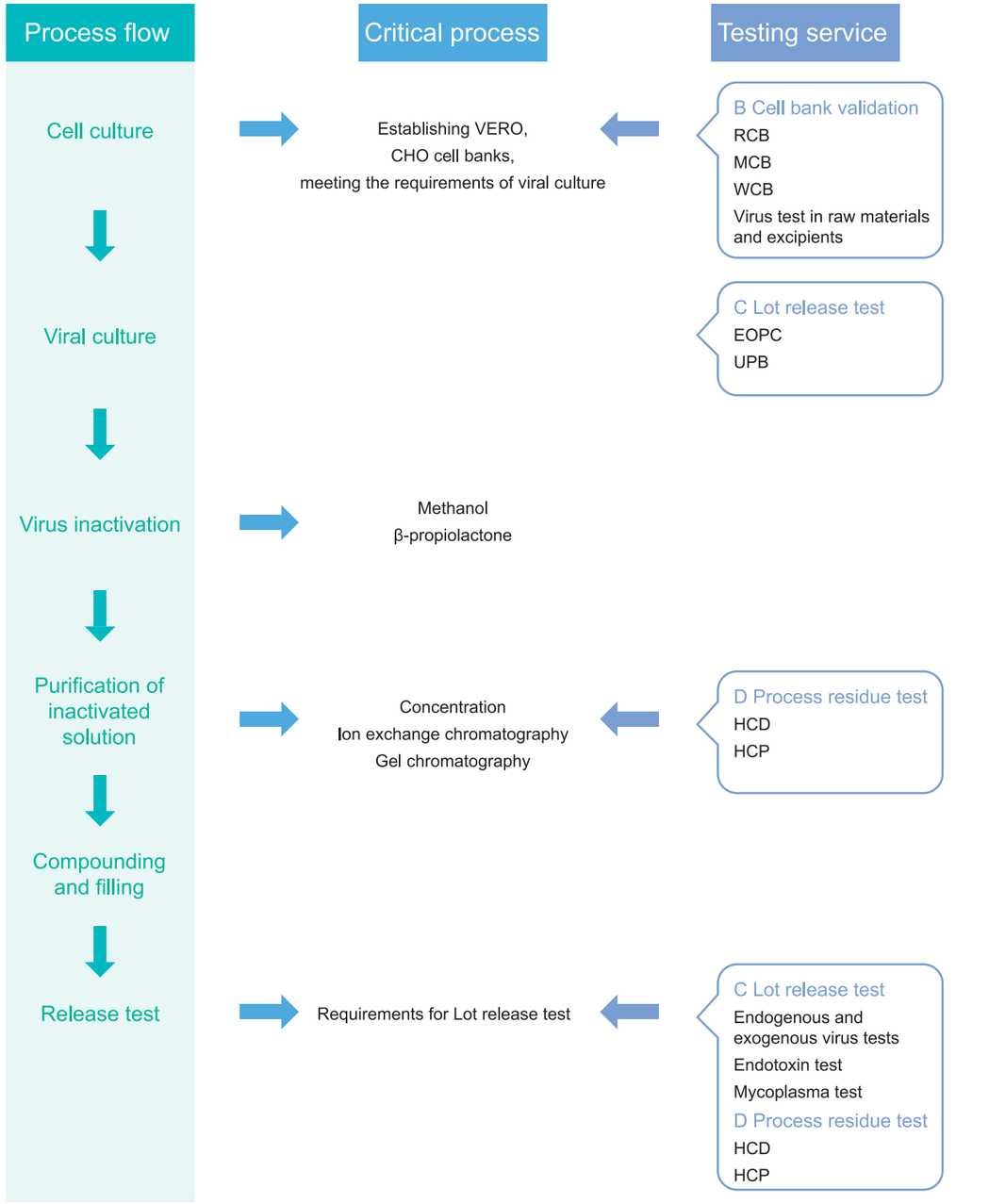
Literature source:

[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 & Zelenaia, 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 → Refinement → Virus removal → Sterile dispensing

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	EMEA/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 Pharmacopoeia (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 Pharmacopoeia (Ph. Eur.)
14	EMA Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products, EMEA/CHMP/BWP/398498/2005 (July 2008)

Committed to biological testing, safeguarding life and health

One-Stop Biosafety Services

Anti body

Preclinical studies	IND Application	Clinical Phase	BLA Application	commercialization
• Cell line characterization • Virus clearance/ inactivation validation • Kits for QC release (HCD、HCP detection)	• Cell line characterization • Virus clearance/ inactivation validation • Kits for QC release (HCD、HCP detection)	• Lot release T est • Virus clearan ce/ inactivation validation	• Genetic stability testing • Cell line characterization • Virus clearance/ inactivation validation	• Lot release Test • Kits for QC release (HCD、HCP detection)
• RCV detection (RCL/ RCR/RCA/rcAAV) • Kits for QC release (HCD、HCP detection) • Virus clearance/ inactivation validation • Cell line characterization • Characterization for AAV: rcAAV、TCID50	• RCV detection (RCL/ RCR/RCA/rcAAV) • Kits for QC release (HCD、HCP detection) • Virus clearance/ inactivation validation • Cell line characterization • Characterization for AAV: rcAAV、TCID50 • Genetic stability testing	• RCV detection (RCL/RCR/RCA /rcAAV) • Virus clearanc e/ inactivation va lidation • Lot release Te st • Characterizati on for AAV: rcAAV、TCID5 0 • Genetic stabili ty testing	• Cell line characterization • Virus clearance/ inactivation validation • RCV detection (RCL/ RCR/RCA/rcAAV) • Genetic stability testing	• RCV detection (RCL/ RCR/RCA/rcAAV) • Kits for QC release (HCD、HCP detection) • Characterization for AAV: rcAAV、TCID50 • Lot release Test

Cell/Gene Therapy

Committed to biological testing, safeguarding life and health

HYQURG

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**

Committed to biological testing, safeguarding life and health

Investors and Representative Clients
> 60M USD in 4 financing rounds

2020.12 金浦健康基金 Healthcare Capital

2021.08 承樹投資 CS Capital

2022.07 海邦投资 Growth 国方创新

2024.03 30M Series B funding 招银国际 CMB INTERNATIONAL, HEDO@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

2020 Capacity Establishment

2021 Market Exploration

BIOTHEUS 普米斯生物技术, HEALSUN, 易慕峰, 百奥泰 BIO-THERA, brigene, OBiO CELL & GENE THERAPY CRO & CDMO

2022 Accelerated Expansion

CSPC PHARMA., BioRay 博锐生物, PORTON ADVANCED, InnoStellar Biotherapeutics 朗信生物, Kexing Biopharm 科兴制药

2023 Top Domestic Clients

AbelZeta, chime BIOLOGICS, innovent, IASO BIOTHERAPEUTICS, ProBio, BioDlinK, Akesobio

2024 Top Global Clients

BeOne, Johnson&Johnson 强生, AstraZeneca, LEGEND BIOTECH

130+	60+	10+
IND&BLA Approved Cases	Global Approved Cases by FDA, EMA, TGA etc	Successfully Licensed Out to Global MNCs