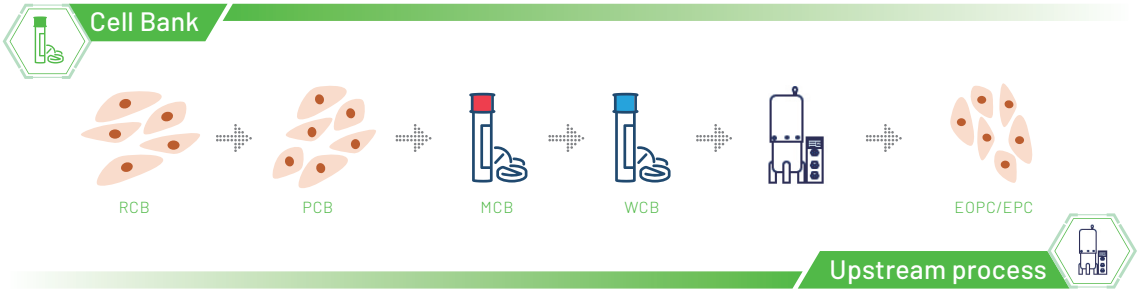
Quality Control of CHO Cell Matrix

Chinese Hamster Ovary (CHO) cells are the most commonly used non-human mammalian cell lines in the production of biopharmaceuticals. As a critical raw material for producing monoclonal antibody biopharmaceuticals,CHO cells need to comply with the "Good Manufacturing Practices for Drug Products" for the establishment, qualification, and management of cell banks according to a three-tier system, which includes the Master Cell Bank (MCB), the Working Cell Bank (WCB), and the Primary Cell Bank (PCB). The End-of-Production Cell (EOPC/EPC) for *in vitro* production, also known as the Limited Cell Bank (CAL), refers to the cells harvested at or beyond the end of production, prepared in production-scale for the final production stage.

As a production system for monoclonal antibody drugs, the qualification of CHO cells must adhere to regulations and guidelines. This primarily includes identification of cell identity, purity testing, and safety testing. The qualification of CHO cells directly affects the quality and safety attributes of downstream biopharmaceutical products.



Regulatory for CHO CLC Testing

Administration	Guideline
World Health Organization	• 2010, Recommendations for the evaluation of animal cell cultures as substrates for the manufacture of biological medicinal products and for the characterization of cell banks (TRS 878) • 2013, Recommendations for the evaluation of animal cell cultures as substrates for the manufacture of biological medicinal products and for the characterization of cell banks (TRS 978)
ICH harmonisation for better health	• ICHQ5A Quality of Biotechnological Products: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin • ICHQ5B Analysis of the expression construct in cells used for production of rDNA-derived protein products. • ICHQ5D Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products
国家药品监督管理局 National Medical Products Administration	• 2006 General Principles for the Evaluation of Mammalian Cell Quality Control Technology for the Production of Recombinant Products • Pharmacopoeia of the People' s Republic of China, 2020 Edition - Procedures for Preparation and Quality Control of Animal Cell Substrates for the Production and Testing of Biopharmaceuticals. • Pharmacopoeia of the People' s Republic of China, 2020 Edition - General Monographs for Human Use of Recombinant Monoclonal Antibody Products.
FDA	• EP 5.14 Gene Transfer Medicinal Product for Human Use • EP 5.2.3 Cell Substrates for the Production of Vaccines for Human Use. • 2008, Guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells. • 2005, Guideline on development and manufacture of lentiviral vectors. • 2009, Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products
EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH	• 1993, Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals • 1997, Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use • 2010, Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications

Category	Testing items	PCB/ Cell seed	MCB	WCB	EOPC/ CAL
Viability	Viability Determination of Mammalian Cell Bank	Y	Y	Y	Y
	Cell Morphology	Y	Y	Y	Y
Identity	DNA Barcode Assay for Cell Line Authentication	Y	Y	Y	Y
Purity	Sterility Testing by Direct Inoculation	Y	Y	Y	Y
	Mycoplasma Detection-Cultivation and Indicator Cell Method	Y	Y	Y	Y
	Culture Method for Mycobacterium Detection	Y	Y	NA	Y
Safety	*in-vitro* Screening of Adventitious Viral Contaminants using Indicator Cell	NA	Y	Y	Y
	in-vivo Screening of Adventitious Viral Contaminants	NA	Y	NA	Y
	Transmission Electron Microscopy for Contamination Detection	NA	Y	NA	Y
	Infectious Retroviruses Detection by Co-cultivation	NA	Y	NA	Y
	Murine Virus Detection- Antibody Production	NA	Y	NA	NA
	Murine Minute Virus Detection Using QPCR	NA	Y	NA	Y
	in-vitro Screening of Porcine Viral Contaminants	NA	Y*	Y*	Y*
	Porcine Virus Detection Using QPCR	NA	Y*	Y*	Y*
	in-vitro Screening of Bovine Viral Contaminants	NA	Y*	Y*	Y*
	Bovine Virus Detection Using QPCR	NA	Y*	Y*	Y*

* Indicates the tests required according to the specific characteristics of the cells, their passage history, and the culture process.

BRC Biotechnology's detection scheme strictly meets the requirements of the Chinese Pharmacopoeia, the United States Pharmacopoeia, and the European Pharmacopoeia for CHO cell line substrates in terms of biological safety control.

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