

Reliable | Efficient | *In Vivo* Biosafety Testing Services to Accelerate International IND and BLA Applications

In vivo Biosafety Testing Services

Animal-derived cells are mainly used as host cell for biologicals production. Animal original cell might contact with operator or environmental contamination, causing the potential viral safety hazards. As the recommendations in ICHQ5A and regulatory guidelines, *in vivo* virus screening and antibody production assay should be used to ensure the safety and quality of the biological products.

As injectable medication, abnormal toxicity testing is conducted to evaluate the toxicity of biological impurities, ensuring clinical safety. According to the requirements of the Parenteral Drug Association and different pharmacopeias.

BRC Biotech provides comprehensive solutions for viral screening and abnormal toxicity evaluation using SPF-grade animal models, including mice, rats, guinea pigs, hamsters, and chicken embryos. All the testing services are verified for domestic and international IND and BLA applications.

Comprehensive Animal Testing Capabilities

- ✓ Chicken Embryo Model for *in vivo* Virus Screening
- ✓ Rodent Model for *in vivo* Virus Screening
- ✓ Mouse, Rat, and Hamster Antibody Production
- ✓ Biochemical Analysis for Animal Blood
- ✓ Serological Examination by ELISA
- ✓ Abnormal Toxicity Evaluation
- ✓ Humanized Mice

International Compliant Quality System

- ✓ CNAS qualified Animal experiment
- ✓ Methods comply with the Chinese Pharmacopoeia, United States Pharmacopoeia, and European Pharmacopoeia
- ✓ ABSL-2: Animal Pathogen Biosafety Level 2 laboratory
- ✓ Reliable animal sources / quarantine periods, etc.

Facilities and Utilities

~1,000 SQM Animal Laboratory

- ✓ 8 Animal Rooms for Mice
- ✓ 2 Animal Rooms for Rat
- ✓ 1 Animal Room for Hamster
- ✓ 1 Animal Room for Guinea Pig
- ✓ 1 Animal Room for Chicken Embryo

Complete Experimental and Auxiliary facilities

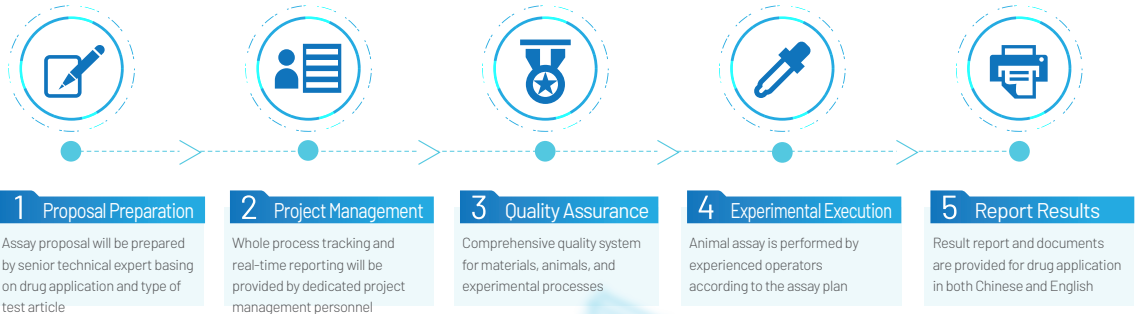
- ✓ Class A2 Biological Safety Cabinet
- ✓ Double-door Steam sterilizer
- ✓ Independently Animal Husbandry Cages
- ✓ Quarantine Room, Dissection Room, etc.

Animal Welfare Assurance

- ✓ 3Rs Principle
- ✓ Comprehensive IACUC Committee and Management System

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Animal Experiment Procedure and Advantages Experimental Plans Base



Experimental Content and Duration*

Chicken Embryo, Suckling Mice, Adult Mice, Guinea Pig	In vivo Screening (ChP)	30 Days
Chicken Embryo, Suckling Mice, Adult Mice, Guinea Pig	In vivo Screening (USP)	35 Days
SPF-grade Mouse for 16 Viruses Screening**	Mouse Antibody production	40 Days
SPF-grade Hamster for 5 Viruses Screening**	Hamster Antibody Production	40 Days
SPF-grade Rat for 9 viruses screening**	Rat Antibody Production	55 Days
Mouse, Guinea Pig	Abnormal Toxicity	10 Days
Other Animal Models, Humanized Animal Modes, etc.	Customized Animal Assay	According to TA

* The experimental period is calculated based on calendar days
 ** According to ICH05A(R2)

Regulatory and Guidance for in vivo Assay

CHP Chinese pharmacopoeia of Part 3 <Preparation and Quality Control of animal cell Matrix for the production and verification of biological Products> Chinese pharmacopoeia of Part 3 <3303 Test Method for Murine Virus> Chinese pharmacopoeia of Part 3 <1101 Abnormal toxicity test> Chinese pharmacopoeia of Part 3 <3302 Preparation and Quality Control of animal cell Matrix for the production and verification of biological Products>
FDA FDA Guidance 1993: Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals. FDA Guidance 1997: Points to Consider in the Manufacture and Testing of Monoclonal Antibody Products for Human Use. FDA Guidance 2010: Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications.
ICH ICH Quality Guidance Q5A (R2): Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin CPMP/ICH/295/95, ICH Topic Q5 A (R1): Quality of Biotechnological Products: Viral Safety Evaluation of Biotechnology Products Derived from Cells Lines of Human or Animal Origin



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