charles river

Vaccine Development Services

Charles River has effectively supported the vaccine industry for decades with our unique range of products and related services. Our global network of scientific, technical and regulatory experts provides vaccine developers with the right expertise early in the development process to boost productivity, efficiency and profitability and get the safest and most effective vaccines to market.

Discovery to Lead Candidate Optimization

It is important to research and eliminate unsuccessful programs through *in vitro* and *in vivo* techniques in order to find the best lead candidate. With our unmatched knowledge of animal models, safety testing and immunology, Charles River can assist you in selecting your most promising vaccine candidates and provide the information you need to develop better vaccines.

- Animal efficacy modeling
- Formulation development
- Research-grade influenza viruses
- Minimum potency determination
- Adjuvant selection
- Immunogenicity
- Assay development and validation
- Immunology services

Safety Assessment

Charles River has the breadth of services and expertise to help you successfully initiate and complete critical phases of preclinical drug development by designing, performing and documenting safety tests that meet the appropriate regulatory requirements before and after clinical trials begin. Our Navigator Consulting Services group can also assist with a vaccine development strategy that covers early development through to market.

Our capabilities include vaccine and vector safety studies in multiple species via multiple dose routes. These studies provide the efficacy and safety testing data required for your vaccines and other anti-infective agents. We design and perform studies in CDC-approved quarantine facilities with Biosafety Level (BSL)-2 and BSL-3 upgrade ratings to fulfill your preclinical regulatory needs in a Good Laboratory Practice (GLP)-compliant environment.

Capabilities

- Discovery to Lead Candidate Optimization
- Safety Assessment
- Manufacturing and Analytical Services

Regulatory and Scientific Support

- International network of scientific experts in the areas of discovery, immunology, pathology and manufacturing
- Regulatory and scientific advisors
- FDA and pharmaceutical industry experience
- 360-degree support

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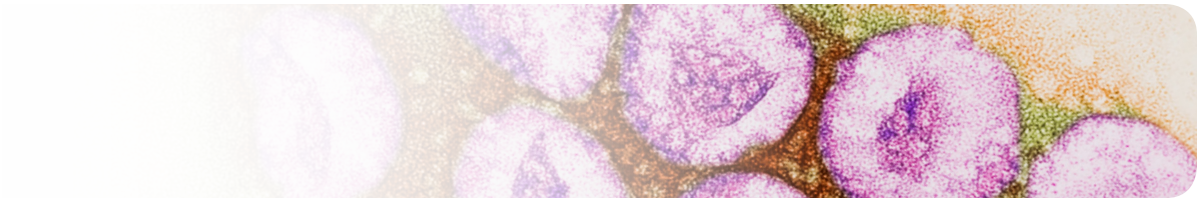

In Vivo Studies

- Safety and efficacy
- Immunotoxicology
- Potency and dose response
- Biodistribution
- Tumorigenicity
- Local tolerance
- Neurovirulence safety testing
- Reproductive toxicology

Laboratory Support

- Inapparent virus assay
- Molecular and cell biology
- Microbiology
- Immunology
- Virology
- Clinical and anatomical pathology

Manufacturing and Analytical Services

Charles River offers multiple products and services in support of the development, manufacture and analytical testing of vaccines. We offer endotoxin testing for product release and embryonated, specific pathogen-free (SPF) eggs for the production of veterinary and human vaccines and vaccine testing.

We have experience in the manufacture of live and attenuated viral vaccines in both cell- and egg-based expression systems under current Good Manufacturing Practice (cGMP) requirements for both preclinical studies and early-phase clinical trials. We offer testing from release of cell banks and viral stocks to the release of bulk and final vaccine product.

- SPF eggs that meet USDA and EU Pharmacopoeia requirements
- Embryo-based primary cell products
- Bulk antigen production
- Avian pathogen testing includes 9CFR and product evaluation studies
- Antigens, antisera and poultry diagnostic reagents
- cGMP cell banking and characterization
- Virus seed preparation and testing
- Pilot scale virus manufacturing
- Potency assays
- Storage and global distribution

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