



Vaccine Development Services

Vaccines are medicinal agents intended to elicit an immune response by increasing antibody production and/or specific T-cell responses. With time, vaccines have evolved from conventional prophylactic uses to more complex and novel therapeutic products. These advances require careful scientific consideration of a vaccine's properties and its clinical use.

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 provide 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.

Capabilities:

- Discovery to Lead Candidate Optimization
- Safety Assessment
- Manufacturing Support
- Regulatory and Scientific Support

| EVERY STEP OF THE WAY

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 in selecting the most promising vaccine candidates and provide the information our clients 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 clients 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. We 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 vaccines and other anti-infective agents. We design and perform studies in CDC-approved quarantine facilities with Biosafety Level (BSL)-2 upgrade ratings to fulfill our client's preclinical regulatory needs in a Good Laboratory Practice (GLP)-compliant environment.

***In Vivo* Studies**

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

Laboratory Support

- Molecular and cell biology
- Microbiology
- Immunology
- Virology
- Clinical and anatomical pathology

Vaccine Development

Manufacturing 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 also offer GMP testing of clients' products from release of cell banks and viral stocks to the release of bulk and final vaccine product.

Manufacturing Support	Testing Support
SPF eggs that meet USDA and EU Pharmacopoeia requirements	Efficacy/challenge studies
Embryo-based primary cell products	Adjuvant assessment
Bulk antigen production	<i>In vivo</i> potency assays including lot release of clinical and commercial final products
Avian pathogen testing includes 9CFR and product evaluation studies	Immunopotency assays
Antigens, antisera and poultry diagnostic reagents	<i>In vivo</i> biosafety testing
cGMP cell banking and characterization	Pyrogenicity/endotoxin/monocyte activation test (MAT)
Virus seed preparation and testing	Dose-ranging studies
Pilot scale virus manufacturing	Stability studies

Regulatory and Scientific Support

Charles River has an international network of scientific experts in the areas of discovery, immunology, pathology and GMP vaccine safety, efficacy and release testing. Our regulatory and scientific advisors have both FDA and pharmaceutical industry experience and consult with clients to ensure the appropriate study plans are developed. If questions arise during testing, our team will provide support in developing the most effective path forward.