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BIOLOGICS TESTING SOLUTIONS

Vaccine and Virus Manufacturing and Testing

Services Include:

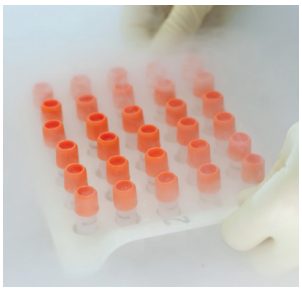
- Formulation development
- SPF egg supply
- Phase I/Phase II clinical trial manufacturing
- Preclinical safety assessment
- GMP safety and efficacy testing
- Product release testing
- Endotoxin testing
- Oncogenicity testing
- Regulatory consulting

Charles River Laboratories can help expedite our clients' vaccine development programs, from manufacturing for early-phase clinical trials through to lot release (potency assays) for commercial products. We have more than 20 years of experience manufacturing vaccines and viruses in cell culture, including dengue, influenza, and respiratory syncytial viruses. We also provide biosafety testing for virus seeds stocks, cell banks, and vaccine products, which is essential to ensure no bacterial, fungal, mycoplasma, or adventitious viral agent contamination is present. In addition, we conduct immunogenicity and adjuvant assessments, as well as all microbiology and *in vivo* services necessary for vaccine efficacy testing.

These development services are accompanied by our scientific and regulatory experience, which allows us to predict and eliminate potential pitfalls early in development while ensuring compliance with all applicable international regulatory standards.

Manufacturing

Our cGMP-compliant manufacturing capabilities complement our testing services to provide a comprehensive portfolio for our clients' products. This allows them to get everything they need from a single, harmonized provider. Our vaccine manufacturing services include cGMP virus seed and cell banking, vaccine manufacturing via cell culture, scale-up for clinical trials, pilot scale virus manufacturing, adaptation of production using animal-component-free reagents, and optimizing processes and raising titers.



Available Testing Services:

- Efficacy/challenge studies
- Adjuvant assessment
- Virus/cell substrate biosafety testing and characterization
- *In vivo* potency assays and vaccine safety
- Immunogenicity and immunopotency assays
- Tumorogenicity/oncogenicity testing
- Dose-ranging studies
- Stability studies
- Anti-sera/polyclonal antibody production

Vaccine Product Development

Our R&D groups assist clients with their vaccine development programs. Two key program components are pilot manufacturing of new formulations and efficacy testing, which includes *in vivo* disease models for challenge studies, *in vivo* rodent research models, adjuvant selection studies, and stability assessment of product formulations.

Testing

Characterization and safety testing of vaccines is an essential part of the safety concept for cell-derived biopharmaceutical products. The master viral seed (MVS) and master cell bank (MCB) used in the manufacture of a vaccine must be extensively characterized, and their biosafety, as well as the safety of raw materials and components, must be demonstrated. Some tests included in this characterization include *in vivo* adventitious agent testing, pyrogenicity/endotoxin testing, and microbial contamination evaluation. Following fill and finish, the vaccine must also go through the same rigorous tests to demonstrate purity and safety.

Integrated Drug Development

Charles River's manufacturing capabilities complement a host of other global services offered to clients who are developing vaccines. We provide SPF eggs for formulation development and master/working seed stock preparation. Preclinical safety assessment offerings include *in vivo* toxicology testing and GLP drug safety studies. Animal health services and endotoxin testing are also available. Additional services include animal model selection, new assay development and validation, method development, technical transfers for assay development, and *ex vivo* and *in vitro* ELISA assay method development and validation.

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