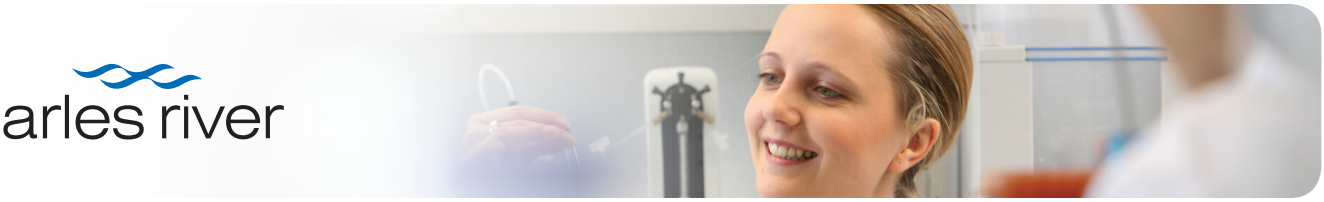
charles river



Vaccine and Virus Manufacturing and Testing

Charles River Biologics Testing Solutions can help you expedite your vaccine development program by providing you with manufacturing for early-phase clinical trials through to lot release (potency assays) for commercial products. We have extensive experience manufacturing vaccines in both cell culture and specific pathogen-free (SPF) egg-based systems. 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 provide immunogenicity and adjuvant assessment, as well as the complete microbiology and in vivo services necessary for vaccine efficacy testing.

Our scientific and regulatory experience allows us to predict and eliminate potential pitfalls early in development while ensuring compliance with all applicable, international regulatory standards.

Manufacturing

We offer more than 20 years of experience and expertise in manufacturing viral vaccines. From virus and viral seed banking to early phase clinical-scale vaccine manufacturing, our cGMP-compliant manufacturing capabilities complement our testing services to provide you with a comprehensive portfolio of services for your product from a single, harmonized provider.

Services

- cGMP virus seed and cell banking
- Vaccine manufacturing via cell culture and SPF eggs
- Vaccines for clinical trials (manufacturing scale – up to 4,500 vials per batch)
- Pilot scale virus manufacturing
- Adaptation of production using animal component free reagents
- Ability to work with clients to optimize processes and raise titers

Examples of Viruses Manufactured

- Dengue virus
- Respiratory syncytial virus
- Influenza virus
- Parainfluenza virus
- Human metapneumovirus
- Rhinovirus

Integrated Services

- Formulation development
- SPF egg supply
- Preclinical safety assessment
- Product release testing
- Endotoxin testing
- Oncogenicity testing

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Vaccine Product Development

Our R&D groups provide the experience and expertise to assist clients with their vaccine development programs.

- Pilot manufacture of new formulations
- Efficacy Testing
  - *In vivo* disease models for challenge studies e.g., Candida
  - *In vivo* rodent research models e.g., oncology
  - Adjuvant selection studies
  - 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. Following fill and finish, the vaccine must also go through the same rigorous tests to demonstrate purity and safety. Our wide range of testing services includes:

- Efficacy/challenge studies
- Adjuvant assessment
- Viral seed, cell substrate, and vaccine testing and characterization
- *In vivo* potency assays and vaccine safety (lot release of developmental formulations, clinical and commercial final product)
- Immunogenicity and immunopotency assays
- *In vivo* biosafety testing
  - Adventitious agents (MAP/HAP/RAP/LCMV)
  - General safety/abnormal toxicity
- Pyrogenicity/endotoxin/monocyte activation test (MAT)
- Tumorigenicity/oncogenicity
- Testing of viral stocks
- Dose-ranging studies
- Stability studies
- Microbiology and identification services
- Anti-sera/polyclonal antibody production

Integrated Drug Development

The manufacturing capabilities of Charles River complement a host of other global services offered to clients who are developing vaccines. Charles River provides SPF eggs for formulation development, SPF egg supply for master seed stocks, preclinical safety assessment to include *in vivo* toxicology testing and drug safety GLP studies, animal health services and endotoxin testing to meet all your vaccine research needs. Additional services include:

- Animal model selection
- New assay development and validation
- Method development
- Technical transfers for assay development
- *Ex vivo* and *in vitro* ELISA assay method development and validation

Regulatory Consulting

Our experienced regulatory and scientific consulting group is on hand to assist throughout the development process. The development path of discovery to market runs parallel to the manufacturing path of laboratory-scale to production-scale. Charles River's experience and resources can assist you on both fronts, providing the products and services needed to develop a successful vaccine.

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