



# Vaccine Manufacturing and Testing

Charles River Biopharmaceutical Services (BPS) can help you expedite your vaccine development program by providing you with manufacturing, quality safety testing, and regulatory guidance. Our vaccine experience includes both prophylactic and therapeutic vaccines. In addition we provide immunogenicity and adjuvant assessment, as well as complete microbiology services and *in vivo* services necessary for efficacy testing of a vaccine.

Charles River BPS provides current Good Manufacturing Practice (cGMP) compliant manufacturing and testing of viral vaccines for early-phase clinical trials and potency assays (lot release) of commercial product. We have extensive experience manufacturing vaccines in both cell culture and specific pathogenfree (SPF) egg-based systems. Biosafety testing is essential to ensure that cell lines used for vaccine production are free from bacterial, fungal, mycoplasma, and adventitious viral agent contamination. In addition, working with our SPF eggs to produce a vaccine, plus the safety testing necessary for production, provides platform flexibility. Our 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 clinical-scale vaccine manufacturing, our cGMP-compliant manufacturing capabilities complement our testing services to provide you with a comprehensive portfolio of services for your biopharmaceutical product from a single, harmonized source.

## Services

- cGMP virus seed and cell banking
- Vaccine manufacturing via cell culture and SPF eggs
- Vaccines for clinical trials (manufacturing scale – up to 7,500 vials per batch)
- Pilot scale virus manufacturing

## Integrated Services

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





## 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 must be demonstrated along with biosafety of raw materials and components. 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 include:

- Viral seed and cell bank characterization
- Microbiology services
- *In vivo* potency assays and vaccine safety (lot release of commercial products)
- Immunogenicity and immunopotency assays
- Adjuvant assessment
- Efficacy/challenge studies
- Biosafety and product release testing for clinical and commercial application
- Cell substrate/vaccine testing and characterization
- Testing of viral stocks
- Dose ranging studies
- Fill and finish
- Stability studies
- Tumorigenicity
- Discovery & development
- Pyrogenicity/endotoxin/Monocyte activation test (MAT)

## 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, early phase clinical trials, 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 vaccine-related products and services needed to develop a successful vaccine.