Overview

BioMARC is a not-for-profit biologics Contract Development & Manufacturing Organization owned and operated by Colorado State University (CSU) serving biopharma companies and government agencies. We specialize in high containment: Biosafety Level 2 and 3, CDC Tier 1 select agents, and spore-forming microorganisms.

We apply a deep understanding of the cGMP production requirements to projects ranging from the pre-clinical stage up through human clinical trials. Regulatory and scientific risks are identified and mitigated at each step in the process. Cost-effective development and manufacturing strategies are used to create custom service packages to efficiently move products forward in a timely manner.

Services include technology transfer and product development / manufacturing. Projects are conducted in FDA- and CDC-inspected state-of-the-art facilities. Team members are personally invested in project success.

Expertise

Process and Product Development
- New Technology Implementation
- Design of Experiment
- Mammalian Cell Culture
  - Adherent
  - Non-Adherent
- Bacterial Cell Culture
  - Aerobic
  - Anaerobic
- Vaccine Production
  - Whole Virus
  - Recombinant Virus Platforms
  - Polysaccharide
- Downstream Processing
  - Purification (Chromatography)
  - Filtration (UF/DF, TFF)

CGMP Production
- Cell Banking and Viral Seed Stocks
- Vaccine Production
- Diagnostic Reagent Production

Project Management
- Proactive Collaboration
- Project Reporting
- Transparent Communication

Analytical Method Lifecycle Support
- Method Development
- Method Verification/Qualification/Validation

Robust Quality Oversight
- FDA, WHO, ICH guidelines

High Containment

Biological Agents Handling
- Biosafety / EHS
- BSL-2/3 Production Suites
- Tier 1 Select Agent CDC Registered
- Contamination Control Master Plan

Services

- Technology Transfer
- Process Development and Optimization
- Process Scale-Up
- Cell Expansion
  - Stem Cell Therapy
  - Master/Working Stocks and Banking; Cell, Bacteria, and Virus
- cGMP Bulk Drug Substance Manufacturing
- cGMP Finished Drug Product
  - Aseptic / Viral Fill Finish
- Quality Control Support
  - In-Process / Release testing
  - Stability Monitoring and Storage

Example Projects

BioMARC serves clients at all stages in the development spectrum: Preclinical® Clinical® Commercial
- Vaccines
  - HIV
  - Eastern, Western, and Venezuelan Equine Encephalitis Virus
  - West Nile Virus
  - Pediatric Diarrhea
- Therapeutics
  - C. botulinum Toxin
  - Bacterial Cancer Therapeutic
- Diagnostic reagents
  - Chikungunya, Zika, West Nile, Dengue (1-4)
  - Yellow Fever Test Kit
  - M. tuberculosis
Phase-Appropriate cGMP Application

Specific regulatory framework is applied at each stage of development, ensuring regulatory compliance and reasonable cost.

![The GMP Continuum: a Risk-Based Approach for Development Projects](image)