

Biologics Contract Development & Manufacturing

BioMARC Data sheet

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*

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BioMARC Biopharmaceutical Manufacturing & Academic Resource Center

Phase-Appropriate cGMP Application

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

