

BIOPHARMACEUTICAL MANUFACTURING AND ACADEMIC RESOURCE CENTER (BIOMARC) at CSU

High Containment BioManufacturing (HCBM) and Contract Manufacturing Organization (CMO) Capabilities

EXECUTIVE SUMMARY

BioMARC, as a **not-for profit service entity at Colorado State University (CSU)**, specializes in the production of biologic products that require **high containment facilities**, including **Biosafety Level 3 (BSL-3)**, **CDC tier 1 select agents**, as well as spore forming microorganisms. BioMARC has been working as a CMO since 2006, with contract experience for commercial manufacturing dating from 2009 that includes **FDA and CDC inspections**.

BioMARC was created to fill an **industrial need** of high containment biologics manufacturing. BioMARC is **one of only three HCBM CMOs in the U.S.** Combined, these HCBM CMOs represent **significant infrastructure and capabilities in the US** for the prevention and response to emerging infectious diseases.

BioMARC has experience in developing and optimizing product manufacturing processes (upstream and downstream) and related in-process and release test methods for **biological therapeutics, vaccines, and diagnostic products**. To-date, BioMARC has brought a diagnostic parenteral product through clinical trial and commercial production, manufactured a virus vaccine for a phase I clinical study, established several master and working cell banks, developed and qualified cell based and analytical assays for product testing and release, and established a controlled process for manufacturing a therapeutic product for preclinical studies in non-human primates bridging to a phase I study in humans.

What makes BioMARC unique is our **state-of-the-art BSL-3 cGMP facility**, our internally managed quality system and quality assurance group, our industry focus and our ability to leverage the extensive expertise in high containment practices and infectious disease techniques while maintaining a **highly qualified full-time professional staff**, who focus 100% of their time to running the clinical and commercial manufacturing operations of BioMARC.



BioMARC’s development and manufacturing facility (**See Figure 1**) located at the Infectious Disease Research Center (IDRC) and are inside of the Rocky Mountain Regional Biocontainment Laboratory (RMRBL) at Colorado State University’s Foothills Campus at 3185 Rampart Rd, Fort Collins, CO 80521 USA. The facility is located within the secure confines of the IDRC across the street to the offices and laboratories of the US CDC.

In total, BioMARC manages **approximately 9,000 sq. ft. of controlled manufacturing space** that comprises a variety of classified and non-classified controlled spaces. The BioMARC facilities include BSL-2 and BSL-3 suites, Quality Control laboratory and support areas, along with document storage and office space.

BioMARC’s high containment **biologics operations handle highly infectious and/or potent bioterror agents** through a controlled manufacturing system through the use of BSL-3 infrastructure with a capability for closed system processing. For each biological agent introduced, significant product reviews are performed to **ensure safety of BioMARC staff and the community**. BioMARC complies with all applicable laws with respect to the environment, occupational health and safety, public health, and waste disposal, and holds all current and applicable governmental licenses, approvals, permits and authorizations.