

Biocontainment/Biosafety

“It is a mindset ... It is a process and the process is the product.”

Can you introduce a new BSL1 class microbe in your GLSP facility?

Can you accommodate the scale-up from BSL2 to BSL2-LS as needs change quickly?

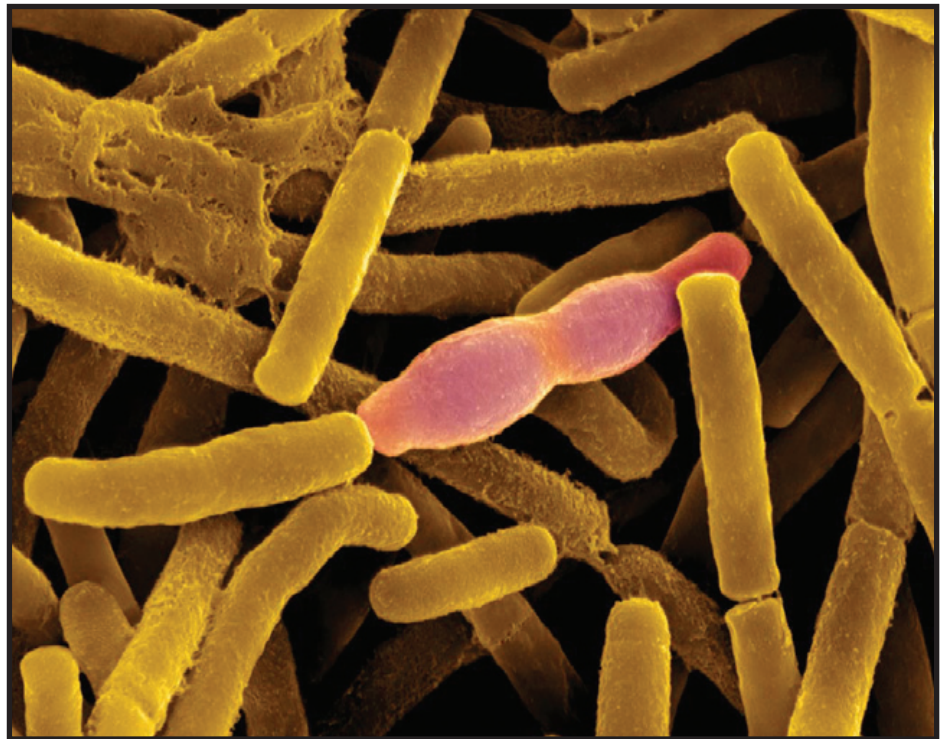
Is your fermentor designed with the proper safeguards for biocontainment?

Is your autoclave designed for decontamination of BSL3 microbes?

You already face enough challenges bringing new products to a global market. Concerns over biosafety should not be left to chance. Clark, Richardson and Biskup Consulting Engineers (CRB) has a proven track record in biosafety and biocontainment design with over 25 years' experience in the life sciences industry, particularly pharmaceutical and biotech research and production facilities. Our experience has included BSL3-LS and BSL3-AG research and production facilities totaling over 1.9 million square feet.

The right solutions include systems that are simple to operate and maintain, regulatory-compliant, with flexibility and adaptability to meet your current and future needs. We are engineers and

communicators who have grown up in the biotech industry. We listen to your needs... understand your requirements... then strive to deliver solutions that meet your expectations.



BIOCONTAINMENT/BIOSAFETY PLANNING AND DESIGN

Process and Facility Integration

Whether renovating an existing facility or constructing a new one, CRB brings the knowledge and experience of working with over 35 universities and private companies in the biologics research and manufacturing sectors to efficiently integrate process and facility into an effective manufacturing unit. A well-conceived biocontainment philosophy is an integral component of our projects. Product protection, environmental protection, and personnel safety are integrated into every solution.

Regulatory Guidelines

Adherence to the appropriate industry and global guidelines is dependent on the process and scale of operation and is considered for research laboratories and small- and large-scale biologics manufacturing facilities. CRB has developed several project tools and methods to assure compliance with NIH/CDC standards of biocontainment for small and large projects. Your project may also include compliance requirements such as cGMP and/or GLP. CRB is well-versed and experienced in regulatory presentation assistance.

Mechanical/HVAC/Security Systems

A sound biocontainment philosophy includes all aspects of facility design including core mechanical systems. CRB's engineering philosophy places the process foremost into the design approach to assure that building systems meet research and production goals. Developing segregation and containment philosophy in conjunction with effective cleaning/sterilization systems is critical. Security is also a critical consideration for biocontainment facilities. CRB's experience includes biometric scanners, card access systems, camera monitoring, security portal vestibules, and vehicular building barriers.

Biowaste Deactivation System Design

Is biowaste inactivation a bottleneck in your facility? Is batch or continuous deactivation right for your process? Is a chemical or thermal deactivation method appropriate? These are typical issues confronting governmental/institutional agencies, as well as small and large biotech companies. With increased interest in vaccines and new expression systems, an appropriate biowaste system is essential for success. CRB has a wide range of experience in biowaste inactivation systems design and can provide a solution for your operation whether bench-scale or large-scale.

Production Planning

CRB approaches every project with the client's production goals in mind. CRB's commitment to a sound biocontainment philosophy includes the impact of biosafety on current and future facility needs and expectations. Whether through process modeling or biosafety audits, CRB's skilled technical professionals can serve you better.

