Bora Biologics

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Making Success More Certain

Fully integrated CMC solutions expedite total development and manufacturing timelines with uncompromising quality

CDMO: Biologics CMC Pioneer Meeting Global Quality Standards

Full-Range Capabilities from DNA to IND Enabling Package

Full Control over In-House Drug Development Process

Direct control over most demanding steps of the manufacturing process gives **Bora Bio** exceptional quality control

Expedited Timelines and Full Resource Dedication

Comprehensive CMC Expertise to meet timelines: 10-12 months CLD to GMP

Phased and Risk-Based Regulatory Approval Strategy

Innovative global clinical trials strategy creates fastest path to market

Entirely Integrated Biologics Platform

As a top CDMO, Bora's platform approach allows us to perform activities needed to transform biologics from concept to therapeutic

State-of-the-Art Manufacturing Facility

Top-notch manufacturing site with solid track record and expansion potential

Development Expertise and Capabilities

International expertise and know-how especially on Cell Line Process, Analytical, and Formulation Development

Focus on Customer Satisfaction

Close collaboration with clients enabling flexible offerings and efficient service delivery

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Bora Bio's Facility : cGMP and PIC/S Manufacturing Plant

Bora Biologics has built a leading-edge company, boasting a cGMP-certified facility passing **many EU QP and client audits** with development and manufacturing capabilities for complex proteins.

Flexible Single-use Manufacturing Technologies

Our facility employs state-of-the-art single use mammalian cell culture technologies in upstream and downstream process development mirrored in design with our cGMP manufacturing for consistent and robust tech transfer and scale-up. From cell line development through cGMP production along with associated analytical development and validation, Bora delivers high-yield, high-quality processes for our client programs – even with the most challenging molecules.

Analytical Expertise

Bora Biologics provides expertise in phase-appropriate, extensive physico-chemical and functional assay (particularly Bioassays) packages to support cell line, formulation or process development, comparability studies, reference material qualifications and full analytical characterization.

Cell Engineering

Developing therapeutic proteins requires precise methods, strategies, and techniques to overcome the variability of biological systems and yield a reproducible platform. At Bora Biologics, we have designed a robust proprietary cell line platform to engineer and screen thousands of high-expressing clones to identify the top performer followed by efficient process development and manufacturing operations to generate clinical trial material for our clients.

Experienced Across Multiple Protein Classes

- Monoclonal Antibodies
- Fc Fusion Proteins
- Enzymes and other Recombinant Proteins
- Bi-Specifics and Tri-Specifics
- mAbs used in ADC construction
- Protein Conjugates

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