



BioPartnering Solutions

// **Your Protein Therapeutic Candidate**

// **Our Industry-leading
Biotech Process Development
& Manufacturing**

Together,

let's bring your monoclonal antibodies
and protein therapeutics from the
discovery bench to patients on a
global scale.



Biotech@Bayer

Bringing difficult to make products to patients

Bayer has been developing and manufacturing biopharmaceuticals for more than 30 years. In fact, we developed and manufacture recombinant protein molecules that are among the most complex on the market. Our CMC strategy and cGMP facilities have met the rigorous regulatory expectations in more than 50 global markets, including major health authorities in the U.S., Europe and Asia.

We're an innovator in biologics manufacturing. Bayer was among the first to develop production techniques leveraging single-use technologies, helping establish what is now an industry standard. We continue to innovate our protein therapeutic manufacturing processes and apply our deep process engineering know-how to the design of new production platforms for new modalities. When you work with Bayer, you're working with a company focused on continuous improvement and innovation.

At Biotech@Bayer, we know what it takes to bring protein therapeutic products to patients with accelerated development concepts that build in quality-by-design at every step. We are a global organization with a proven record of winning collaborations and internal programs that progress through development and manufacturing across different sites, and we bring strong technology-transfer expertise to your product candidate. In addition to our protein therapeutics development labs, we have preclinical, clinical and commercial launch scale manufacturing capacities up to 2000L. In fact, our latest facility – the Cell Culture Technology Center – is fully qualified, and we have fill/finish operations on-site to complete production of your product.

We're ready to help you develop and launch your protein therapeutic.



Biotech@Bayer

Expertise you can trust.

We develop your product candidate as if it was part of our own pipeline. That means high touch, high engagement with you and your product in a way other contract development/manufacturing organizations just can't match.

Your product will be developed using advanced manufacturing platforms by a team that knows how to de-risk the process.

Through our **BioPartnering Solutions**, we provide you with a single source of IND- and BLA-enabling development; bioprocess and biochemical engineering; clinical and commercial manufacturing. You have access to a range of complementing support service functions such as supply chain management, procurement, quality, and CMC strategy support for your regulatory filings.



“Our team is passionate for patients. With this as our driving force, you can be assured that we’ll bring the same passion and commitment we have for our pipeline to your product candidate. Let’s make a difference together.”



- Jens Vogel
Sr. Vice President, Biotech



Where science gets big.

We're ready to help you advance to the next level.

Bayer offers flexible, modular facilities to take protein therapy product candidates from development and clinical study volumes and industrialize these with platforms to consistently serve launch and commercial market needs. Let us help you take your product to patients around the globe.

Early-Stage Options:

- Tech Transfer of developed process & analytics or Process & analytics development
- Production to Support Tox & GMP Ph 1 Clinical Studies
- Options for Analytics, Drug Product, Quality Assurance, Project Management, Regulatory Support

Late-Stage Options:

- Tech Transfer of developed process & analytics or Process & analytics development for Ph 2/3
- Production to Support Late-Stage Clinical Programs
- Process Characterization
- Process Validation & Filing Support
- Commercial Submission and Launch



Biotech@Bayer

At Bayer, we have room to support your growth.

We can help you avoid tech transfer time, costs and the risk of delay that may arise from moving your project from a contract development organization (CDO) to a contract manufacturing organization (CMO) for clinical supply and to another CMO for commercial supply.

Our primary biotech operations are in one of the world's leading biotechnology hubs: California's San Francisco Bay Area. In Berkeley, we have a 46-acre biotech innovation campus with a master plan that can support nearly 1 million additional square feet of **development laboratories, manufacturing suites, and supporting teams**, including warehousing, supply chain management, and quality.

Expertise you can trust – the roughly 1,000 biotech employees in Berkeley bring a wealth of expertise and industry experience to your product candidate. And, we can tap into additional biotech professionals, development labs and manufacturing capacities at our sites in Germany as needed to support your needs.

Experience

 15+ Average Years Industry Experience

 11 Years Average Bayer Tenure



Why partner with Bayer

for your protein therapeutic development and manufacturing?

Our focus is a clear path to rapidly commercialize your product. Our teams are skilled in a variety of technology platforms that can be used in the protein therapy manufacturing process. Our years of experience enable us to provide you with insight on best practices and scale-up to not only improve safety, but also decrease cost of goods.

CAPABILITIES

- Manufacturing Science and Technology (MSAT)
- Quality management systems (early phase through commercial)
- Quality control/release testing
- CMC strategy
- Clinical operations and logistics
- Assay development
- Validation and qualification
- Process and platform development

EQUIPMENT

Comprehensive small to large scale equipment including:

- Automated Cell line Development ClonePix
- Ambr15, Ambr 250, 2-200 L fed-batch bioreactors, 15 L perfusion bioreactors
- MCB/WCB banking, 200-2000 L single use bioreactors for clinical manufacturing
- Purification scale filtration and chromatography skid matching cell culture
- Clinical and commercial drug product filler

FACILITIES

- Biosafety Level 1 development labs
- Clinical manufacturing Center
- Protein Drug substance clinical, launch and commercial facility
- Protein Drug product fill clinical, launch and commercial facility

TECHNOLOGY

- Monoclonal antibody platform
- Automated cell line development suite
- Genetic characterization for MCB, WCB
- Cell culture development at various scale (fed-batch and perfusion, process intensification)
- Purification development at various scale (HTPD, conventional, membrane adsorber, continuous, and fibro chromatography)
- Viral clearance
- Robust analytics for complex and extended protein characterization (identity, purity, safety, efficacy, potency, impurity, compendial, and raw material ID testings)
- Formulation and drug product fill process development (liquid, lyophilized), delivery device development

As your trusted provider of development and manufacturing services, Bayer's BioPartnering Solutions team will manage any (or all) aspects of your product development lifecycle and associated supply chain. We can integrate supply chains, coordinate scheduling across multiple parties, and provide temperature and/or controlled storage before, during and after shipping with various providers.





BioPartnering Solutions

Offering flexible models to fit your needs

We know that one size does not fit all when it comes to partnering. Each partner has a unique product and a different set of needs based on the stage of the product candidate, timelines, and your inhouse capabilities. Because we are a large, integrated biopharmaceutical company, we can meet you where you are at with flexible service models that grow with you as your product advances. Whether its fee for service today or another model to fit your current financial situation, let's find a way to work together to meet the needs of patients.

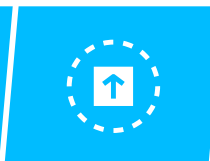
PRODUCT / PROCESS DEVELOPMENT



IND Enabling CMC Development & Characterization



Preclinical Study Supply



Tech Transfer & Scale Up

cGMP MANUFACTURING



Early Phase GMP Clinical Supply



BLA Enabling CMC Development & Characterization



Late Stage GMP Clinical Supply



Processes Validation including PPQ



Commercial Launch & Market Supply



YOU DECIDE

Identify where along the process you'd like Bayer's support in developing and manufacturing your product

DEVELOPMENT SUPPORT



- Raw Material Characterization
- Stability & Ref Std. Generation
- Cell Bank Characterization
- Potency Assay
- Quality by Design (QbD)

COMPREHENSIVE SUPPORT



- Supply / Chain Management
- Fill / Finish
- Packaging / Logistics
- Distribution
- CMC Strategy for Regulatory Filings
- Quality & Compliance
- Product Characterization





Work with one of the most trusted brands in the life sciences.

The Bayer Cross is one of the best-known trademarks in the world. For generations, Bayer has stood for competence, quality and trust. In 2021 Bayer was named among the world's:

“Top Brands” ranking in fourth place, in the pharmaceutical industry according to the *“Global 500 – Annual Report on the Most Valuable and Strongest Global Brands”* by the London-based rating agency *Brand Finance*.

“Most Admired Companies” by U.S. business magazine *Fortune*, ranking fifth among all chemical companies worldwide in terms of its image. The Group enjoys a strong reputation in the industry, in particular in the areas of innovation, global competitiveness, social responsibility and people management.

The company ranked 227 on **Fortune’s Global 500 in 2021**. Bayer is not only one of Germany’s largest corporations, it also is among the 60 largest companies in the U.S. based on sales revenues as compared to the Forbes top 100 U.S. companies. The company was named by *Forbes* as one of **“America’s Best Employers”** in 2021 for the fourth consecutive year.

In 2021, according to the *San Francisco Business Times*, Bayer was ranked as the fourth largest Biopharma company, among the **Top 10 “Best Places to Work”** (among employers with 1000+ employees), and one of the largest manufacturer across industry sectors in the Bay Area. For the fifth consecutive year, Bayer U.S. has obtained a perfect score of 100 on the Human Rights Campaign Foundation’s 2022 Corporate Equality Index (CEI).

Contact us

To find out more about how we can help you bring your therapeutic candidate to clinical study and market scale, contact us at:

biotech@bayer.com

