



BioPartnering Solutions

- // **Your Cell Therapy Candidate**
- // **Our Industry-leading Biotech
Process Development &
Manufacturing Capacities**

Together,

let's take cell therapy treatments 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. Our expertise includes the development of innovative manufacturing platforms to bring products to the clinic and commercial market across a variety of modalities, including cell therapies. We were among the first to develop production techniques leveraging single-use technologies, helping establish what is now an industry standard in biotechnology.

We know what it takes to bring products to patients with accelerated development concepts that build in quality-by-design at every step and CMC strategies that meet the expectations of health authorities around the world. We have a proven track record of creating winning collaborations through our strong experience in alliance management.

Bayer is investing significantly in new infrastructure including new cell therapy development laboratories recently opened and our first cell therapy launch facility opening in 2023 (late-stage clinical and commercial manufacturing capacity). Our team includes biotech professionals with in-depth experience in CAR-T and iPSC characterization, process development and manufacturing. We have analytical experts for cell-based assays like next generation sequencing (NGS), flow cytometry and state of the art PCR techniques that will help you defining the right assays for your needs.

We're ready to help you develop and launch your cell therapy product.



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.



**We're joining forces
with early-stage R&D
partners to bring
new therapies to life.**

"Our Biotech@Bayer team is passionate about purpose of 'Science for a Better Life.' We believe that ensuring patients have access to new cell therapies depends on designing the process for scaling up production for clinical studies and then successfully transferring this process into reliable commercial manufacturing. It's what we do and we're looking forward to helping cell therapy innovators transform the medical care with potentially curative medicines."



- Jens Vogel
Sr. Vice President, Biotech



Biotech@Bayer

Where science gets big.

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

Bayer offers flexible, modular facilities to take cell 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.

We can support cell culture and viral transduction of autologous and allogeneic cell types and starting materials including:

- **Immune cell populations** (i.e. T-cells, NKs, TRegs, etc.)
- **Stem cells** (i.e. MSCs, HSCs, etc.)
- **Other cell types as needed**



Automation is essential throughout the development and manufacturing process. We use the latest technologies from high throughput screening equipment to automated manipulators for large scale adherent cell culture.



At Bayer, we have room to support your growth.

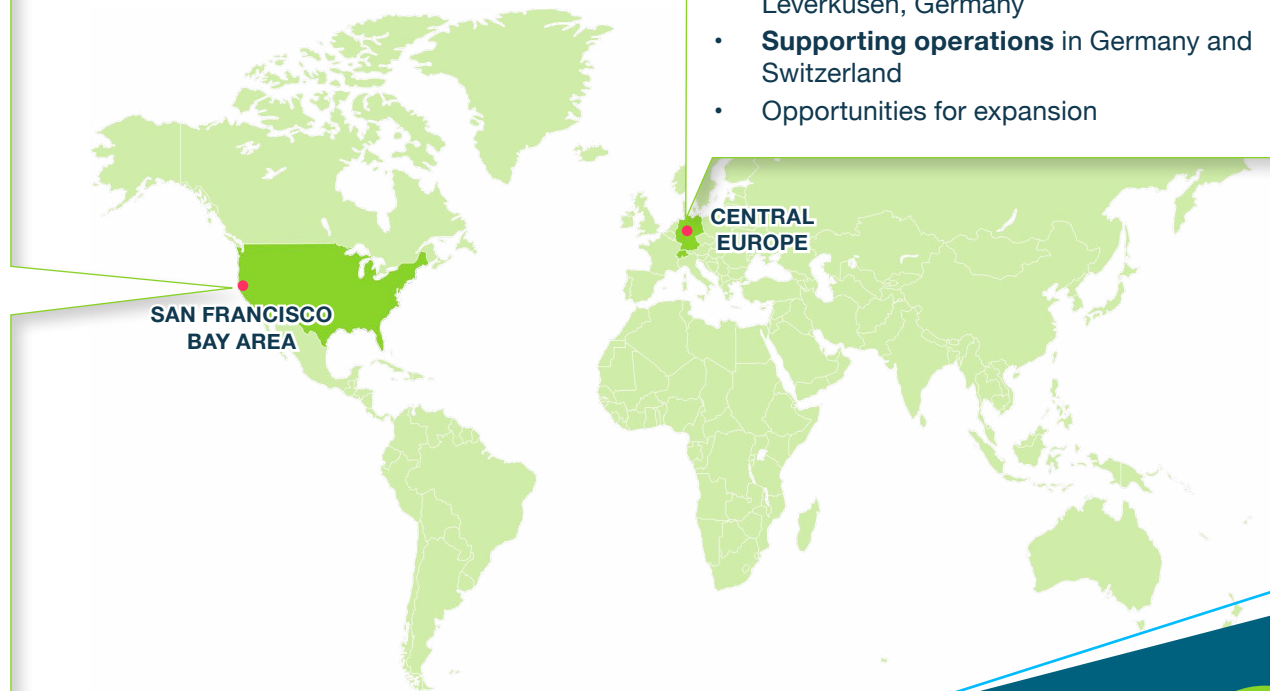
We can help you avoid tech transfer time, costs and the risk of delay that may arise from moving your project from a contract development organization (CDO) to a contract manufacturing organization (CMO) for clinical supply and to another CMO for commercial supply.



Berkeley, CA in San Francisco's Life Sciences Community

Our primary biotech operations are in one of the world's leading biotechnology hubs: California's San Francisco Bay Area. There, we have a 46-acre biotech innovation campus with more than 1,000 dedicated professionals. The campus includes:

- A new **cell therapy development lab**
- A **Cell Therapy Launch Facility** for clinical and commercial manufacturing, which will be operational in 2023
- Expansion space for nearly 1 million additional square feet of **laboratories, manufacturing suites, and supporting teams**, including warehousing, supply chain management, and quality



European Biotech Operations

We have centrally located services to support cell therapy innovators in Europe. These include:

- **Cell therapy development lab** in Wuppertal Germany
- **Bioengineering center** of expertise in Leverkusen, Germany
- **Supporting operations** in Germany and Switzerland
- Opportunities for expansion

Why partner with Bayer

for your cell therapy 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 cell 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

TECHNOLOGY

- Suspension cell culture
- Adherent cell culture
- Automated cell processing
- Viral & nonviral transduction
- Closed end-to-end process automation
- Robust analytics for cellular phenotype identity, purity, safety, efficacy and potency characterization

FACILITIES

- Biosafety Level 2 development (7,000 sq. ft.)
- Flexible clinical manufacturing space (35,000 sq. ft.)
- Class C-F (ISO 7+) GMP cleanrooms with Class A (ISO 5)

EQUIPMENT

Comprehensive small to large scale equipment including:

- 0.3-50 L suspension bioreactors for cell culture & viral vector development
- 200-2000 L single-use bioreactors for GMP manufacturing
- Shake flasks to cell factories with robotic cell manipulator for adherent cell culture
- Manual to full-automated cell processing systems (e.g. Sepax, Sefia, Prodigy, etc.)
- Manual to semi-automated bag and vial fillers
- Liquid N2 controlled rate and cryostorage freezers
- Analytical technologies

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.

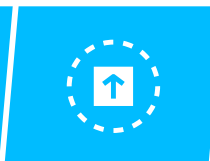
PRODUCT / PROCESS DEVELOPMENT



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

