

Turn to the world's leading biopharmaceutical consulting company to maximize success, reduce time to market, and increase company value.

Strategic, Technical,
Regulatory, and Business
Biopharmaceutical Consulting

>From clone to commercial[®]



> BioProcess
Technology
Consultants[®]

www.bioprocessconsultants.com



> Give your products, technologies, and business a competitive advantage.



BioProcess Technology Consultants is the world leader in providing strategic, technical, regulatory and business consulting services to the biopharmaceutical industry. We can help ensure your success in all CMC (Chemistry, Manufacturing, and Control) related activities. Our services can shorten your time to market and enhance your company's value as you navigate the hurdles along the path *from clone to commercial*.[®]

PROVEN WORTH

Our proven track record in product development, process optimization, scale-up, cGMP manufacturing, and commercialization makes us the leading international technical and strategic biopharmaceutical consulting group.

Since 1994, we have served hundreds of companies globally, from start-ups through multinational giants. Whatever your company's size, product portfolio, or stage of development, BioProcess Technology Consultants can give you the targeted analysis, solid strategies, and desired results you require.

Our fully integrated discovery, product development, CMC (Chemistry, Manufacturing, and Controls) and business services allow us to provide you with solutions that promote the success of your business and strength of your products in the marketplace.

We can provide you with powerful decision-making tools, such as guidelines for product development, cost analysis, and technical risk assessments to support development and commercial decisions.

BROAD EXPERIENCE

Companies save substantial time and expense by turning to leaders who understand their issues. We have the necessary expertise to provide services ranging from technical input on specific issues to oversight and management of entire CMC and manufacturing development programs. We will help you advance your product from preclinical process development through clinical and commercial manufacturing, providing guidance and management from bulk drug production to packaging, labeling, and distribution. We plan, manage, review, and author CMC information for regulatory filings. We have supported development and commercial submissions in US, Canada and Europe.

Our services span every aspect of product development, manufacturing, regulatory, and strategic business decisions for biopharmaceuticals.

Our expertise covers a wide range of technologies and products, including:

- Monoclonal and polyclonal antibodies
- Fc-Fusion proteins
- Recombinant proteins
- Natural and synthetic peptides
- Oligonucleotides
- Viral vector and plasmid DNA products for gene therapy and other applications
- Cell therapy
- Toxin-antibody and similar drug-carrier conjugates
- Natural products
- Vaccines
- Combination products, especially those incorporating biologics in medical devices
- Diagnostics
- Biosimilars



PROCESS AND PRODUCT DEVELOPMENT

We can help you proceed from early discovery to commercialization faster, at less expense and risk. Whether your product is in preclinical development, clinical trials, or on the market, we can help increase its value by finding ways to improve yields, increase process robustness, reduce costs, and reduce processing times.



DUE DILIGENCE AND TECHNOLOGY/MARKET ANALYSIS

Allow us to assess your Technology, Product and/or Market for due diligence, product licensing, or mergers and acquisitions. Our experts can evaluate the utility and marketability of new or existing technologies, and evaluate products for in-licensing or acquisition. We can conduct interviews, perform market surveys, and determine market need and perception of your new products or services.



QUALITY AND REGULATORY

Get valuable guidance and support for all aspects of global quality, regulatory and cGMP compliance. Our expert consultants can solve your most complex quality and regulatory challenges as well as provide assistance in establishing quality systems and performing vendor and facility compliance audits.



OUTSOURCING AND SUPPLY CHAIN MANAGEMENT

We'll help you decide between a large capital investment in manufacturing facilities and infrastructure, or outsourcing through "Make versus Buy" analysis. We can provide comprehensive CMC supply chain and outsourcing services, including the identification, qualification, management and integration of appropriate service providers. We also have extensive experience in the design, construction, validation and acquisition of cGMP manufacturing facilities.



MANUFACTURING OPERATIONS AND SUPPORT

We can support manufacturing operations starting with production of preclinical batches for animal studies to the manufacture of clinical and conformance batches in support of human clinical trials, and finally commercial batches for market supply. We can manage technology transfer, serve as the person in the plant, generate and review batch records, and contribute to investigations and troubleshooting.



BUSINESS STRATEGY AND OPERATIONAL EXCELLENCE

We can help you define and capture business opportunities while identifying and responding to market threats, both near and long term. We can help you through the challenge of developing consistent CMC and project management approaches as your organization grows more complex.



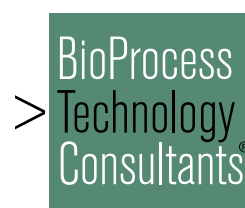
SUPPLY AND DEMAND DATABASES

We maintain proprietary databases covering the Supply and Demand for biopharmaceutical manufacturing capacity. The Demand Database covers nearly 300 biopharmaceutical products currently in development or on the market. The Supply Database covers biologics manufacturing capacity at over 150 manufacturers, including Product Development Companies and Contract Manufacturing Organizations.



SPECIAL REPORTS

BioProcess Technology Consultants offers unique, actionable information resources for the biopharmaceutical industry. The insightful analysis in our reports is designed to help decision makers build and put to work comprehensive business and technical strategies for the complicated topics covered.



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Biopharmaceutical
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Prominent leaders in their fields, our consultants understand the strategic, technical and business pressures affecting your company. Benefit from the in-depth knowledge and creativity they have used to bring about the successful commercialization of many biologic products.



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who know and
understand your
science, markets,
and business.

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