GET TO KNOW BDO

BIOPROCESS TECHNOLOGY GROUP

Accelerating the biotherapeutic development process from clone to commercial®

BDO's BioProcess Technology Group (BPTG) provides an integrated approach to de-risking the technical and regulatory challenges in the development and commercialization of biopharmaceutical products.

OUR PEOPLE

BPTG is a team of committed, knowledgeable industry veterans. We have decades of extensive real-world industry and technical experience in the development, manufacture, quality control, quality assurance and regulatory support of all types of pharmaceutical products.

In the last six years, we have:

- Successfully completed over 1,000 consulting projects
- Worked with more than 300 companies internationally
- Assisted with over 100 global regulatory submissions
- Supported the commercialization of multiple products, ranging from monoclonal antibodies to cell and gene therapies

OUR CLIENTS

BPTG has supported a wide range of clients, including:

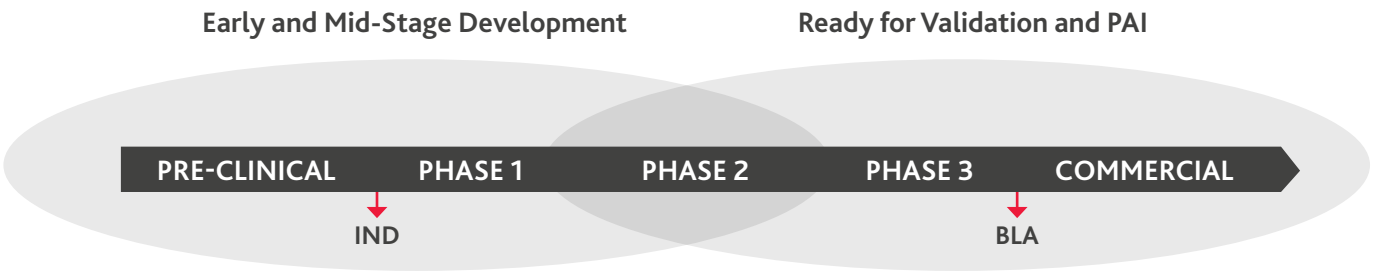
- Multi-national biopharmaceutical companies with major clients in the U.S., Europe and Asia
- Venture-backed, early-stage biotechnology companies
- Fully integrated pharmaceutical companies
- Cell and gene therapy companies
- CDMOs and CMOs
- Investors
- Service providers
- Suppliers
- Law, PE and VC firms
- …and more.

Our product experience includes:

- Recombinant Proteins
- Monoclonal Antibodies
- Biosimilars
- Antibody-Drug Conjugates
- Vaccines
- Cell and Gene Therapies
- Peptides
- Nucleic Acids
- mRNA
- Lipids
- AAV and Plasmid Development

Our Approach

PROFESSIONAL ADVICE AND GUIDANCE THROUGHOUT DEVELOPMENT



Process & Analytical Development	Cell Line Development	Phase-appropriate Process Development	Analytical Method Development and Validation	Validation Planning and Support
Quality & Regulatory Services	CMC Regulatory Strategy	Quality System Design and Management	Compliance Audits Risk Assessments	Preparation of Global Regulatory Submissions
Manufacturing Strategy & Operations	"Make vs. Buy" Supply Chain Options	Facility Conceptual Design/Validation	Identify and Manage Service Providers	Project Management and Communications

BUSINESS SERVICES TO SUPPORT STRATEGIC INITIATIVES

bioTRAK® DATABASE

Determine how much API manufacturing capacity is available

Understand who is investing in capacity

Gain insights into what product pipelines look like over time

Identify suppliers to meet complex product requirements

Support biopharmaceutical manufacturing market assessments

PROCESS MODELING

Estimate manufacturing costs

Evaluate economic impact of new technologies or process changes

Assess relative costs of manufacturing options

Make or Build vs. Buy decisions

DUE DILIGENCE

Support mergers and acquisitions

Critically review CMC status and probability of regulatory success

Define critical steps and activities for product advancement

Act as expert witness for patent protection

MARKET & TECHNOLOGY ANALYSIS

Identify market opportunities and client/customers needs

Competitive intelligence and market research

Evaluate technology trends and tools

Our Services

We understand the challenges of developing and commercializing new products and technologies and provide flexible and responsive consulting services, to support you through the complex technical and regulatory requirements and achieve your key development and business milestones.

MANUFACTURING STRATEGY AND OPERATIONS

Our Chemistry, Manufacturing and Controls (CMC) specialists will help you develop and implement manufacturing strategies throughout all stages of your product's lifecycle to support regulatory filings and material supply for:

- Global clinical trials
- Regulatory approval
- In-market supply

QUALITY AND REGULATORY SUPPORT

BPTG's quality services can help you address the quality, regulatory, and compliance needs of your product and organization at all stages of product development and commercialization.

- cGXP compliance assessments
- cGXP audits
- PAI readiness assessments and gap analysis
- GMP document review
- Quality Management systems implementation
- Acting head of Quality and Regulatory
- u Phase-appropriate regulatory strategy road maps
- Regulatory gap analysis and ad-hoc advice
- eCTD filings and amendments (pre-and post-approval)
- Regulatory Agency interactions

PROCESS MODELING

BPTG's process modeling services can help you evaluate manufacturing costs, compare manufacturing options, identify bottlenecks in your manufacturing processes, and improve your bottom-line performance.

PROCESS AND ANALYTICAL DEVELOPMENT

Our knowledgeable consultants leverage their extensive experience across product modalities to provide you with the expert technical input and expertise you need to establish and implement strategies for upstream and downstream process development, process optimization, development of analytical methods, and more in support of your product development. Our services help you accelerate product development and minimize the technical and regulatory risks of product development.

OPPORTUNITY ASSESSMENT

Our scientific and technical due diligence team provides in-depth review and objective analyses of products, technologies, or markets to help you identify potential hurdles or risks and inform your strategic and financial investment decisions.

RISK REMEDIATION

The industry is increasingly being subjected to regulatory audits by a variety of regulators. There may be serious outcomes arising from regulatory inspections that have to be resolved. We have deep experience to help you identify and resolve remediation issues, including:

- Support with resolution of FDA 483s
- Support with "For Cause" audits and FDA consent decrees
- Project management and execution of corrective action plans

bioTRAK® DATABASE

Whether you are assessing the market potential for your product or determining if there is enough manufacturing capacity to meet a certain type of biopharmaceutical product demand considering an investment, BPTG's proprietary bioTRAK® database can help.

People who know Life Sciences, know BDO's BioProcess Technology Group.

www.bdo.com/bptg

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