

GET TO KNOW BDO

Bioprocess Technology Group

Accelerating the biotherapeutic development process from candidate selection to commercial launch.

BDO's BioProcess Technology Group (BPTG)

provides an integrated approach to de-risking the technical, operational, and regulatory challenges throughout all stages of the development lifecycle for biologics and cell & gene therapies, from candidate selection through marketing authorization approval and beyond.

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 biologic and cell and gene therapy 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:

- ▶ Monoclonal Antibodies
- ▶ Recombinant Proteins
- ▶ Biosimilars
- ▶ Cell and Gene Therapies
- ▶ Antibody-Drug Conjugates
- ▶ mRNA
- ▶ Nucleic Acids
- ▶ Lipids
- ▶ Microbiome
- ▶ Vaccines
- ▶ Peptides
- ▶ Viral Vectors

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

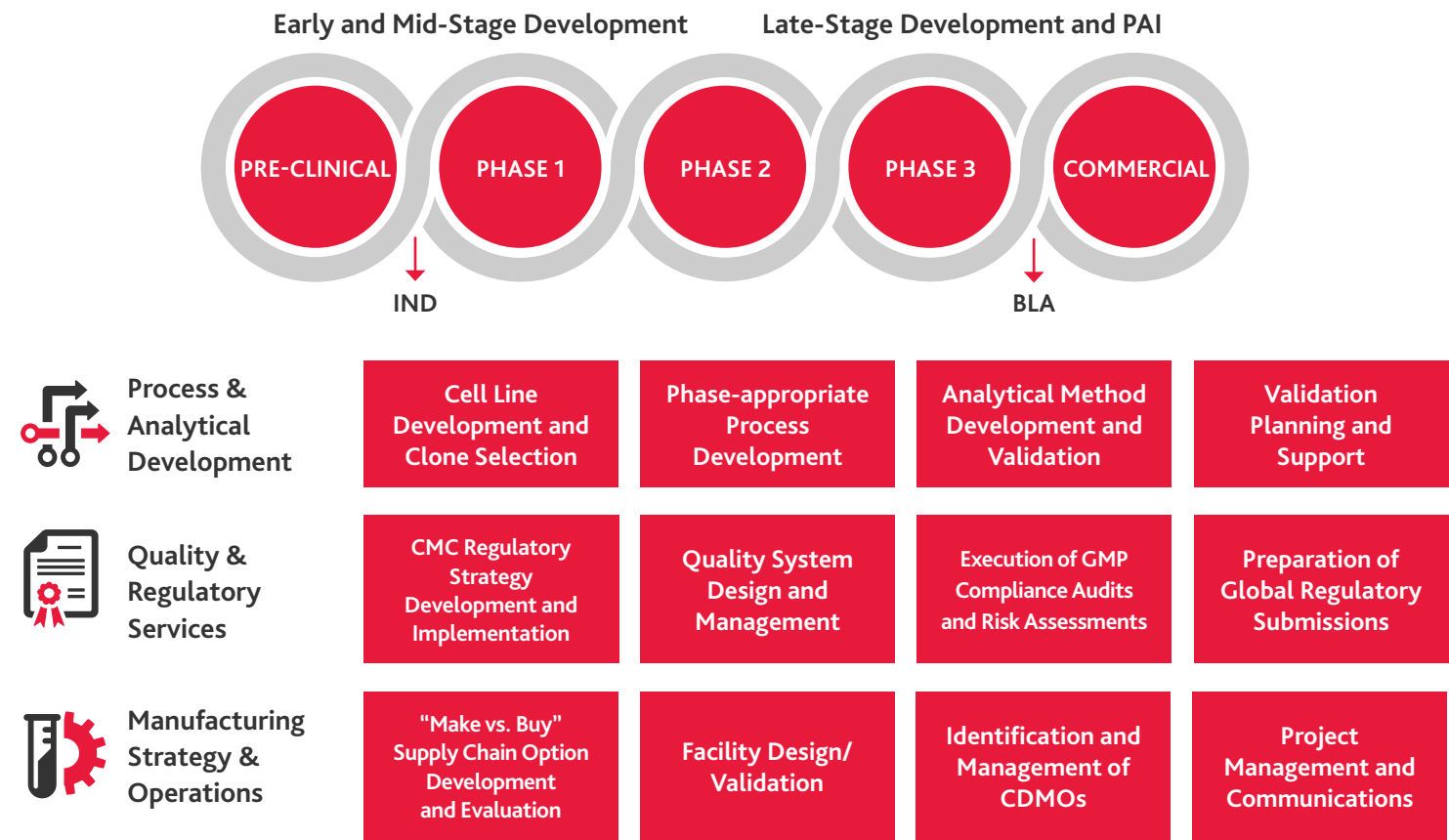
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Our Approach

FULL SPECTRUM CMC SUPPORT ACROSS THE DEVELOPMENT LIFECYCLE



BioTRAK® DATABASE

- Determine how much API manufacturing capacity is available
- Understand who is investing in capacity
- Gain insights into how biopharmaceutical pipelines evolve 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
- Facilitate make 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 based on clients' needs
- Compile and analyze competitive intelligence and market research
- Evaluate technology trends and tools