



21ST ANNUAL

Report and Survey of Biopharmaceutical Manufacturing Capacity and Production

*A Study of Biotherapeutic Developers and
Contract Manufacturing Organizations*



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April 2024



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Eric S. Langer, Publisher

ABOUT BIOPLAN ASSOCIATES, INC.

BioPlan Associates, Inc. is a biotechnology and life sciences market analysis, research, and publishing organization. We have managed biotechnology, biopharmaceutical, diagnostic, and life sciences research projects for companies of all sizes for over 30 years. Our extensive market analysis, research and management project experience covers biotechnology and biopharmaceutical manufacturing, vaccine and therapeutic development, contract research services, diagnostics, devices, biotechnology supply, physician office labs and hospital laboratory environments.

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METHODOLOGY

This report is the 21st in our annual evaluations of the state of the biopharmaceutical manufacturing (bioprocessing) industry. The strength of this study's methodology remains in its breadth of coverage, which yields a composite view from the respondents closest to the industry, its 21-year longevity, industry familiarity and high response rates. These permit a consistent approach which delivers reliable data and analysis.

Note, "biopharmaceutical" here refers to the classic biotechnology-grounded definition: involving manufacture of pharmaceuticals using biotechnology/bioprocessing. The term does not refer to the entire pharmaceutical industry or just those parts considered innovative, with "biopharmaceutical" now simply commonly substituted where "pharmaceutical" or "drug" were formerly used.

This year, BioPlan Associates, Inc. surveyed 220 qualified and responsible individuals at biopharmaceutical manufacturers and contract manufacturing organizations in 23 countries plus 179 industry vendors and direct suppliers of materials, services, and equipment to this industry segment. Using a web-based survey tool, we obtained and evaluated information including regarding respondents' current capacity, production, novel technology adoption, human resources, quality, and outsourcing issues. We also assessed respondents' projected reasons for bottlenecks, and their perception of how these bottlenecks might be resolved.

This year, we continue to include new questions and chapters, including Continuous Bioprocessing and Process Intensification (Chapter 11.) Over the past few years, advances in technologies, platforms, expression systems, and single-use applications have increasingly made the bioprocessing segment an area of interest for such innovation.

We continue to partner with worldwide media and membership organizations to ensure a high response rate, and the most accurate overview of the worldwide biopharmaceutical industry and its bioprocessing sector. Our industry partners are cited in our acknowledgments section. In addition, to supporting this coverage, we also acknowledge our media partners, whose assistance enables us to reach the many high-quality respondents required for this quantitative survey and analysis.

Further information on methodology, breakouts on specific segments, and data from earlier surveys, may be requested by contacting us at the address below.

Thank you for your participation and interest in this important research.

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CHAPTER 0: DEMOGRAPHICS

INTRODUCTION

This consulting report presents a comprehensive analysis based on survey responses from a diverse group of senior managers, executives, and scientists involved in biopharmaceutical development and manufacturing. These respondents represent a wide spectrum of roles within the industry, including those from Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs).

Now in its 21st year, this international project is conducted annually, gathering insights from professionals at organizations around the globe. This year's survey includes contributions from individuals in 23 countries, ensuring a truly global perspective.

In addition to the general survey results, Chapter 12 specifically focuses on responses from bioprocessing suppliers and vendors. As in previous years, the survey captures data from companies of various sizes and types worldwide. All respondents have a direct involvement in bioprocessing and manufacturing, providing a well-rounded view of the industry's current state and future trends.

The diversity of the respondents enriches the report, offering an inclusive view of the biopharmaceutical sector. The experienced professionals who participated are deeply involved in the management of biopharmaceutical manufacturing activities globally. The insights gathered from these surveys reflect both current perspectives within the industry and projections for its future trajectory.

The report further categorizes data by organization type, distinguishing between CMOs and biotherapeutic manufacturers/therapeutic developers. This classification allows for a detailed analysis of the unique challenges and opportunities within these two major segments of the industry. Topics such as business drivers, risk profiles, and costs of capital are thoroughly examined for each organization class, providing valuable insights for stakeholders.

By presenting this data, we aim to offer a detailed understanding of the biopharmaceutical industry's dynamics, informed by the expertise of those who are actively shaping its future.

0-1 RESPONDENTS' AREA OF INVOLVEMENT

For this year's 2024 survey, we asked respondents in which area of biopharmaceutical manufacturing is your organization currently involved.

Of the biopharmaceutical manufacturers and contract manufacturing organizations responding to this year's survey:

- 26.4% were primarily involved in *Large-scale cell culture production for therapeutics*, down slightly from 28.0% in 2023
- 19.1% were primarily involved in *Process development for biopharmaceutical manufacturing*, down from 26.1% in 2023

15.9% were in *Scale-up (or clinical-scale) production of biopharmaceuticals primary*, up from 12.6% in 2023 and higher than 13.5% in 2022

Respondents involved with *Large-scale contract manufacturing (CMO) for biopharmaceuticals* continue to vary each year, with 12.7% in 2024 survey, up from 10.6% in 2023, and still relatively consistent with prior years. *Fill/Finish operations* continue to ebb and flow with respondents, with 2.3% this year, slightly down 3.9% in 2023.

Vaccine production respondents had a small increase to 6.8%, from 5.8% in 2022, but still overall down from levels reported in the mid-2010s.

This year saw a big decrease with process development respondents, and an uptick with scale-up (clinical-scale) production respondents. *Vaccine production* and *large-scale microbial fermentation for therapeutic respondents* saw virtually no change from 2023.

For Ordering Information on the Full Report

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Twenty-First Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production

Another report in the BioPlan Associates, Inc's biopharmaceutical series:

- Top1000 Global Biomanufacturing Facilities – Global analysis and ranking of capacity, employment, and pipelines, www.top1000bio.com
- Top200 Cell and Gene Facility Index and Biomanufacturers Subscription Database – Global analysis and ranking of dedicated Cell and Gene Therapy facilities, top200cellgene.com
- Top300Bio CDMO Facility Index and Biomanufacturers Subscription Database – Global analysis and ranking of capacity, employment and pipeline for CDMOs, top300cdmo.com
- Growth of Biopharmaceutical Contract Manufacturing Organizations in China: An In-depth Study of Emerging Opportunities, 2020
- Top 60 Distributors of Bioprocessing Supplies in China: Opportunities for Global Biopharma Suppliers to Find and Manage Local Distributors in China, 2020
- Top 100 Biopharmaceutical Organizations in China, Online Database
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- Biosimilars Pipeline Database, <http://www.biosimilarspipeline.com/index.html>
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- Quick Guide to Biotechnology in the Middle East
- Quick Guide to Biofuels

The 21st Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production is the most recent study of biotherapeutic developers and contract manufacturing organizations' current and projected future capacity and production. The survey includes responses from 220 responsible individuals at biopharmaceutical manufacturers and contract manufacturing organizations from 23 countries. The survey methodology includes input from an additional 179 direct suppliers of raw materials, services, and equipment to this industry. In addition to current capacity issues, this study covers downstream processing problems, new technologies, expression systems, quality initiatives, human resources and training needs of biopharmaceutical manufacturers, growth rates of suppliers to this industry, and many other areas.

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