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TRENDS AND ANALYSIS FOR THE BIO/PHARMA INDUSTRY 22 YEARS

22ND ANNUAL

Report and Survey of Biopharmaceutical Manufacturing Capacity and Production

A Study of Biotherapeutic Developers and Contract Manufacturing Organizations

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22th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production

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- Dominic Clarke, PhD, VP of Technical Operations, IntegriCell for Cryoport Systems
- Katrina Cordovado, MBDC, Business Development Manager, ENABLE Biotech
- Renaud Jacquemart, PhD, MBA, CEO, Omnium Global
- Paul Priebe, Single-Use Bioprocess Expert Consultant
- Stefan Schmidt, PhD, CEO, Evitria AG

We would also like to recognize our Institution Partners, and our Media Sponsors. Their efforts in assuring the cooperation and participation in the survey of their respective memberships helped guarantee the large group of survey participants to ensure data accuracy.

Our ***Institution Partners,*** all of whom contributed their time and effort to ensure the broad, international coverage of this project, include:

- AusBiotech (Malvern, Victoria, Australia)
- Bio-Process Systems Alliances/SOCMA (BPSA) (Washington, D.C., USA)
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- Evaluating Biopharma (Rockville, MD, USA)
- North Carolina Biotechnology Center (Research Triangle Park, NC, USA)
- Pharma & Biopharma Outsourcing Association (PBOA) (Ringwood, NJ, USA)

To ensure global coverage for this project, we again invited major ***Media Sponsors*** to support our outreach to biopharmaceutical decision-makers. Our media sponsors, who helped ensure broad and representative coverage of industry participation, include:

- American Pharmaceutical Review/Pharmaceutical Outsourcing (South San Francisco, CA, USA)
- BioPharm International (Iselin, NJ, USA)
- BioProcess International (Westborough, MA, USA)
- BioProcess Online (Eric, PA, USA)
- Contract Pharma, (Ramsey, NJ, USA)
- CPhI (London, UK)
- Pharmaceutical Manufacturing (Schaumburg, IL, USA)
- Pharmaceutical Technology/Pharmaceutical Technology Europe (Iselin, NJ, USA)

The early participation of our authors and sponsors in evaluating the areas and trends to be surveyed this year ensured the project was designed to cover the most relevant issues in biopharmaceutical manufacturing today. As always, their continued support was critical to the success of the project.

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.

We prepare custom studies and provide public information our clients require to make informed strategic decisions, define objectives, and identify customer needs. With market information, our clients are better able to make informed, market-based decisions because they understand the trends and needs in high technology industries.

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Mr. Langer is President and Managing Partner at BioPlan Associates, Inc., a biotechnology, and life sciences consulting company that has been providing management and market strategy services, and technology analysis to biopharmaceutical and healthcare organizations since 1989. He has over 30 years' experience in biotechnology and life sciences management and market assessment. He is an experienced medical and biotechnology industry practitioner, strategist, researcher, and science writer. He has held senior management and marketing positions at biopharmaceutical supply companies. He teaches Biotechnology Marketing, Marketing Management, Services Marketing, Advertising Strategy, and Bioscience Communication at Johns Hopkins University, American University, and lectures extensively on pricing and channel management topics. Mr. Langer has a degree in Chemistry and a Masters in International Business. He has written and consulted extensively for companies involving large scale biopharmaceutical manufacturing, global biotechnology in China, Asia, and the Middle East; he has expertise in cell culture markets, media, sera, tissue engineering, stem cells, diagnostic products, blood products, genetics, DNA/PCR purification, blood components, and many other areas.

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Donnie E. Gillespie is Director, Research Projects at BioPlan Associates. She has over 20 years' experience in marketing and healthcare research. She is editor and manager of several industry publications, reports, and databases, including the Report and Survey of Biopharmaceutical Manufacturing Capacity and Production and the Top1000Bio Facility Index and Database. She also oversees the Biotechnology Industry Council (BIC), a panel of subject matter experts in the biopharmaceutical industry providing in-depth knowledge to research projects. In addition, she provides secondary marketing research services as well as primary qualitative research.

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Dominic Clarke, PhD, VP of Technical Operations, IntegriCell for Cryoport Systems

Dr. Dominic Clarke serves as Vice President of Technical Operations, IntegriCell for Cryoport Systems after spending the past two years as CSO at Discovery Life Sciences. Previously, he held the role of Director of Global Cell Therapy Strategy and Innovation at Charles River Laboratories (CRL) with overall responsibilities for developing and expanding the cell supply business unit. Prior to joining CRL, he was the Global Head of Cell Therapy at HemaCare where he helped expand overall visibility which subsequently aided in the acquisition by CRL. He started his career in cryobiology and led the research & development efforts for BioLife Solutions before transitioning to delivering industry leading single-use solutions at Charter Medical. Dominic has nearly 20 years in cell & gene therapies and has been serving as the Chair of the International Society for Cell & Gene Therapies (ISCT) Process Development and Manufacturing industry sub-committee for the past 5 years.

Katrina Cordovado, MBDC, Business Development Manager, ENABLE Biotech

Katrina Cordovado is a biomedical commercialization specialist with a strong background in business development, market strategy, and client engagement for life science and biomanufacturing companies. At Enable Biotech, she leads outreach and proposal development efforts to support early-stage companies in cell therapy, gene-modified cell therapy, and exosome-based therapeutics. She plays a key role in ensuring smooth onboarding and long-term collaboration between clients and the CDMO's technical and commercial teams. Her experience also includes contributing to commercialization, market intelligence, and corporate development efforts at organizations such as Fina BioSolutions, a leading recombinant protein manufacturer, and Omnium Global, a strategic advisory firm serving biotech and CDMO clients. Katrina has supported projects involving regulatory and reimbursement strategy, QMS implementation, and investor communications across several ventures in the advanced therapies space.

Renaud Jacquemart, PhD, MBA, CEO, Omnium Global

Dr. Renaud Jacquemart is a strategic leader and biopharmaceutical product development expert with 25 years of international experience. His expertise spans the full lifecycle of biologics—from early-stage development to commercialization—with a focus on cost-effective, scalable solutions. He provides strategic guidance on go-to-market planning, CMC program design and execution, and M&A, helping biopharma companies achieve growth, operational excellence, and competitive advantage. He previously held leadership roles at Sanofi Pasteur, Merck KGaA, Batavia Biosciences, and BioVectra, where he led global health programs and advanced next-generation manufacturing platforms for biologics and ATMPs. Renaud has directed engineering and technology transfer projects across five continents, including the design of large-scale vaccine facilities, modular and microfacility platforms, and decentralized manufacturing strategies. He has played a key role in bringing innovative bioprocess technologies to market and enabling successful partnerships and acquisitions by major industry players. In addition to leading Omnium Global, he holds executive and board positions with several emerging ventures. He has contributed to global health and access-

to-technology initiatives in over 30 countries, supporting the development and distribution of affordable, life-saving biologics in collaboration with international organizations, NGOs, and private-sector partners. His dual expertise in technical innovation and business strategy ensures that bioprocess solutions are not only robust and compliant but also aligned with real-world market needs.

Paul Priebe, Single-Use Bioprocess Expert Consultant

Paul Priebe currently works as an independent consultant. He primarily consults on bioprocess technology commercialization, product and market strategy, product management and go-to-market approaches. He specializes in all aspects of single use technologies for bioprocess applications. Previously he spent close to 4 years at Qosina, where he led product and market strategy and launched the Qosina BioProcess brand and product portfolio. His nearly 18 years previous experience at Sartorius Stedim biotech included leadership roles in product and application management for all Sartorius bioprocess technologies, with a specialty in single use technology. He is a current member of ASME BPE and the BPSA Scientific Advisory Council and served as a long-time board member of the BPSA, and active member of the PDA, ASTM E55 and Biophorum Supply Partner Phorum. He was a contributing author of PDA TR66 and ASTM E3051 and served on several important task groups within ASME BPE.

Stefan R. Schmidt, PhD, CEO, Evitria AG

Dr. Stefan R. Schmidt serves as CEO at Evitria AG in Zürich, Switzerland after spending five years as COO at BioAtrium AG, a Lonza and Sanofi JV. Previously he held the position as CSO and other senior executive roles at Rentschler Biopharma with overall responsibilities for development, production, and innovation. Before that, he was CSO at ERA Biotech in Barcelona, directing the company's R&D efforts. Prior to that, he worked at AstraZeneca in Sweden where he led the unit of Protein Sciences as Associate Director. He started his leadership career in Munich more than 25 years ago where he built up protein biochemistry teams for Connex and GPC-Biotech. During his academic education he earned a PhD in Biochemistry and an MBA in Marketing.

22st Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production • April 2025

A Study of Biotherapeutic Developers and Contract Manufacturing Organizations

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METHODOLOGY

This report is the 22nd 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 22-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 203 qualified and responsible individuals at biopharmaceutical manufacturers and contract manufacturing organizations in 21 countries plus 116 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

KEY TAKEAWAYS

This is the 22nd year that we are capturing the evolution of the biomanufacturing industry and providing an internationally recognized and data-based analysis of its past, present, and future.

- Survey respondents are professionals whose roles extend into the senior-most levels of strategic decision-making within global biopharmaceutical organizations.
- The 2025 edition of this report incorporates survey responses from professionals across 21 countries, reflecting a global perspective with insights spanning North America, Europe, Asia-Pacific, and other strategically important regions.
- The distribution of respondents' involvement across development phases of biomanufacturing offers wholistic cover of expertise and opinions—from early-stage research through clinical trials and commercial production.
- The facilities that were represented in this study make up a significant portion of their overall organizations' biomanufacturing activity.
- A longitudinal review of the reviewed facilities shows a shift from lower-volume single-use bioreactors toward larger, commercial-scale capacities. Stainless steel systems are still actively used in comparatively larger capacities but there is no expansion of this legacy systems.

INTRODUCTION

This report presents a comprehensive analysis based on the insights of a global cohort of senior executives, technical leaders, and scientific experts engaged in biopharmaceutical development and manufacturing. Respondents span a wide range of organizational roles and company types, including both Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs), as well as biotherapeutic developers operating across diverse therapeutic areas.

Now in its 22nd year, this internationally recognized research initiative continues to serve as a benchmark for the biomanufacturing sector. The 2025 edition draws on survey responses from professionals in 21 countries, capturing perspectives from across North America, Europe, Asia-Pacific, and other key regions. This global reach ensures that the report reflects both the local nuances and shared challenges that shape the biopharmaceutical industry today.

This year's report goes beyond the general industry snapshot to include focused data segments. Chapter 12 specifically highlights input from bioprocessing suppliers and technology vendors, offering an additional layer of insight into the supply-side dynamics influencing manufacturing strategy and innovation. As in prior years, participating organizations range in size, market focus, and development stage, but all respondents share direct involvement in bioprocessing and manufacturing operations—ensuring a grounded, practical understanding of current trends.

The strength of this report lies in the diversity and depth of experience represented. Contributors include professionals actively managing and executing biopharmaceutical manufacturing operations worldwide. Their collective input provides a real-time view of how the industry is evolving, where the most pressing challenges lie, and what strategic directions are gaining traction.

To support nuanced interpretation, responses are analyzed not only in aggregate but also by organization type, distinguishing between CMOs and innovator biotherapeutic manufacturers. This segmentation allows for more targeted insight into how different stakeholders are navigating business drivers, risk exposure, capital investment decisions, and operational strategy.

By presenting these data, this report aims to deliver a clear, data-driven view of the industry's current landscape and future outlook—shaped by those at the forefront of biomanufacturing innovation and execution.

0-1 RESPONDENTS' AREA OF INVOLVEMENT

In the 2025 survey, the highest number of respondents reported direct involvement in large-scale cell culture production for therapeutic use and in process development for biopharmaceutical manufacturing. These two areas have consistently represented the largest share of respondent roles throughout our longitudinal study, due to their central importance within the biomanufacturing ecosystem.

This trend is reflective of the broader industry landscape, where upstream production and process development remain foundational to biopharmaceutical success. Large-scale cell culture production is the engine of commercial biologics manufacturing. Likewise, process development plays a critical role in translating discovery into scalable, regulatory-compliant manufacturing, making it a focal point for innovation, investment, and staffing across organizations.

Note, over 34.4% indicated a Supplier role, and are featured in Chapter 12.

For Ordering Information on the Full Report

Contact BioPlan Associates, Inc.

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Twenty-Second 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
- Top300Bio CDMO Facility Index and Biomanufacturers Subscription Database – Global analysis and ranking of capacity, employment and pipeline for CDMOs, https://www.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
- Advances in Biopharmaceutical Technology in China, 2nd Ed., Soc. Ind. Microbiology, Biotech
- Quick Guide to Clinical Trials, 2nd Ed., 2017
- Biosimilars Pipeline Database, http://www.biosimilarspipeline.com/index.html
- Biopharmaceutical Expression Systems and Genetic Engineering Technologies
- Advances in Biopharmaceutical Manufacturing and Scale-up Production, Amer. Soc. Micro.
- Biopharmaceutical Products in the U.S. and European Markets, 8th Ed.
- Advances in Biopharmaceutical Technology in India
- Top 60 Biopharmaceutical Organizations in India
- Quick Guide to Biotechnology in the Middle East
- Quick Guide to Biofuels

The 22nd 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 203 responsible individuals at biopharmaceutical manufacturers and contract manufacturing organizations from 21 countries. The survey methodology includes input from an additional 116 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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