BioPlan associates, inc.

APRIL 2024

TRENDS AND ANALYSIS FOR THE BIO/PHARMA INDUSTRY 21 YEARS

21ST ANNUAL

Report and Survey of Biopharmaceutical Manufacturing Capacity and Production

A Study of Biotherapeutic Developers and Contract Manufacturing Organizations

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- Laura Brey, Senior Manager Market Intelligence, AGC Biologics
- Dominic Clarke, PhD, VP of Technical Operations, IntegriCell for Cryoport Systems
- Nick Kotlarski, PhD, President and COO, Bioworkshops
- Paul Priebe, Single-Use Bioprocess Expert Consultant
- Stefan Schmidt, PhD, CEO, Evitria AG
- Christoph Winterhalter, PhD, Chief Business Officer, AGC Biologics
- Avril Vermunt, Biologics, Global Manufacturing & Supply, Telix Pharmaceuticals Ltd.

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)
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- 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 and President 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 25 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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Dr. Laura Brey serves as Senior Manager for Market Intelligence at AGC Biologics, a global biopharmaceutical CDMO with sites in US, EU, and Japan. In her role, Laura monitors the evolution and trends of the Biopharmaceutical market and advises Leadership Management. Prior to that she worked for several years as the Cell and Gene Therapy Proposal Manager. She holds a PhD in Synthetic Biology from the University of Copenhagen.

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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.

Nick Kotlarski, PhD, President and COO, Bioworkshops

Dr. Nick Kotlarski is a co-founder of the CDMO, Bioworkshops, where he currently leads international business development. He has more than 25 years of industry experience spanning product development through to commercial manufacture focused on biologics. The bulk of his experience is divided nearly equally between production of microbial and mammalian-based recombinant products, but also includes manufacturing of CGT, cell therapies, and natural products for clinical trials. In the past 10 years he has led the build, start-up, and operation of five bioprocessing facilities in Greater China all using mammalian cell culture. Nick is a Chartered Engineer (CEng) and Member of the Institution of Chemical Engineers (MIChemE).

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.

Christoph Winterhalter, PhD, Chief Business Officer, AGC Biologics

Dr. Christoph Winterhalter has 25 years of experience in Life Science and serves as Chief Business Officer at AGC Biologics, a global biopharmaceutical CDMO with sites in US, EU, and Japan. Before that, he was the Senior Vice President Business Development at AGC Biologics and heading Business Development globally at Rentschler Biopharma with a strong contribution to the tremendous growth phase from 2013-2017 were sales more than tripled. Prior to joining Rentschler Biopharma, he served as Vice President Biosolutions at Wacker Chemical Corporation in Michigan US heading a 100 Mil USD business for Life Science. Before that he held several positions at Wacker Chemie AG in Germany, where he started in 1995 to develop the first fermentation route to cysteine by metabolic design in E. coli. He also holds a Ph.D. in Microbiology at the Technical University of Munich.

Avril Vermunt, VP, Biologics, Global Manufacturing & Supply, Telix Pharmaceuticals Ltd.

Avril Vermunt is currently VP, Biologics, Global Manufacturing & Supply at Telix Pharmaceuticals Ltd. Avril loves contributing her 20+ years of experience towards biopharmaceutical innovation to enable compliant operations and improve patient accessibility & affordability. Her previous experiences include leadership positions at EQRx and Adverum Bio, technology strategy and management roles at Cytiva, process development at Amgen, and manufacturing at Fujifilm Diosynth. She has been an ISPE member since joining the student chapter at North Carolina State University, where she received her degree in Chemical Engineering. She also completed the Executive MBA program at the University of Colorado and is in progress in the Doctorate of Engineering program at Pennsylvania State University.

21st Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production • April 2024

A Study of Biotherapeutic Developers and Contract Manufacturing Organizations

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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
- Advances in Biopharmaceutical Technology in China, 2nd Ed., Soc. Ind. Microbiology, Biotech
- Quick Guide to Clinical Trials, 2nd Ed.
- 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 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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