



# China's Position in Global BioManufacturing

*A Comparison of China's Emerging  
Position vs Established Regions'  
Manufacturing Capacity and  
Production*



*An in-depth review of emerging trends and  
opportunities, with comparative data from  
BioPlan's 19th Annual Report and Survey  
of Biopharmaceutical Manufacturing*

November 2022

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BioPlan Associates, Inc.  
One Research Court, Ste. 450  
Rockville, MD 20850 USA  
+1 301.921.5979  
[www.BioPlanassociates.com](http://www.BioPlanassociates.com)

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BioPlan Associates, Inc. at 1 301-921-5979, or [info@BioPlanassociates.com](mailto:info@BioPlanassociates.com)

Managing Editor: Vicky Xia, Leo Yang  
Editor: Donnie E. Gillespie, Shriya Bhatkhande

Industry Expert Reviewers:

Nick Kotlarski, PhD. President and COO Bioworkshops, Suzhou, Jiangsu, China  
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We prepare custom studies, and our publications provide public information our clients require to make informed strategic decisions, define objectives, and identify customer needs. With market and strategic information, our clients and publication readers are better able to make informed, market-based decisions because they understand the trends and needs in high technology life sciences industries.

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[www.BioPlanassociates.com](http://www.BioPlanassociates.com)  
Tel: 1 301-921-5979

# Preface

BioPlan Associates' report on China's Position in Global BioManufacturing: A Comparison of China's Emerging Position vs Established Regions' Manufacturing Capacity and Production covers industry developments within China, in comparison to regions with decades more experience in biologics, including US and Western Europe. We aggregated geographical respondent data from BioPlan's 2022 19th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production. This on-going project will be updated in the future to also provide trend information and relevant new in-depth insights into the rapidly growing and changing Chinese biologics industry.

We wish to acknowledge the contributions of our reviewers who have provided additional analysis and peer insights into this report. Without their support, this project would not have been possible.

Vicky Qing Xia, Sr. Director, Research

Leo Yang, Director, Research

BioPlan Associates, Inc.

November 2022

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## *A Comparison of Regions' Manufacturing Capacity and Production*

*November 2022*

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# Introduction

The objective of this analysis is to compare the relatively rapidly growing biopharma segment in China with that of more experienced regions. Since 2000 China has placed biotechnology prominently in its 5-year Plans (guidelines). And the current guidance makes the “Made in China 2025” a priority focus. The country is actively addressing nationally vital technologies, including biopharma, which lack a domestic core platform. In the recent past, Chinese products were perceived internationally to be of inferior quality. This has been changing, and investments continue to be made to address quality, productivity, and innovation.

Both domestic Chinese, and global investors have recognized the pattern for sustained growth and a global position for China in biotech. The Chinese government has continued to invest heavily to expand Chinese companies and their innovations. Because biotechnology remains a prominent part of many of China's Five-Year Plans for strategic economic growth and investment, the segment will continue to receive major investment.

The genesis of the project, based on BioPlan's 30+ years' experience and knowledge of the market segment, is the growth in the biopharmaceutical segment, including the emerging regions such as China and India. China, in particular, has advanced rapidly, and with those advances comes the need for updated perspectives. Since the publication of the first edition of BioPlan's peer-reviewed study, *Advances in Biopharmaceutical Technology in China*, 1st Ed, in 2004, China has entered the global market for biopharmaceutical manufacturing, and is likely to remain a key industry player.

BioPlan surveys the global industry annually to identify key trends in the industry. This year, we see the need to compare how the Chinese industry itself perceives the challenges and opportunities, and how these trends compare to the global situation (primarily the leaders in the US and Western Europe).

This is timely because so many changes have taken place over the past two decades in China's biopharma that the industry has now evolved into a stage few could have imagined back then. Innovation is clearly delivering profitability for this industry which used to be dominated by generic small molecule APIs. Today, many revolutionary changes in bio-manufacturing are occurring, and China is aggressively avoiding legacy technologies in favor of more modern approaches. In China, the awareness that future efficiency and productivity depends on using modern techniques is a strong driver. The regulatory authorities

in China have also taken on rather substantial reforms to help innovation at all levels, including manufacturing to help achieve parity in line with that of Western peers. China's export ambitions, based on BioPlan's prior analyses, include a strong focus on participating as a commercial partner in Western regulated markets and to meet the quality and performance needs expected of a GMP provider. There are many biopharma fields in China that are energized, and that are beginning to present exciting improvements. Contract Manufacturing Organizations (CMOs) such as WuXi Biologics have taken a global stage, and, in fact, in 2021, became the second largest CMO in terms of revenue, according to BioPlan's recent research and publications. And WuXi AppTec's biopharmaceutical drug substance facility in Wuxi, China recently won a Facility of the Year award from the International Society of Pharmaceutical Engineers, a first-ever for China.

China aspires to become one of, if not the leading, country contributor to the global pharmaceutical and biopharmaceutical industry by 2030. Large companies in this sector—both international firms expanding their own footprint within China and domestic companies are establishing internal and global footprints—and have witnessed double-digit growth for much of the past 10 years. Strategies for growth are tailored to suit the dynamics of a particular region, but all the elements of that strategy are also part of a coordinated overall plan. The development curve in certain key areas such as the creation of new product pipelines or the establishment of operations in emerging markets may differ from company to company, but the driving factors behind those changes apply to all companies. The global pharmaceutical and biopharmaceutical industry itself, not just that within China, has entered a period of substantial change.

Drivers for success in the future will be based on how the industry managed the COVID Pandemic, and how supply chains permitted the flexibility necessary to meet a global crisis. Supply structures that were designed for the realities of the past 15 years have been adapted by force for the realities of the next 10 years. Enterprise and supply chain strategies based upon old paradigms will fail in this new future. China's reaction to the Pandemic has been different from Western responses, in general. But the impact on global supply for biologics remains a constant. Some of the data in this review show that trend.

# Research Methodology

For the purposes of this report, the following areas were used to breakout demographics for United States (US), Western Europe (W. Europe), and Rest of World (ROW.)

**The following countries represent Western Europe countries:**

- Albania
- Austria
- Belgium
- Bulgaria
- Denmark
- Finland
- France
- Germany
- Greece
- Holland
- Hungary
- Ireland
- Italy
- Luxembourg
- Netherlands
- Norway
- Poland
- Portugal
- Slovenia
- Spain
- Sweden
- Switzerland
- United Kingdom

**The following countries represent ROW (Rest of World):**

- Argentina
- Australia
- Brazil
- Canada
- Chile
- Cuba
- Egypt
- Estonia
- Iceland
- India
- Indonesia
- Iran
- Israel
- Japan
- Korea
- Lithuania
- Malaysia
- Mexico
- New Zealand
- Pakistan
- Philippines
- Puerto Rico
- Russia
- Singapore
- South Africa
- Taiwan
- Turkey
- Vietnam

## Areas Explored from 19th Annual Report

In this analysis, we cover the following areas, based on data from the BioPlan 19th Annual Report:

- 1. Single Biomanufacturing Trend Of 2022:** What is the SINGLE most important biomanufacturing trend/operational area the industry must focus efforts on in 2021?

- 2. Novel Bioprocessing System To Test:** Which novel bioprocessing systems or innovations do you plan to evaluate or test within your facility/company in the next 12 months? [Select all that apply]
- 3. Average Cost For Recombinant Protein:** What is your AVERAGE cost per gram for your Facility's PRIMARY Recombinant Protein manufactured at your facility (\$USD)? (For Protein/mAb, not finished product)
- 4. Titer Range:** Approximately, what range of titers are you currently obtaining for each of the following?
- 5. Current Percent of Total Capacity for Facility Operation, by Production System:** Consider your facility's total capacity, and the current "percent of capacity".
- 6. Capacity Constraints:** To what extent do you believe your facility is experiencing production capacity constraints today?
- 7. Downstream Bioprocessing Steps Creating Overall Capacity Constraints:** Describe the extent to which your purification/chromatography steps create OVERALL capacity constraints at your facility?
- 8. Important Areas to Address for Industry to Avoid Significant Capacity Constraints:** If this industry is to avoid significant capacity constraints, the most important areas to be addressed today are?
- 9. Budget and Funding Percentage Changes Over the Next 12 Months:** By about what percent do you believe your BUDGET and FUNDING will change for each of the following over the next 12 months?
- 10. Actions to Reduce Overall Bioprocessing Costs During the Past 12 Months:** During the past 12 months, which actions has your facility undertaken to reduce overall costs?
- 11. Single-use/disposable Biomanufacturing Systems:** About what percent of your biomanufacturing systems (e.g., # of major components/devices) would you describe as 'single-use' or disposable?
- 12. Change in Spending on OUTSOURCING for R&D or Manufacturing in the Next 12 Months:** How will your spending on OUTSOURCING of R&D or manufacturing change in the next 12 months?
- 13. Outsourcing Activities:** How much outsourcing of the following activities is done by your facility today?
- 14. Top 3 New Bioprocessing Expenditures For Suppliers:** In which new areas were your facility's top 3 NEW bioprocessing expenditures in the past year?

For Ordering Information on the Full Report

Contact BioPlan Associates, Inc.

+1 301-921-5979

[info@bioplanassociates.com](mailto:info@bioplanassociates.com)

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**For more information contact:**

**BioPlan Associates Inc.**  
One Research Court, Ste. 450  
Rockville, MD 20850 USA  
[www.bioplanassociates.com](http://www.bioplanassociates.com)  
+1 301 921 5979  
[info@bioplanassociates.com](mailto:info@bioplanassociates.com)

