BioPlan associates, inc.

2ND ANNUAL 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 20th Annual Report and Survey of Biopharmaceutical Manufacturing

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ISBN: 978-1-934106-48-8

About BioPlan Associates, Inc.

BioPlan Associates, Inc. is a biotechnology and life sciences market analysis, research, and publishing organization. We have managed biotechnology, biopharmaceutical, 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; vaccines and other biopharmaceuticals development; contract research services; biotechnology supply; and testing and R&D laboratory activities.

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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Preface

This BioPlan Associates' report China vs Global Biomanufacturing a Competitive Analysis compares industry insights in China with the rest of the world. To provide detailed market insights we aggregated geographical respondent data from BioPlan's 2023 20th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production. This report is part of an ongoing data set and allows us to provide an insight into the historical trends while keeping an eye on the outlook of the industry.

Arvind Deol, Senior Director of Strategic Research

BioPlan Associates, Inc.

May 2023

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Introduction

Biopharmaceutical manufacturing in the US and Europe has expanded rapidly and matured during the 20 years we have been evaluating the industry's capacity, production, and trends. This report compares the more mature biomanufacturing centers such as the US and Europe to those in China and the rest of the world. Since well before the turn of the millennium China had turned its attention to biotechnology. Over the past decades the industry has grown, now China has a regional capacity and concentration of biomanufacturing facilities larger than any country in the world, other than the United States.

The Chinese government has recognized the importance of biomanufacturing capabilities for its own domestic population, as well as for the potential global opportunities. It has invested heavily to develop the capabilities. With both internal and external investment and strategic considerations, this market will continue to grow over the next few years.

This report is based on BioPlan's 30+ years' experience and knowledge of the market segment, is the growth in the biopharmaceutical segment around the world. China, in particular, has advanced rapidly. 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.

Innovation in China has led to high profitability, today bio-manufacturing in 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. 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.

With this rate of expansion and progress China is a major player in the global pharmaceutical industry and may end up becoming the industry leader in the years to come. "Big-Phama" companies are increasingly growing their footprint in the region with new manufacturing facilities springing up to provide for the growing international demand for pharmaceutical products.

With the country recovering from the pandemic, China has now set an economic growth target of about 5% and set domestic consumption as a key policy goal for the coming year. Due to the emphasis on positive economic growth for the country combined with the increased focus and investment in the biopharmaceutical industry (both nationally and internationally) influenced by COVID-19, there will undoubtedly be increased public sector investment into the market. Thus, the prominence and contribution of the biomanufacturing industry in China will continue to grow in the coming years.

RESEARCH METHODOLOGY

For the purposes of this report, the following areas were used to breakout demographics for United States (U.S.), 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 20TH ANNUAL REPORT

In this comparative analysis, we identified 14 areas in biomanufacturing, from BioPlan's extensive 20th Annual Report, where we found significant differences in responses based on respondents' region (US, EU, China, and Rest of World). These included the following topic areas, with the key question(s) from the Annual Survey:

01 **Single Biomanufacturing Trend of 2023:**
What is the SINGLE most important biomanufacturing trend/operational area the industry must focus efforts on in 2023?

02 **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?

03 **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)

04 **Titer Range:**
Approximately, what range of titers are you currently obtaining for each of the following?

05 **Current Percent of Total Capacity for Facility Operation, by Production System:**
Consider your facility's total capacity, and the current "percent of capacity" at which your facility is operating.

06 **Capacity Constraints:**
To what extent do you believe your facility is experiencing production capacity constraints today?

07 **Downstream Bioprocessing Steps Creating Overall Capacity Constraints:**
Describe the extent to which your purification/chromatography steps create OVERALL capacity constraints at your facility?

08 **Important Areas to Address for Industry to Avoid Significant Capacity Constraints:**
If this industry is to avoid significant capacity constraints, what are the most important areas to be addressed today.

09 **Budget and Funding percentage Changes Over the Next 12 Months:**
By about what percent do you believe your BUDGET and FUNDING will change 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 for R&D or manufacturing change in the next 12 months?

13 **Outsourcing Activities:**
How much outsourcing 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?

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