

Microbiome Manufacturing Market (3rd Edition): Industry Trends and Global Forecasts, till 2035: Distribution by Type of Product Manufactured (API and FDF), Type of Formulation (Solid, Liquid and Others), Type of Primary Packaging Used (Blister Packs, Glass / Plastic Bottles, Pouches / Sachets and Vials), Scale of Operation (Clinical and Commercial), Company Size (Small, Mid-sized, and Large and Very Large), Key Geographical Regions (North America, Europe, Asia-Pacific, and Rest of the World) and Leading Developers

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Abstracts

Microbiome Manufacturing Market (3rd Edition): Distribution by Type of Product Manufactured (API and FDF), Type of Formulation (Solid, Liquid and Others), Type of Primary Packaging Used (Blister Packs, Glass / Plastic Bottles, Pouches / Sachets and Vials), Scale of Operation (Clinical and Commercial), Company Size (Small, Mid-sized, and Large and Very Large), Key Geographical Regions (North America, Europe, Asia-Pacific, and Rest of the World) and Leading Developers: 2023-2035

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The microbiome manufacturing market is expected to reach USD 27 billion by 2023 anticipated to grow at a CAGR of 17% during the forecast period 2023-2035.



The human body hosts various communities of microbes, encompassing both beneficial and harmful species, collectively known as microbiota. Similarly, the ecosystem of commensal, symbiotic, and pathogenic microorganisms within a host system is termed the microbiome. The role of microbiota in disease development and pathogenesis has led to growing interest in microbiome-based therapeutics within the medical science community. Over the past two decades, significant advancements have been made in microbiome therapy research and its therapeutic applications. Live biotherapeutic products (LBPs), a category of microbiome therapy, utilize live microorganisms, such as bacteria, viruses, or fungi, to prevent or treat various diseases. LBPs are specifically designed for the rapeutic purposes and are regulated as medicinal products or biologics in many countries. These therapeutic modalities consist of wellcharacterized specific strains of microorganisms extensively researched for their intended medical applications, followed by rigorous testing and clinical trials to demonstrate safety and efficacy in treating or preventing specific medical conditions. Furthermore, the microbiome-based therapeutic approach holds potential in profiling the patient's microbiome composition using gene sequencing, leading to the development of tailored treatment options.

It is noteworthy that in November 2022, the US Food and Drug Administration (FDA) approved the first microbiome-based therapy, RBX2660 (developed by Rebiotix), for the treatment of recurrent Clostridium difficile infection. With several promising microbiomebased live biotherapeutic products advancing through clinical pipelines, this emerging therapeutic segment is expected to become one of the fastest-growing global markets within the pharmaceutical industry in the coming years. Despite numerous developments in microbiome-based therapies and decades of experience in growing bacteria to produce biologics, the biotech industry still lacks sufficient infrastructure for microbiome manufacturing, including live biotherapeutic products manufacturing. Largescale manufacturing of live bacterial therapies faces various challenges. Some key concerns for contemporary innovators include prolonged development timelines, stringent temperature control requirements, complex engineering of diverse aerobic/anaerobic strains (depending on the type of microbe), and inconsistencies related to the quality attributes of the final product. Consequently, outsourcing microbiome therapeutics manufacturing to Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs) has emerged as a lucrative option for developers of human microbiome therapies to address existing manufacturing issues. These CMOs and CDMOs, part of the broader biologics contract manufacturing market, are increasingly focusing on enhancing their offerings by incorporating novel technologies to streamline microbiome manufacturing processes, increase production efficiency, and improve quality. This trend is expected to further



drive growth in both the microbiome and microbiome manufacturing markets.

Report Coverage

The report comprehensively examines the microbiome manufacturing market based on type of product manufactured, type of formulation, type of primary packaging used, scale of operation, company size, key geographical regions and leading developers.

It thoroughly analyzes market influences such as drivers, restraints, opportunities, and challenges, while evaluating competitive landscapes for top players. Forecasts are provided for segment revenues across major regions.

The report provides a comprehensive overview of the human microbiota and microbiome concept, covering various microbiome therapeutics. It discusses the functions of the microbiota, highlighting insights from the Human Microbiome Project (HMP). Additionally, it outlines the manufacturing process of microbiome therapeutics, including challenges and the growing trend of outsourcing. It also lists crucial factors for innovator companies to consider when selecting a Contract Manufacturing Organization (CMO) partner.

A detailed analysis of the current landscape of microbiome manufacturing services for developing microbiome therapeutics is presented, considering parameters such as establishment year, company size, headquarters, scale of operation, type of product manufactured, primary packaging, type of microbe, services offered, number of manufacturing facilities, and microbial species used. The report also includes information on in-house manufacturers of live biotherapeutic products and microbiomes.

An in-depth overview of strategically positioned microbiome manufacturing facilities in major geographical regions (North America, Europe, and Asia-Pacific) is provided, highlighting pivotal manufacturing centers for microbiome products.

The competitiveness of microbiome manufacturing service providers is evaluated, considering factors such as establishment year, scale of operation, product type, formulation, primary packaging, number of facilities, and services offered.



Detailed profiles of companies offering contract manufacturing services for live biotherapeutic products at clinical and commercial scales are presented, focusing on company overviews, service portfolios, microbiome manufacturing facilities, recent advancements, and future prospects.

An evaluation of microbiome-centric initiatives by major pharmaceutical corporations is conducted, including partnerships, financial commitments, pipeline development, therapeutic focus areas, and portfolio breadth. A spider web analysis is used to compare these companies' activities across various parameters.

A comprehensive examination of completed, ongoing, and anticipated clinical trials involving diverse microbiome therapeutics is provided, considering parameters such as trial registration date, status, phase, patient demographics, sponsoring entity, industry participants, study methodology, therapeutic focus, and geographical regions.

The total manufacturing capacity for microbiome-based therapies is estimated based on data disclosed by industry participants, emphasizing capacity allocation across different company scales and major geographic regions.

Estimation of the annual clinical and commercial demand for microbiome therapeutics involves analyzing the target patient population participating in ongoing and planned clinical trials sponsored by both industry and non-industry entities, considering factors such as disease prevalence, trial enrollment, and market trends.

A qualitative assessment outlines key considerations for microbiome therapeutics developers when determining whether to internally manufacture their products or outsource to a Contract Manufacturing Organization (CMO).

A case study examines the current market environment of contract research organizations specializing in microbiome studies and providers of dietary supplements, detailing their founding year, organizational size, and headquarters location.

Key Market Companies



Biose

BJP Laboratories

Capsugel

Chr. Hansen

Inpac Probiotics

NIZO

WACKER

Winclove

Microbiome Manufacturing Market (3rd Edition): Industry Trends and Global Forecasts, till 2035: Distribution b...



Contents

1. PREFACE

- 1.1. Live Biotherapeutic Products and Microbiome Manufacturing Market Overview
- 1.2. Key Market Insights
- 1.3. Scope of the Report
- 1.4. Inclusions and Exclusions
- 1.5. Key Questions Answered
- 1.6. Chapter Outlines

2. RESEARCH METHODOLOGY

- 2.1. Chapter Overview
- 2.2. Research Assumptions
- 2.3. Project Methodology
- 2.4. Forecast Methodology
- 2.5. Robust Quality Control
- 2.6. Key Market Segmentations
- 2.7. Key Considerations
 - 2.7.1. Demographics
 - 2.7.2. Economic Factors
 - 2.7.3. Government Regulations
 - 2.7.4. Supply Chain
 - 2.7.5. COVID Impact / Related Factors
 - 2.7.6. Market Access
 - 2.7.7. Healthcare Policies
 - 2.7.8. Industry Consolidation

3. ECONOMIC AND OTHER PROJECT SPECIFIC CONSIDERATIONS

- 3.1. Chapter Overview
- 3.2. Market Dynamics
 - 3.2.1. Time Period
 - 3.2.1.1. Historical Trends
 - 3.2.1.2. Current and Future Estimates
 - 3.2.2. Currency Coverage
 - 3.2.2.1. Overview of Major Currencies Affecting the Market
 - 3.2.2.2. Impact of Currency Fluctuations on the Industry



3.2.3. Foreign Exchange Impact

3.2.3.1. Evaluation of Foreign Exchange Rates and Their Impact on Market

3.2.3.2. Strategies for Mitigating Foreign Exchange Risk

3.2.4. Recession

3.2.4.1. Historical Analysis of Past Recessions and Lessons Learnt

3.2.4.2. Assessment of Current Economic Conditions and Potential Impact on the Market

3.2.5. Inflation

3.2.5.1. Measurement and Analysis of Inflationary Pressures in the Economy

3.2.5.2. Potential Impact of Inflation on the Market Evolution

4. EXECUTIVE SUMMARY

4.1. Chapter Overview

5. INTRODUCTION

- 5.1. Chapter Overview
- 5.2. Concept of Human Microbiota and Microbiome
- 5.3. Overview of Gut Flora
 - 5.3.1. Role of Gut Flora in Healthy Individuals
- 5.3.2. Factors Affecting Human Gut Flora
- 5.4. The Human Microbiome Project (HMP)
- 5.5. Overview of Microbiome Therapies
- 5.5.1. Types of Microbiome Therapies
 - 5.5.1.1. Probiotics

5.5.1.2. Prebiotics

- 5.5.2. Applications of Microbiome Therapies
- 5.5.3. Microbiome Therapies Supply Chain
- 5.6. Manufacturing of Microbiome-based Therapeutics
 - 5.6.1. Key Steps Involved
 - 5.6.2. Challenges Associated with Manufacturing of Microbiome Therapeutics
- 5.6.3. Demand for Contract Manufacturing Services
- 5.7. Key Considerations while Selecting a Suitable CMO Partner
- 5.8. Concluding Remarks

6. MARKET LANDSCAPE

6.1. Chapter Overview

Microbiome Manufacturing Market (3rd Edition): Industry Trends and Global Forecasts, till 2035: Distribution b...



6.2. Live Biotherapeutic Products and Microbiome Contract Manufacturers: Market Landscape

- 6.2.1. Analysis by Year of Establishment
- 6.2.2. Analysis by Company Size
- 6.2.3. Analysis by Location of Headquarters
- 6.2.4. Analysis by Scale of Operation
- 6.2.5. Analysis by Type of Product Manufactured
- 6.2.6. Analysis by Type of Formulation
- 6.2.7. Analysis by Scale of Operation and Type of Formulation
- 6.2.8. Analysis by Type of Primary Packaging Used
- 6.2.9. Analysis by Type of Formulation and Type of Primary Packaging Used
- 6.2.10. Analysis by Type of Microbe Used
- 6.2.11. Analysis by Type of Microbe Used and Location of Headquarters
- 6.2.12. Analysis by Type of Service Offered
- 6.2.13. Analysis by Number of Manufacturing Facilities (Region)
- 6.2.14. Analysis by Number of Manufacturing Facilities (Country)
- 6.2.15. Analysis by Type of Microbial Species Used
- 6.3. Live Biotherapeutic Products and Microbiome In-House Manufacturers: Market Landscape
 - 6.3.1. Analysis by Year of Establishment
 - 6.3.2. Analysis by Company Size
 - 6.3.3. Analysis by Location of Headquarters
 - 6.3.4. Analysis by Scale of Operation
 - 6.3.5. Analysis by Location of Manufacturing Facilities

7. REGIONAL CAPABILITY ANALYSIS

- 7.1. Chapter Overview
- 7.2. Key Assumptions and Parameters

7.3. Live Biotherapeutic Products and Microbiome Contract Manufacturers in North America

7.4. Live Biotherapeutic Products and Microbiome Contract Manufacturers in Europe

7.5. Live Biotherapeutic Products and Microbiome Contract Manufacturers in Asia-Pacific

8. COMPANY COMPETITIVENESS ANALYSIS

- 8.1. Chapter Overview
- 8.2. Key Assumptions and Parameters



8.3. Methodology

8.4. Live Biotherapeutic Products and Microbiome Contract Manufacturers: Company Competitiveness Analysis:

8.5. Capability Benchmarking of Top Microbiome Contract Manufactures

9. COMPANY PROFILES

9.1. Chapter Overview

9.2. Leading Live Biotherapeutic Products and Microbiome Contract Manufacturers in North America

- 9.2.1. Capsugel (Acquired by Lonza)
 - 9.2.1.1. Company Overview
 - 9.2.1.2. Service Portfolio
 - 9.2.1.3. Facilities Dedicated to Microbiome Manufacturing
 - 9.2.1.4. Recent Developments and Future Outlook
- 9.3. Other Prominent Live Biotherapeutic Products and Microbiome Contract

Manufacturers in North America

- 9.3.1. Arranta Bio
 - 9.3.1.1. Company Overview
- 9.3.1.2. Service Portfolio
- 9.3.2. FUJIFILM Diosynth Biotechnologies
 - 9.3.2.1. Company Overview
- 9.3.2.2. Service Portfolio
- 9.3.3. List Biological Laboratories
- 9.3.3.1. Company Overview
- 9.3.3.2. Service Portfolio
- 9.3.4. ProbioFerm
 - 9.3.4.1. Company Overview
 - 9.3.4.2. Service Portfolio
- 9.4. Leading Live Biotherapeutic Products and Microbiome Contract Manufacturers in

Europe

- 9.4.1. Biose Industrie
- 9.4.1.1. Company Overview
- 9.4.1.2. Service Portfolio
- 9.4.1.3. Facilities Dedicated to Microbiome Manufacturing
- 9.4.1.4. Recent Developments and Future Outlook
- 9.4.2. Cerbios-Pharma
- 9.4.2.1. Company Overview
- 9.4.2.2. Service Portfolio



- 9.4.2.3. Facilities Dedicated to Microbiome Manufacturing
- 9.4.2.4. Recent Developments and Future Outlook
- 9.4.3. Chr. Hansen
- 9.4.3.1. Company Overview
- 9.4.3.2. Financial Information
- 9.4.3.3. Service Portfolio
- 9.4.3.4. Facilities Dedicated to Microbiome Manufacturing
- 9.4.3.5. Recent Developments and Future Outlook
- 9.4.4. Inpac Probiotics
 - 9.4.4.1. Company Overview
- 9.4.4.2. Service Portfolio
- 9.4.4.3. Facilities Dedicated to Microbiome Manufacturing
- 9.4.4.4. Recent Developments and Future Outlook
- 9.4.5. NIZO
- 9.4.5.1. Company Overview
- 9.4.5.2. Service Portfolio
- 9.4.5.3. Facilities Dedicated to Microbiome Manufacturing
- 9.4.5.4. Recent Developments and Future Outlook
- 9.4.6. WACKER
 - 9.4.6.1. Company Overview
- 9.4.6.2. Service Portfolio
- 9.4.6.3. Facilities Dedicated to Microbiome Manufacturing
- 9.4.6.4. Recent Developments and Future Outlook
- 9.4.7 Winclove Probiotics
- 9.4.7.1. Company Overview
- 9.4.7.2. Service Portfolio
- 9.4.7.3. Facilities Dedicated to Microbiome Manufacturing
- 9.4.7.4. Recent Developments and Future Outlook
- 9.5. Other Prominent Live Biotherapeutic Products and Microbiome Contract

Manufacturers in Europe

- 9.5.1. BacThera
- 9.5.1.1. Company Overview
- 9.5.1.2. Service Portfolio
- 9.5.2. Evologic Technologies
- 9.5.2.1 Company Overview
- 9.5.2.2. Service Portfolio
- 9.5.3. Probiotical
 - 9.5.3.1. Company Overview
 - 9.5.3.2. Service Portfolio



- 9.5.4. QUAY Pharma
 - 9.5.4.1. Company Overview
 - 9.5.4.2. Service Portfolio

9.6. Leading Live Biotherapeutic Products and Microbiome Contract Manufacturers in Asia-Pacific

- 9.6.1. BJP Laboratories
 - 9.6.1.1. Company Overview
 - 9.6.1.2. Service Portfolio
 - 9.6.1.3. Facilities Dedicated to Microbiome Manufacturing
 - 9.6.1.4. Recent Developments and Future Outlook
- 9.7. Other Prominent Live Biotherapeutic Products and Microbiome Contract
- Manufacturers in Asia-Pacific
 - 9.7.1. Aumgene Biosciences
 - 9.7.1.1 Company Overview
 - 9.7.1.2. Service Portfolio
 - 9.7.2. AcuraBio
 - 9.7.2.1. Company Overview
 - 9.7.2.2. Service Portfolio
 - 9.7.3. Meteoric Biopharmaceuticals
 - 9.7.3.1. Company Overview
 - 9.7.3.2. Service Portfolio
 - 9.7.4. Probiotics Australia
 - 9.7.4.1. Company Overview
 - 9.7.4.2. Service Portfolio
 - 9.7.5. Unique Biotech
 - 9.7.5.1 Company Overview
 - 9.7.5.2. Service Portfolio

10. LIKELY PARTNER ANALYSIS

- 10.1. Chapter Overview
- 10.2. Key Assumptions and Key Parameters
- 10.3. Scope and Methodology

10.4. Key Potential Strategic Partners for Live Biotherapeutic Products and Microbiome Contract Manufacturers

- 10.4.1. Likely Partners in North America
- 10.4.2. Likely Partners in Europe
- 10.4.3. Likely Partners in Asia-Pacific



11. BIG PHARMA INITIATIVES

- 11.1. Chapter Overview
- 11.2. Methodology
- 11.3. Live Biotherapeutic Products and Microbiome-related Initiatives of Big

Pharmaceutical Players

- 11.3.1. Analysis by Portfolio Diversity
- 11.3.2. Analysis by Trial Phase
- 11.3.3. Analysis by Type of Therapy
- 11.3.4. Analysis by Type of Molecule
- 11.3.5. Analysis by Therapeutic Area

12. RECENT DEVELOPMENTS AND INITIATIVES

- 12.1. Chapter Overview
- 12.2. Partnerships and Collaborations
- 12.2.1. Partnership Models
- 12.2.2. Live Biotherapeutic Products and Microbiome Manufacturing: List of
- Partnerships and Collaborations
 - 12.2.3. Analysis by Year of Partnership
 - 12.2.4. Analysis by Type of Partnership
 - 12.2.5. Analysis by Year and Type of Partnership
 - 12.2.6. Analysis by Type of Organization
 - 12.2.7. Analysis by Type of Partnership and Type of Organization
 - 12.2.8. Analysis by Therapeutic Area
 - 12.2.9. Most Active Players: Analysis by Number of Partnerships
 - 12.2.10. Analysis by Geography
 - 12.2.10.1. Intracontinental and Intercontinental Agreements
 - 12.2.10.2. Local and International Agreements
- 12.3. Live Biotherapeutic Products and Microbiome Manufacturing: Mergers and

Acquisitions

- 12.3.1. Cumulative Year-wise Trend of Merger / Acquisition
- 12.3.2. Analysis by Key Value Drivers
- 12.3.3. Analysis by Year of Acquisition and Key Value Drivers
- 12.4. Live Biotherapeutic Products and Microbiome Manufacturing: Recent Expansions
 - 12.4.1. Analysis by Year of Expansion
 - 12.4.2. Analysis by Purpose of Expansion
 - 12.4.3. Analysis by Year and Purpose of Expansion
 - 12.4.4. Analysis by Scale of Operation



- 12.4.5. Analysis by Purpose of Expansion and Scale of Operation
- 12.4.6. Analysis by Geography
- 12.4.6.1. Analysis by Location of Expanded Facility (Region)
- 12.4.6.2. Analysis by Location of Expanded Facility (Country)
- 12.4.7. Analysis by Purpose of Expansion and Location of Expanded Facility (Region)

13. CLINICAL TRIAL ANALYSIS

- 13.1. Chapter Overview
- 13.2. Scope and Methodology
- 13.3. Live Biotherapeutic Products and Microbiome Manufacturing: Clinical Trial Analysis
 - 13.3.1. Analysis by Trial Registration Year
 - 13.3.2. Analysis by Trial Status
 - 13.3.3. Analysis by Trial Registration Year and Trial Status
 - 13.3.4. Analysis by Trial Phase
 - 13.3.5. Analysis by Trial Registration Year and Trial Phase
 - 13.3.6. Analysis of Enrolled Patient Population by Trial Registration Year
 - 13.3.7. Analysis of Enrolled Patient Population by Trial Phase
 - 13.3.8. Analysis by Type of Sponsor
 - 13.3.9. Most Active Players: Analysis by Number of Registered Trials
 - 13.3.10. Analysis by Study Design
 - 13.3.11. Analysis by Therapeutic Area
 - 13.3.12. Analysis of Number of Registered Trials by Geography
 - 13.3.13. Analysis of Number of Registered Trials by Trial Status and Geography
 - 13.3.14. Analysis of Enrolled Patient Population by Geography
 - 13.3.15. Analysis of Enrolled Patient Population by Trial Status and Geography

14. CAPACITY ANALYSIS

- 14.1. Chapter Overview
- 14.2. Key Assumptions

14.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing: Global Installed Capacity

- 14.3.1. Analysis by Company Size
- 14.3.2. Analysis by Geography

14.3.2.1. Analysis of Installed Live Biotherapeutic Products and Microbiome Contract Manufacturing Capacity in North America

14.3.2.2. Analysis of Installed Live Biotherapeutic Products and Microbiome Contract



Manufacturing Capacity in Europe

14.3.2.3. Analysis of Installed Live Biotherapeutic Products and Microbiome Contract Manufacturing Capacity Asia-Pacific and Rest of the World

15. DEMAND ANALYSIS

15.1. Chapter Overview

15.2. Methodology

15.3. Global Clinical Demand for Live Biotherapeutic Products and Microbiome

Manufacturing

- 15.3.1. Analysis by Number of Trials Conducted
- 15.3.2. Analysis by Enrolled Patient Population
- 15.3.3. Analysis by Trial Phase
- 15.3.4. Analysis by Geography
 - 15.3.4.1. Clinical Demand in North America
 - 15.3.4.2. Clinical Demand in Europe
 - 15.3.4.3. Clinical Demand in Asia-Pacific and Rest of the World

15.4. Global Commercial Demand for Live Biotherapeutic Products and Microbiome Manufacturing

16. MAKE VERSUS BUY DECISION MAKING FRAMEWORK

- 16.1. Chapter Overview
- 16.2. Key Assumptions and Parameters

16.3. Live Biotherapeutic Products and Microbiome Contract Manufacturers: Make versus Buy Decision Making Framework

- 16.3.1. Scenario
- 16.3.2. Scenario
- 16.3.3. Scenario
- 16.3.4. Scenario
- 16.4. Concluding Remarks

17. CASE STUDY: LIVE BIOTHERAPEUTIC PRODUCTS AND MICROBIOME CONTRACT RESEARCH ORGANIZATIONS (CROS) AND DIETARY SUPPLEMENT MANUFACTURERS

- 17.1 Chapter Overview
- 17.2. Live Biotherapeutic Products and Microbiome CROs
- 17.3. Live Biotherapeutic Products and Microbiome CROs: Market Landscape



- 17.3.1. Analysis by Year of Establishment
- 17.3.2. Analysis by Company Size
- 17.3.3. Analysis by Location of Headquarters
- 17.4. Microbiome Dietary Supplement Manufacturers: Market Landscape
- 17.4.1. Analysis by Year of Establishment
- 17.4.2. Analysis by Company Size
- 17.4.3. Analysis by Location of Headquarters

18. MARKET IMPACT ANALYSIS: DRIVERS, RESTRAINTS, OPPORTUNITIES AND CHALLENGES

- 18.1. Chapter Overview
- 18.2. Market Drivers
- 18.3. Market Restraints
- 18.4. Market Opportunities
- 18.5. Market Challenges
- 18.6. Conclusion

19. LIVE BIOTHERAPEUTIC PRODUCTS AND MICROBIOME CONTRACT MANUFACTURING MARKET

- 19.1. Chapter Overview
- 19.2. Key Assumptions and Methodology

19.3. Global Live Biotherapeutic Products and Microbiome Contract Manufacturing Market, 2023-2035

- 19.4. Scenario Analysis
- 19.4.1. Conservative Scenario
- 19.4.2. Optimistic Scenario
- 19.5. Key Market Segmentations

20. LIVE BIOTHERAPEUTIC PRODUCTS AND MICROBIOME CONTRACT MANUFACTURING MARKET, BY TYPE OF PRODUCT MANUFACTURED

- 20.1. Chapter Overview
- 20.2. Key Assumptions and Methodology

20.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Type of Product Manufactured, 2023 and 2035

20.3.1. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for API, 2023-2035



20.3.2. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for FDF, 2023-2035

20.4. Data Triangulation

21. LIVE BIOTHERAPEUTIC PRODUCTS AND MICROBIOME CONTRACT MANUFACTURING MARKET, BY TYPE OF FORMULATION

21.1. Chapter Overview

21.2. Key Assumptions and Methodology

21.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market:

Distribution by Type of Formulation, 2023 and 2035

21.3.1. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Solids, 2023-2035

21.3.2. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Liquids, 2023-2035

21.3.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Others, 2023-2035

21.4. Data Triangulation

22. LIVE BIOTHERAPEUTIC PRODUCTS AND MICROBIOME CONTRACT MANUFACTURING MARKET, BY TYPE OF PRIMARY PACKAGING USED

22.1. Chapter Overview

22.2. Key Assumptions and Methodology

22.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market:

Distribution by Type of Primary Packaging Used, 2023 and 2035

22.3.1. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Blister Packs, 2023-2035

22.3.2. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Glass / Plastic Bottles, 2023-2035

22.3.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Sachets / Pouches, 2023-2035

22.3.4. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Vials, 2023-2035

22.4. Data Triangulation

23. LIVE BIOTHERAPEUTIC PRODUCTS AND MICROBIOME CONTRACT MANUFACTURING MARKET, BY SCALE OF OPERATION

Microbiome Manufacturing Market (3rd Edition): Industry Trends and Global Forecasts, till 2035: Distribution b...



23.1. Chapter Overview

23.2. Key Assumptions and Methodology

23.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market:

Distribution by Scale of Operation, 2023 and 2035

23.3.1. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Clinical, 2023-2035

23.3.2. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Commercial, 2023-2035

23.4. Data Triangulation

24. LIVE BIOTHERAPEUTIC PRODUCTS AND MICROBIOME CONTRACT MANUFACTURING MARKET, BY COMPANY SIZE

24.1. Chapter Overview

24.2. Key Assumptions and Methodology

24.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Company Size, 2023 and 2035

24.3.1. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Small Companies, 2023-2035

24.3.2. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Mid-sized Companies, 2023-2035

24.3.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Large and Very Large Companies, 2023-2035

24.4. Data Triangulation

25. LIVE BIOTHERAPEUTIC PRODUCTS AND MICROBIOME CONTRACT MANUFACTURING MARKET, BY KEY GEOGRAPHICAL REGIONS

25.1. Chapter Overview

25.2. Key Assumptions and Methodology

25.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Key Geographical Regions, 2023 and 2035

25.3.1. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in North America, 2023-2035

25.3.2. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in Europe, 2023-2035

25.3.3. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in Asia-Pacific, 2023-2035

25.3.4. Live Biotherapeutic Products and Microbiome Contract Manufacturing Market



in Rest of the World, 2023-2035 25.4. Data Triangulation

26. LEADING DEVELOPERS FOR LIVE BIOTHERAPEUTIC PRODUCTS AND MICROBIOME THERAPIES

- 26.1. Chapter Overview
- 26.2. Key Assumptions and Methodology
- 26.3. Live Biotherapeutic Products and Microbiome Therapeutics Market: Distribution by Leading Developers
- 26.4. Data Triangulation

27. EXECUTIVE INSIGHTS

27.1. Chapter Overview

27.2. Osel

27.2.1. Company Snapshot

27.2.2. Interview Transcript: Peter P. Lee, Founder and Executive Chairman

- 27.3. Unique Biotech
 - 27.3.1. Company Snapshot
- 27.3.2. Interview Transcript: Ratna Sudha and Jayanthi, Managing Director and

Scientific Head

- 27.4. Meteoric Biopharmaceuticals
- 27.4.1. Company Snapshot

27.4.2. Interview Transcript: Gaurav Kaushik, Managing Director and Chief Executive Officer

27.5. Biomedic

27.5.1. Company Snapshot

27.5.2. Interview Transcript: Veronika Oudova, Co- Founder and Chief Executive Officer

27.6. Siolta Therapeutics

27.6.1. Company Snapshot

27.6.2. Interview Transcript: Nikole Kimes, Founder and Chief Executive Officer 27.7. BiomX

- 27.7.1. Company Snapshot
- 27.8.2. Interview Transcript: Assaf Oron, Chief Business Officer

27.8. Vedanta Biosciences

27.8.1. Company Snapshot

27.8.2. Interview Transcript: Daniel Couto, Chief Operating Officer





- 27.9. Universal Stabilization Technologies
 - 27.9.1. Company Snapshot

27.9.2. Interview Transcript: Alexander Segal, Former Vice President, Business

Development

27.10. Arranta Bio

27.10.1. Company Snapshot

27.10.2. Interview Transcript: Traci Kyes, Former Vice President, Commercial

Operations

27.11. Assembly Biosciences

- 27.11.1. Company Snapshot
- 27.11.2. Interview Transcript: JP Benya, Former Vice President, Business

Development

- 27.12. List Biological Laboratories
- 27.12.1. Company Snapshot

27.12.2. Interview Transcript: Debbie Pinkston, Former Vice President. Sales and

Business Development

27.13. Luina Bio

27.13.1. Company Snapshot

27.13.2. Interview Transcript: Max Rosetto, Head of Business Development

27.14. WACKER

27.14.1. Company Snapshot

27.14.2. Interview Transcript: Rob Van Dijk, Business Development Manager

28. CONCLUDING REMARKS

29. APPENDIX I: TABULATED DATA

30. APPENDIX II: LIST OF COMPANIES AND ORGANIZATIONS

Table 5.1 Different Types of Microbiota in the Gastrointestinal Tract

Table 5.2 Various Food Items Containing Prebiotics

Table 5.3 Harvey Ball Analysis: Comparison of Key Factors for the Selection of CMOs

Table 6.1 List of Live Biotherapeutic Products and Microbiome Contract Manufacturers:Market Landscape

Table 6.2 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Information on Type of Product Manufactured

Table 6.3 Live Biotherapeutic Products and Microbiome Contract Manufacturers:



Information on Type of Formulation Table 6.4 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Information on Type of Primary Packaging Used Table 6.5 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Information on Type of Microbe Used Table 6.6 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Information on Type of Service Offered Table 6.7 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Information on Manufacturing Facilities Table 6.8 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Information on Type of Microbial Species Used Table 6.9 List of Live Biotherapeutic Products and Microbiome In-House Manufacturers: Market Landscape Table 7.1 List of Live Biotherapeutic Products and Microbiome Contract Manufacturers in North America Table 7.2 List of Live Biotherapeutic Products and Microbiome Contract Manufacturers in Europe Table 7.3 List of Live Biotherapeutic Products and Microbiome Contract Manufacturers in Asia-Pacific Table 9.1 Capsugel: Company Overview Table 9.2. Arranta Bio: Company Overview Table 9.3. FUJIFILM Diosynth Biotechnologies: Company Overview Table 9.4 List Biological Laboratories: Company Overview Table 9.5 ProbioFerm: Company Overview Table 9.6 Biose: Company Overview Table 9.7 Biose: Recent Developments and Future Outlook Table 9.8 Cerbios-Pharma: Company Overview Table 9.9 Cerbios Pharma: Recent Developments and Future Outlook Table 9.10 Chr. Hansen: Company Overview Table 9.11 Chr Hansen: Recent Developments and Future Outlook Table 9.12 Inpac Probiotics: Company Overview Table 9.13 Inpac Probiotics: Recent Developments and Future Outlook Table 9.14 NIZO: Company Overview Table 9.15 NIZO: Recent Developments and Future Outlook Table 9.16 WACKER: Company Overview Table 9.17 WACKER: Recent Developments and Future Outlook Table 9.18 Winclove Probiotics: Company Overview Table 9.19 Winclove Probiotics: Recent Developments and Future Outlook Table 9.20 BacThera: Company Overview



Table 9.21 Evologic Technologies: Company Overview

Table 9.22 Probiotical: Company Overview

Table 9.23 QUAY Pharma: Company Overview

Table 9.24 BJP Laboratories: Company Overview

Table 9.25 BJP Laboratories: Recent Developments and Future Outlook

Table 9.26 Aumgene Biosciences: Company Overview

Table 9.27 AcuraBio: Company Overview

Table 9.28 Meteoric Biopharmaceuticals: Company Overview

Table 9.29 Probiotics Australia: Company Overview

Table 9.30: Unique Biotech: Company Overview

Table 10.1 Likely Partners for Live Biotherapeutic Products and Microbiome Contract Manufacturers in North America

Table 10.2 Likely Partners for Live Biotherapeutic Products and Microbiome Contract Manufacturers in Europe

Table 10.3 Likely Partners for Live Biotherapeutic Products and Microbiome Contract Manufacturers in Asia-Pacific

Table 12.1 Live Biotherapeutic Products and Microbiome Manufacturing: List of Partnerships and Collaborations, 2016-2023

Table 12.2 Partnerships and Collaborations: Information on Type of Agreement, 2016-2023

Table 12.3 Mergers and Acquisitions: Information on Key Value Drivers, 2016-2022 Table 12.4 Live Biotherapeutic Products and Microbiome Manufacturing: List of Recent Expansions, 2019-2023

Table 14.1 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Information on Total Capacity (Sample Data Set)

Table 14.2 Live Biotherapeutic Products and Microbiome Contract Manufacturers:Average Capacity by Company Size (Sample Data Set)

Table 15.1 Global Clinical Demand for Live Biotherapeutic Products and MicrobiomeManufacturing: Information on Number of Enrolled Patients and Trial Phase

Table 15.2 Global Commercial Demand for Live Biotherapeutic Products and

Microbiome Manufacturing: List of Microbiome-based Live Biotherapeutic Products

Table 17.1 List of Live Biotherapeutic Products and Microbiome CROs: Market Landscape

Table 17.2 Microbiome Dietary Supplement Manufacturers: Market Landscape Table 26.1 List of Leading Live Biotherapeutic Product and Microbiome Contract Manufacturing Companies

Table 27.1 Osel: Company Snapshots

Table 27.2 Unique Biotech: Company Snapshots

Table 27.3 Meteoric Biopharmaceuticals: Company Snapshots



Table 27.4 Biomedic: Company Snapshots

Table 27.5 Siolta Therapeutics: Company Snapshots

Table 27.6 BiomX: Company Snapshots

Table 27.7 Vedanta Biosciences: Company Snapshots

Table 27.8 Universal Stabilization Technologies: Company Snapshots

Table 27.9 Arranta Bio: Company Snapshots

Table 27.10 Assembly Biosciences: Company Snapshots

Table 27.11 List Biological Laboratories: Company Snapshots

Table 27.12 Luina Bio: Company Snapshots

Table 27.13 WACKER: Company Snapshots

Table 29.1 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Year of Establishment

Table 29.2 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Company Size

Table 29.3 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Location of Headquarters

Table 29.4 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Scale of Operation

Table 29.5 Microbiome Therapeutics Contract Manufacturers: Distribution by Type of Product Manufactured

Table 29.6 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Formulation

Table 29.7 Live Biotherapeutic Products and Microbiome Contract Manufacturers:Distribution by Scale of Operation and Type of Formulation

Table 29.8 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Primary Packaging Used

Table 29.9 Live Biotherapeutic Products and Microbiome Contract Manufacturers:

Distribution by Type of Formulation and Type of Primary Packaging Used

Table 29.10 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Microbe Used

Table 29.11 Live Biotherapeutic Products and Microbiome Contract Manufacturers:Distribution by Type of Microbe Used and Location of Headquarters

Table 29.12 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Service Offered

Table 29.13 Live Biotherapeutic Products and Microbiome Contract Manufacturers:Distribution by Number of Manufacturing Facilities (Region)

Table 29.14 Live Biotherapeutic Products and Microbiome Contract Manufacturers:Distribution by Number of Manufacturing Facilities (Country)

Table 29.15 Live Biotherapeutic Products and Microbiome Contract Manufacturers:



Distribution by Type of Microbial Species Used

Table 29.16 Live Biotherapeutic Products and Microbiome In-House Manufacturers: Distribution by Year of Establishment

Table 29.17 Live Biotherapeutic Products and Microbiome In-House Manufacturers: Distribution by Company Size

Table 29.18 Live Biotherapeutic Products and Microbiome In-House Manufacturers: Distribution by Location of Headquarters

Table 29.19 Live Biotherapeutic Products and Microbiome In-House Manufacturers: Distribution by Scale of Operation

Table 29.20 Live Biotherapeutic Products and Microbiome In-House Manufacturers: Distribution by Location of Manufacturing Facilities

 Table 29.21 Partnerships and Collaborations: Distribution by Year of Partnership

Table 29.22 Partnerships and Collaborations: Distribution by Type of PartnershipTable 29.23 Partnerships and Collaborations: Distribution by Year and Type of

Partnership

Table 29.24 Partnerships and Collaborations: Distribution by Type of Organization Table 29.25 Partnerships and Collaborations: Distribution by Type of Partnership and Type of Organization

Table 29.26 Partnerships and Collaborations: Distribution by Therapeutic Area

Table 29.27 Most Active Players: Distribution by Number of Partnerships

Table 29.28 Partnerships and Collaborations: Intracontinental and Intercontinental Agreements

Table 29.29 Partnerships and Collaborations: Local and International Agreements

Table 29.30 Mergers and Acquisitions: Year-wise Cumulative Trend, 2016-2023

Table 29.31 Mergers and Acquisitions: Distribution by Key Value Drivers

Table 29.32 Mergers and Acquisitions: Distribution by Year of Mergers and Acquisitions and Key Value Drivers

Table 29.33 Recent Expansions: Distribution by Year of Expansion

Table 29.34 Recent Expansions: Distribution by Purpose of Expansion

Table 29.35 Recent Expansions: Distribution by Year and Purpose of Expansion

Table 29.36 Recent Expansions: Distribution by Scale of Operation

Table 29.37 Recent Expansions: Distribution by Purpose of Expansion and Scale of Operation

Table 29.38 Recent Expansions: Distribution by Location of Expanded Facility (Region) Table 29.39 Recent Expansions: Distribution by Location of Expanded Facility (Country) Table 29.40 Recent Expansions: Distribution by Purpose of Expansion and Location of Expanded Facility (Region)

Table 29.41 Clinical Trial Analysis: Distribution by Trial Registration Year, Pre-2015-2023



Table 29.42 Clinical Trial Analysis: Distribution by Trial Status Table 29.43 Clinical Trial Analysis: Distribution by Trial Registration Year and Trial Status, Pre-2015-2023 Table 29.44 Clinical Trial Analysis: Distribution by Trial Phase Table 29.45 Clinical Trial Analysis: Distribution by Trial Registration Year and Trial Phase, Pre-2007-Post-2018 Table 29.46 Clinical Trial Analysis: Distribution of Enrolled Patient Population by Trial Registration Year, Pre-2015-2023 Table 29.47 Clinical Trial Analysis: Distribution of Enrolled Patient Population by Trial Phase Table 29.48 Clinical Trial Analysis: Distribution by Type of Sponsor Table 29.49 Most Active Players: Distribution by Number of Registered Trials Table 29.50 Clinical Trial Analysis: Distribution by Study Design Table 29.51 Clinical Trial Analysis: Distribution by Therapeutic Area Table 29.52 Clinical Trial Analysis: Distribution of Number of Registered Trials by Geography Table 29.53 Clinical Trial Analysis: Distribution of Number of Registered Trials by Trial Status and Geography Table 29.54 Clinical Trial Analysis: Distribution of Enrolled Patient Population by Geography Table 29.55 Clinical Trial Analysis: Distribution of Enrolled Patient Population by Trial Status and Geography Table 29.56 Capacity Analysis: Distribution by Company Size Table 29.57 Capacity Analysis: Distribution by Geography Table 29.58 Global Installed Live Biotherapeutic Products and Microbiome Contract Manufacturing Capacity in North America Table 29.59 Global Installed Live Biotherapeutic Products and Microbiome Contract Manufacturing Capacity in Europe Table 29.60 Global Installed Live Biotherapeutic Products and Microbiome Contract Manufacturing Capacity in Asia-Pacific and Rest of the World Table 29.61 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing, 2023-2035: Distribution by Number of Trials Conducted Table 29.62 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing, 2023-2035: Distribution by Number of Enrolled Patient Population Table 29.63 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing: Distribution by Trial Phase Table 29.64 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing: Distribution by Geography

Table 29.65 Global Clinical Demand for Live Biotherapeutic Products and Microbiome



Manufacturing in North America, 2023-2035

Table 29.66 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing in Europe, 2023-2035

Table 29.67 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing in Asia-Pacific, 2023-2035

Table 29.68 Global Clinical Demand for Live Biotherapeutic Products and MicrobiomeManufacturing in Rest of the World, 2023-2035

Table 29.69 Global Commercial Demand for Live Biotherapeutic Products and Microbiome Manufacturing, 2023-2035: Distribution by Number of Target Patient Population (in Million)

Table 29.70 Global Commercial Demand for Live Biotherapeutic Products and Microbiome Manufacturing, 2023-2035 (in cfu)

Table 29.71 Live Biotherapeutic Products and Microbiome CROs: Distribution by Year of Establishment

Table 29.72 Live Biotherapeutic Products and Microbiome CROs: Distribution by Company Size

Table 29.73 Live Biotherapeutic Products and Microbiome CROs: Distribution by Location of Headquarters

Table 29.74 Microbiome Dietary Supplement Manufacturers: Distribution by Year of Establishment

Table 29.75 Microbiome Dietary Supplement Manufacturers: Distribution by Company Size

Table 29.76 Microbiome Dietary Supplement Manufacturers: Distribution by Location of Headquarters

Table 29.77 Global Live Biotherapeutic Products and Microbiome Contract Manufacturing Market, Conservative, Base and Optimistic Scenarios, 2023-2035 (USD Million)

Table 29.78 Live Biotherapeutic Products and Microbiome Contract Manufacturing Table 29.79 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for APIs: (2023-2035) Conservative, Base and Optimistic (USD Million) Table 29.80 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for FDFs: (2023-2035) Conservative, Base and Optimistic (USD Million) Table 29.81 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Type of Product Formulation, 2023 and 2035 (USD Million) Table 29.82 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Solid: (2023-2035) Conservative, Base and Optimistic (USD Million) Table 29.83 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Solid: (2023-2035) Conservative, Base and Optimistic (USD Million) Table 29.83 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Liquid: (2023-2035) Conservative, Base and Optimistic (USD Million)



Market for Others: (2023-2035) Conservative, Base and Optimistic (USD Million) Table 29.85 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Type of Primary Packaging Used, 2023 and 2035 (USD Million) Table 29.86 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Blister Packs: Future Estimates (2023-2035) Conservative, Base and Optimistic (USD Million)

Table 29.87 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Glass / Plastic Bottles: (2023-2035) Conservative, Base and Optimistic (USD Million)

Table 29.88 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Sachets / Pouches: (2023-2035) Conservative, Base and Optimistic (USD Million)

Table 29.89 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Vials: (2023-2035) Conservative, Base and Optimistic (USD Million) Table 29.90 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Scale of Operation, 2023 and 2035 (USD Million)

Table 29.91 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Clinical: (2023-2035) Conservative, Base and Optimistic (USD Million) Table 29.92 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Commercial: (2023-2035) Conservative, Base and Optimistic (USD Million) Table 29.93 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Company Size, 2023 and 2035 (USD Million)

Table 29.94 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Small Companies: (2023-2035) Conservative, Base and Optimistic (USD Million)

Table 29.95 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Mid-sized Companies: (2023-2035) Conservative, Base and Optimistic (USD Million)

Table 29.96 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Large and Very Large Companies: (2023-2035) Conservative, Base and Optimistic (USD Million)

Table 29.97 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Key Geographical Regions, 2023 and 2035 (USD Million) Table 29.98 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in North America: (2023-2035) Conservative, Base and Optimistic (USD Million) Table 29.99 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in Europe (2023-2035) Conservative, Base and Optimistic (USD Million) Table 29.100 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in Asia-Pacific: (2023-2035) Conservative, Base and Optimistic (USD Million)



Table 29.101 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in Rest of the World: (2023-2035) Conservative, Base and Optimistic (USD Million)

Table 29.102 Live Biotherapeutic Products and Microbiome Therapeutics Market, Distribution by Leading Developers, 2035

Figure 2.1 Research Methodology: Project Methodology

Figure 2.2 Research Methodology: Forecast Methodology

Figure 2.3 Research Methodology: Robust Quality Control

Figure 2.4 Research Methodology: Key Market Segmentations

Figure 4.1 Executive Summary: CMOs Market Landscape

Figure 4.2 Executive Summary: In-house Manufacturers Market Landscape

Figure 4.3 Executive Summary: Recent Developments and Initiatives

Figure 4.4 Executive Summary: Clinical Trial Analysis

Figure 4.5 Executive Summary: Capacity Analysis

Figure 4.6 Executive Summary: Demand Analysis

Figure 4.7 Executive Summary: Market Sizing and Opportunity Analysis

Figure 5.1 Key Benefits of Human Microbiota

Figure 5.2 Factors Affecting the Gut Flora

Figure 5.3 Human Microbiome Project: Key Achievements

Figure 5.4 Types of Microbiome Therapies

Figure 5.5 Probiotic Drugs: Overview of Beneficial Bacterial Strains

Figure 5.6 Microbiome Therapies: Potential Application Areas

Figure 5.7 Key Steps Involved in Microbiome Therapeutics Supply Chain

Figure 5.8 Key Steps Involved in Microbiome Therapeutics Manufacturing

Figure 5.9 Key Challenges in Manufacturing of Microbiome Therapeutics

Figure 5.10 Key Strategies to Increase Efficiency in Manufacturing Microbiome Therapeutics

Figure 6.1 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Year of Establishment

Figure 6.2 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Company Size

Figure 6.3 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Location of Headquarters

Figure 6.4 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Scale of Operation

Figure 6.5 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Product Manufactured

Figure 6.6 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Formulation



Figure 6.7 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Scale of Operation and Type of Formulation Figure 6.8 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Primary Packaging Used Figure 6.9 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Formulation and Type of Primary Packaging Used Figure 6.10 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Microbe Used Figure 6.11 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Microbe Used and Location of Headquarters Figure 6.12 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Service Offered Figure 6.13 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Number of Manufacturing Facilities (Region) Figure 6.14 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Number of Manufacturing Facilities (Country) Figure 6.15 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Distribution by Type of Microbial Species Used Figure 6.16 Live Biotherapeutic Products and Microbiome In-House Manufacturers: Distribution by Year of Establishment Figure 6.17 Live Biotherapeutic Products and Microbiome In-House Manufacturers: Distribution by Company Size Figure 6.18 Live Biotherapeutic Products and Microbiome In-House Manufacturers: Distribution by Location of Headquarters Figure 6.19 Live Biotherapeutic Products and Microbiome In-House Manufacturers: Distribution by Scale of Operation Figure 6.20 Live Biotherapeutic Products and Microbiome In-House Manufacturers: Distribution by Location of Manufacturing Facilities Figure 7.1 Regional Capability Analysis: Live Biotherapeutic Products and Microbiome Contract Manufacturers in North America Figure 7.2 Regional Capability Analysis: Live Biotherapeutic Products and Microbiome Contract Manufacturers in Europe Figure 7.3 Regional Capability Analysis: Live Biotherapeutic Products and Microbiome Contract Manufacturers in Asia-Pacific Figure 8.1 Live Biotherapeutic Products and Microbiome Contract Manufacturers: Company Competitiveness Analysis Figure 8.2 Benchmarking Analysis: Distribution of Top Live Biotherapeutic Products and Microbiome Contract Manufacturers

Figure 9.1 Capsugel: Service Portfolio



Figure 9.2 Biose Industrie: Service Portfolio Figure 9.3 Cerbios-Pharma: Service Portfolio Figure 9.4 Chr. Hansen: Service Portfolio Figure 9.5 Inpac Probiotics: Service Portfolio Figure 9.6 NIZO: Service Portfolio Figure 9.7 WACKER: Service Portfolio Figure 9.8 Winclove Probiotics: Service Portfolio Figure 9.9 BJP Laboratories: Service Portfolio Figure 11.1 Live Biotherapeutic Products and Microbiome Related Initiatives: Spider Web Analysis of Top Big Pharma Players Figure 11.2 Big Pharma Players: Distribution by Portfolio Diversity Figure 11.3 Big Pharma Players: Distribution by Trial Phase Figure 11.4 Big Pharma Players: Distribution by Type of Therapy Figure 11.5 Big Pharma Players: Distribution by Type of Molecule Figure 11.6 Big Pharma Players: Distribution by Therapeutic Area Figure 12.1 Partnerships and Collaborations: Distribution by Year of Partnership Figure 12.2 Partnerships and Collaborations: Distribution by Type of Partnership Figure 12.3 Partnerships and Collaborations: Distribution by Year and Type of Partnership Figure 12.4 Partnerships and Collaborations: Distribution by Type of Organization Figure 12.5 Partnerships and Collaborations: Distribution by Type of Partnership and Type of Organization Figure 12.6 Partnerships and Collaborations: Distribution by Therapeutic Area Figure 12.7 Most Active Players: Distribution by Number of Partnerships Figure 12.8 Partnerships and Collaborations: Intracontinental and Intercontinental Agreements Figure 12.9 Partnerships and Collaborations: Local and International Agreement Figure 12.10 Mergers and Acquisitions: Cumulative Year-wise Trend, 2016-2023 Figure 12.11 Mergers and Acquisitions: Distribution by Key Value Drivers Figure 12.12 Mergers and Acquisitions: Distribution by Year of Mergers and Acquisitions and Key Value Driver Figure 12.13 Recent Expansions: Distribution by Year of Expansion Figure 12.14 Recent Expansions: Distribution by Purpose of Expansion Figure 12.15 Recent Expansions: Distribution by Year and Purpose of Expansion Figure 12.16 Recent Expansions: Distribution by Scale of Operation Figure 12.17 Recent Expansions: Distribution by Purpose of Expansion and Scale of Operation Figure 12.18 Recent Expansions: Distribution by Location of Expanded Facility (Region) Figure 12.19 Recent Expansions: Distribution by Location of Expanded Facility



(Country)

Figure 12.20 Recent Expansions: Distribution by Purpose of Expansion and Location of Expanded Facility (Region)

Figure 13.1 Clinical Trial Analysis: Scope and Methodology

Figure 13.2 Clinical Trial Analysis: Distribution by Trial Registration Year,

Pre-2015-2023

Figure 13.3 Clinical Trial Analysis: Distribution by Trial Status

Figure 13.4 Clinical Trial Analysis: Distribution by Trial Registration Year and Trial Status, Pre-2015-2023

Figure 13.5 Clinical Trial Analysis: Distribution by Trial Phase

Figure 13.6 Clinical Trial Analysis: Distribution by Trial Registration Year and Trial Phase, Pre-2019-2023

Figure 13.7 Clinical Trial Analysis: Distribution of Enrolled Patient Population by Trial Registration Year, Pre-2015-2023

Figure 13.8 Clinical Trial Analysis: Distribution of Enrolled Patient Population by Trial Phase

Figure 13.9 Clinical Trial Analysis: Distribution by Type of Sponsor

Figure 13.10 Most Active Players: Distribution by Number of Registered Trials

Figure 13.11 Clinical Trial Analysis: Distribution by Study Design

Figure 13.12 Clinical Trial Analysis: Distribution by Therapeutic Area

Figure 13.13 Clinical Trial Analysis: Distribution of Number of Registered Trials by Geography

Figure 13.14 Clinical Trial Analysis: Distribution of Number of Registered Trials by Trial Status and Geography

Figure 13.15 Clinical Trial Analysis: Distribution of Enrolled Patient Population by Geography

Figure 13.16 Clinical Trial Analysis: Distribution of Enrolled Patient Population by Trial Status and Geography

Figure 14.1 Global Installed Live Biotherapeutic Products and Microbiome Contract Manufacturing Capacity: Distribution by Company Size

Figure 14.2 Global Installed Live Biotherapeutic Products and Microbiome Contract Manufacturing Capacity: Distribution by Geography

Figure 14.3 Global Installed Live Biotherapeutic Products and Microbiome Contract Manufacturing Capacity in North America

Figure 14.4 Global Installed Live Biotherapeutic Products and Microbiome Contract Manufacturing Capacity in Europe

Figure 14.5 Global Installed Live Biotherapeutic Products and Microbiome Contract Manufacturing Capacity in Asia-Pacific and Rest of the World

Figure 15.1 Global Demand for Live Biotherapeutic Products and Microbiome



Manufacturing, 2023-2035: Distribution by Number of Trials Conducted Figure 15.2 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing, 2023-2035: Distribution by Enrolled Patient Population Figure 15.3 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing, 2023-2035: Distribution by Trial Phase Figure 15.4 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing: Distribution by Geography Figure 15.5 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing in North America, 2023-2035 Figure 15.6 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing in Europe, 2023-2035 Figure 15.7 Global Clinical Demand for Live Biotherapeutic Products and Microbiome Manufacturing in Asia-Pacific and Rest of the World, 2023-2035 Figure 15.8 Global Commercial Demand for Live Biotherapeutic Products and Microbiome Manufacturing, 2023-2035: Distribution by Number of Target Patient Population (in Million) Figure 15.9 Global Commercial Demand for Live Biotherapeutic Products and Microbiome Manufacturing, 2023-2035 (in cfu) Figure 16.1 Make versus Buy Decision Making Framework Figure 16.2 Make versus Buy Decision Making: Possible Scenario Descriptions Figure 17.1 Live Biotherapeutic Products and Microbiome CROs: Distribution by Year of Establishment Figure 17.2 Live Biotherapeutic Products and Microbiome CROs: Distribution by **Company Size** Figure 17.3 Live Biotherapeutic Products and Microbiome CROs: Distribution by Location of Headquarters Figure 17.4 Microbiome Dietary Supplement Manufacturers: Distribution by Year of Establishment Figure 17.5 Microbiome Dietary Supplement Manufacturers: Distribution by Company Size Figure 17.6 Microbiome Dietary Supplement Manufacturers: Distribution by Location of Headquarters Figure 18.1 Live Biotherapeutic Products and Microbiome Contract Manufacturing: Market Drivers Figure 18.2 Live Biotherapeutic Products and Microbiome Contract Manufacturing: Market Restraints Figure 18.3 Live Biotherapeutic Products and Microbiome Contract Manufacturing: Market Opportunities Figure 18.4 Live Biotherapeutic Products and Microbiome Contract Manufacturing:



Market Challenges

Figure 19.1 Global Live Biotherapeutic Products and Microbiome Contract Manufacturing Market, 2023-2035: Base Scenario (USD Million) Figure 19.2 Global Live Biotherapeutic Products and Microbiome Contract Manufacturing Market, 2023-2035: Conservative Scenario (USD Million) Figure 19.3 Global Live Biotherapeutic Products and Microbiome Contract Manufacturing Market, 2023-2035: Optimistic Scenario (USD Million) Figure 20.1 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Type of Product Manufactured, 2023 and 2035 Figure 20.2 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for API, 2023-2035 (USD Million) Figure 20.3 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for FDF, 2023-2035 (USD Million) Figure 21.1 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Type of Formulation, 2023 and 2035 Figure 21.2 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Solids, 2023-2035 (USD Million) Figure 21.3 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Liquids, 2023-2035 (USD Million) Figure 21.4 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Others, 2023-2035 (USD Million) Figure 22.1 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Type of Primary Packaging Used, 2023 and 2035 Figure 22.2 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Blister Packs, 2023-2035 (USD Million) Figure 22.3 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Glass / Plastic Bottles, 2023-2035 (USD Million) Figure 22.4 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Sachets / Pouches, 2023-2035 (USD Million) Figure 22.5 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Vials, 2023-2035 (USD Million) Figure 23.1 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Scale of Operation, 2023 and 2035 Figure 23.2 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Clinical, 2023-2035 (USD Million) Figure 23.3 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Commercial, 2023-2035 (USD Million) Figure 24.1 Live Biotherapeutic Products and Microbiome Contract Manufacturing

Market: Distribution by Company Size, 2023 and 2035



Figure 24.2 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Small Companies, 2023-2035 (USD Million)

Figure 24.3 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Mid-sized Companies, 2023-2035 (USD Million)

Figure 24.4 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market for Large and Very Large Companies, 2023-2035 (USD Million)

Figure 25.1 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market: Distribution by Key Geographical Regions, 2023 and 2035

Figure 25.2 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in North America, 2023-2035 (USD Million)

Figure 25.3 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in Europe, 2023-2035 (USD Million)

Figure 25.4 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in Asia-Pacific, 2023-2035 (USD Million)

Figure 25.5 Live Biotherapeutic Products and Microbiome Contract Manufacturing Market in Rest of the World, 2023-2035 (USD Million)

Figure 26.1 Live Biotherapeutic Products and Microbiome Therapeutics Market,

Distribution by Leading Developers, 2035

Figure 28.1 Concluding Remarks: Overall Market Landscape

Figure 28.2 Concluding Remarks: Recent Developments and Initiatives

Figure 28.3 Concluding Remarks: Clinical Trial Analysis

Figure 28.4 Concluding Remarks: Capacity Analysis

Figure 28.5 Concluding Remarks: Demand Analysis

Figure 28.6 Concluding Remarks: Market Sizing and Opportunity Analysis (I/II)

Figure 28.7 Concluding Remarks: Market Sizing and Opportunity Analysis (II/II)



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