

Live Biotherapeutic Products and Microbiome Manufacturing Market by Type of Product Manufactured (API and FDF), Type of Formulation (Solids, Oral Liquids and Injectables), 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 Key Geographical Regions (North America, Europe, Asia-Pacific and Rest of the World): Industry Trends and Global Forecasts, 2022 – 2035

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Abstracts

The projected value of microbiome manufacturing market is expected to be valued at USD 23 million in 2022 and is anticipated to grow at a CAGR of 20% during the forecast period 2022-2035.

In light of the remarkable progress witnessed in the clinical development of microbiome-based live biotherapeutic products, it is foreseen that this emerging therapeutic sector will emerge as one of the most rapidly expanding markets within the pharmaceutical industry in the forthcoming years. Specifically, in 2020, a noteworthy 575 Investigational New Drug (IND) applications were submitted for these therapies, demonstrating a concerted effort to address a diverse range of disease indications such as autoimmune, gastrointestinal, infectious, metabolic, and oncological disorders. This surge in applications underscores the considerable scientific advancements achieved by these groundbreaking drug candidates.

Of particular significance is the imminent marketing approval expected in 2022 for SER-109, a microbiome-based therapy developed by Seres Therapeutics, by the United States Food and Drug Administration (FDA). This impending approval is poised to catalyze further growth within this sector. Additionally, the year 2020 witnessed the approval of over 640 patents specifically focused on microbiome therapeutics, coupled with a substantial investment of USD 1.5 billion dedicated to the development of microbiome-based therapeutic interventions.

Despite the considerable strides made in the development of live biotherapeutic products, challenges persist due to the intricacies of the manufacturing process. Concurrently, contemporary innovators express concerns regarding the limited availability of expertise, inadequate specialized infrastructure, the necessity for substantial capital investment, and the challenges associated with ensuring compliance with Good Manufacturing Practices (GMP) and capacity constraints.

To effectively address the technical and operational challenges highlighted above, numerous microbiome developers are increasingly relying on contract manufacturing organizations (CMOs). Presently, more than 50 entities engaged in the manufacturing of microbiome-related products operate either in-house or on a contractual basis. The current landscape of microbiome contract manufacturers is characterized by a high degree of fragmentation, featuring a blend of start-ups, mid-sized firms, and established players. Notably, in recent years, strategic alliances and acquisitions have been forged among various industry players, aiming to augment their respective service offerings and evolve into comprehensive one-stop-shops.

As stakeholders actively seek solutions to overcome existing challenges and prioritize innovation to enhance the microbiome production process, we anticipate substantial growth in the microbiome manufacturing market over the next decade.

Research Coverage

An introduction to the human microbiome, exploring various types of microbiome therapeutics. The chapter covers microbiota functions, insights from the Human Microbiome Project (HMP), manufacturing steps, challenges, and the increasing need for outsourcing. It concludes with factors for innovators to consider when choosing a Contract Manufacturing Organization (CMO) partner.

An overview of the microbiome contract manufacturing landscape, analyzing

25+ contract manufacturers based on parameters like establishment year, company size, service offerings, and more.

Detailed microbiome manufacturing facilities in key regions (North America, Europe, Asia-Pacific), including map representations and highlighting manufacturing hubs.

A company competitiveness analysis of microbiome manufacturing service providers, considering product and service strengths.

Detailed profiles of key industry players in North America, Europe, and Asia-Pacific, providing overviews, service portfolios, manufacturing facilities, and recent developments.

Recent developments in the microbiome manufacturing industry, covering partnerships, collaborations, mergers, acquisitions, and expansions from 2016 to 2021.

An in-depth analysis of completed, ongoing, and planned clinical studies of microbiome therapeutics, considering various parameters.

Installed capacity for manufacturing microbiome-based therapies, highlighting distribution by scale of operation, company size, and geographical regions.

An informed estimate of the annual clinical and commercial demand for microbiome therapeutics, considering ongoing and planned trials.

A qualitative analysis, outlining factors for microbiome therapeutics developers to consider when deciding to manufacture in-house or engage CMO services.

Key Market Companies

Capsugel

Jeneil Biotech

UAS Labs

Biose

Cerbios-Pharma

Inpac Probiotics

NIZO

Winlove Probiotics

BJP Laboratories

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