

## **Pharmaceutical Contract Manufacturing Organization (Cmo) Market - Growth, Trends, Covid-19 Impact, and Forecasts (2023 - 2028)**

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### **Report description:**

The Global Pharmaceutical Contract Manufacturing Organization (CMO) Market was valued at USD 134.12 billion in 2021, and it is expected to reach USD 204.14 billion by 2027, registering a CAGR of 6.64% from 2022 to 2027. As a result of the rising demand for generic medicines and biologics, the capital-intensive nature of the business, and the complex manufacturing requirements, many pharmaceutical companies have identified the potential profitability in contracting with a CMO (contract manufacturing outsourcing) for both clinical and commercial stage manufacturing.

### **Key Highlights**

The most significant factor driving the growth of CMOs in the pharmaceutical industry is the growing need for state-of-the-art processes and production technologies, which have proven significantly effective in meeting regulatory requirements.

CMOs are consolidating as a means of enhancing profitability in the competitive market. The large CMOs could expand their geographical presence and penetrate multiple markets through consolidation. For instance, in January 2020, South Korea's Celltrion, a biosimilar maker, announced plans to invest USD 514 million over five years for its new plant in Wuhan, China's most extensive biologics facility with a capacity of 120,000 liters. The new facility is designed to develop and manufacture its biologics for the local market and perform contract work for Chinese biotech companies' emerging wave.

Additionally, the pharmaceutical companies have been directing their priorities toward the core areas of competency. Hence, they prefer not to disperse available resources, expertise, and technology in formulating the final dose of medicines. The increased competition and shrinking profit margins compelled the pharmaceutical companies to revisit their production processes and R&D activities instead of manufacturing the formulated drug to stay competitive in the market.

With the ongoing growth in the pharmaceutical sector, particularly after the Covid-19 pandemic, pharmaceutical innovator companies need to stock their pipelines with new drugs. However, they do not have the resources to discover, develop, and manufacture products. Hence, the requirement for CMOs is quite significant.

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Further, the countries such as China, India, and Japan hold a significant share of the pharmaceutical CMO market, owing to low labor costs, low capital and overhead costs (compared to that of the United States and Europe), tax incentives, and undervalued currency combine that provides a significant cost advantage for pharmaceutical companies outsourcing to these countries. The most significant factor boosting the growth of CMOs in the pharmaceutical industry in the Asia Pacific region is the growing need for robust processes and production technologies, which have proven highly effective in meeting regulatory requirements. The outbreak of COVID-19 positively impacted the market as pharma companies suddenly were faced with the challenge of producing the many millions of vaccine doses that would likely be needed. Many companies such as Pfizer and AstraZeneca transferred non-COVID-19 biologics out of their proprietary manufacturing networks to make room for the new vaccines. Due to compressed timelines and manufacturing scaling challenges for the COVID-19 vaccines and medicines, CMOs signed contract manufacturing service agreements at an unprecedented rate with the onset of the pandemic.

## Pharmaceutical Contract Manufacturing Organization Market Trends

### Active Pharmaceutical Ingredient (API) Manufacturing Accounts for the Largest Market Share

The demand for API manufacturing has been witnessing sustained growth over the last few years. It is anticipated to continue rising steadily, with additional patent expiries expected in the future and a significant increase in the global generic production capacities.

Some of the major factors that are driving the growth of the API manufacturing segment include increasing government initiatives in the healthcare sector, innovation in biologics, and a rise in the incidence of cancer and age-related diseases. However, strict regulatory policies in regions such as Europe may hinder the sector's growth.

Most of the companies in the industry are increasingly focusing on the development of biological APIs, which is driving the API manufacturing segment of the market studied. The general prescription drugs subsegment has more demand for API manufacturing as compared to the OTC drugs.

The increasing emphasis on high-potency APIs is driving the growth of the segment. The novel technologies for HPAPIs can potentially change the in-out balance of CMOs in this fast-growing segment. As the big pharmaceutical companies continue to scale down on manufacturing, better opportunities for CMOs are expected, both in the biopharmaceutical and small molecule API sectors.

There have been various strategic agreements, collaborations, and partnerships made by vendors to enhance their brand image and presence, providing a competitive edge in the market. For instance, In January 2021, 5N Plus Inc, a global producer of specialty chemicals and engineered materials, announced that it had entered into a strategic agreement with Bozeman, Montana-based Microbion Corporation, to expand the company's Active Pharmaceutical Ingredient (API) Portfolio to include compounds for a new class of Antibiotic & Antibiofilm Drugs.

Moreover, according to the Indian Drug Manufacturers Association, as of July 2021, there has been a steep rise in the cost of raw materials for the essential drugs, called active pharmaceutical ingredients (API) in the pharma sector by up to 140% in multiple cases since the pre-pandemic level, which is challenging for the industry. The overall increase, averaging around 50% owing to high-priced imports and supply disruptions from China, has raised concerns regarding the availability of drugs and could lead to shortages, primarily of those crucial in Covid therapy.

### Asia-Pacific is Expected to Register Highest Growth Rate

China is becoming the most attractive outsourcing country. Most CMOs operating in China mainly offer API and bulk drug product manufacturing for approved generic and branded drugs. Some of the country's leading API and chemical intermediate CMOs

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include Asymchem Laboratories, Beijing Second Pharmaceutical, Chongqing Huapont Pharmaceutical, Shandong Xinhua Pharmaceutical, Venturepharm Laboratories, Porton Fine Chemicals, and Tianjin Pharmaceutical.

The country recently surpassed India as the world leader in APIs and bulk drug materials manufacturing. While API manufacturing is common in China, most of the country's CMOs are limited to manufacturing liquid or solid dosage formulations. Many manufacturing facilities have not received the United States or European CGMO certificate. As a result, they cannot produce finished dosage products for sale in these regions.

The past few decades have been very productive for India, as it took a major leap to include contract manufacturing in pharmaceutical production. With the advent of multinational pharmaceutical organizations and their rapidly growing presence in India, the concept of contract manufacturing has steadily evolved and quickly adapted to encompass services, such as formulation development and basic manufacturing of medicinal products.

Further, the pharmaceutical industry in India manufactures a range of bulk drugs, which are the key ingredients with medicinal properties that form the basic raw materials for formulations. Currently, bulk drugs account for approximately one-fifth of the industry output, while formulations account for the rest. The country also has the expertise for active pharmaceutical ingredients (APIs) as it is the source of 60,000 generic brands across 60 therapeutic categories and manufactures more than 500 APIs.

According to the CPhI Pharma Index 2020, India is the primary beneficiary of API manufacturing and CRO chemistry services outsourcing, rebalancing away from China. India has become a global pharmaceutical manufacturing hub for generic drugs and vaccines. One of the largest vaccine manufacturers, namely, the Serum Institute of India, operates from the country.

Moreover, Drug manufacturing in Japan is regulated by GMP (soft regulation) and the Regulations for Buildings and Facilities of Pharmacies (hard regulation). The Pharmaceutical and Medical Device Agency (PMDA) is the regulatory body that, together with the Ministry of Health, Labor, and Welfare (MHLW), assigns responsibility for the production and quality control of drugs and medical devices to manufacturers in Japan. The continuously changing regulatory environment is proving favorable to both foreign and local companies.

Domestic market players in the country are forming alliances to support manufacturing capacities for new product launches. For instance, in April 2021, Bushu Pharmaceuticals, a contract manufacturer, signed a business agreement with Suzuken to offer support services for new pharmaceutical product launches for specialty pharmaceutical manufacturers looking to enter the Japanese market.

Japan is seeing its longest period of steady growth in over a decade, according to an article published on the Drug Discovery and Development website and reiterated by Cphi. By 2021, the pharmaceutical industry is expected to be worth USD 72 billion, reflecting a 17 percent increase from 2011 to 2020.

#### Pharmaceutical Contract Manufacturing Organization Market Competitor Analysis

The Pharmaceutical Contract Manufacturing Organization (CMO) Market is highly competitive and consists of several major players. Furthermore, the industry is currently dominated by a few significant competitors in terms of market share. These major companies are diversifying their consumer base by expanding into foreign countries. These companies are leveraging on strategic collaborative initiatives to increase their market share and increase their profitability. The companies operating in the market are acquiring start-ups focusing on enterprise network equipment technologies to strengthen their product capabilities.

November 2021 - Baxter International Inc. announced an approximately USD 100 million expansion of its sterile fill/finish manufacturing facility located in Halle/Westfalen, Germany. This facility is operated by BioPharma Solutions (BPS), a business unit of Baxter that specializes in partnering with leading pharmaceutical and biotech companies on the development and contract manufacturing of drug products for parenteral (injectable) pharmaceuticals.

August 2021 - Pfizer Inc. and Trillium Therapeutics Inc. announced that the companies have entered into a definitive agreement under which Pfizer will acquire Trillium, a clinical-stage immuno-oncology company developing innovative therapies for the treatment of cancer. Under the agreement terms, Pfizer will acquire all outstanding shares of Trillium not already owned by Pfizer

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for an implied equity value of USD 2.26 billion, or USD 18.50 per share, in cash. This represents a 118% premium to the 60-day weighted average price for Trillium.

August 2021 - Lonza announced that it would invest in establishing drug product manufacturing capabilities in Guangzhou, China. The new investment will fund installing an aseptic drug product fill and finish production line at the 17,000 m2 state-of-the-art cGMP mammalian facility.

Additional Benefits:

The market estimate (ME) sheet in Excel format  
3 months of analyst support

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