

Lyophilization Services for Biopharmaceuticals
Market Forecast to 2028 - COVID-19 Impact and Global
Analysis By Service Type (Lyophilization Cycle
Development, Clinical Manufacturing, Commercial
Manufacturing, and Freeze Drying Analytical
Services), and End User (Pharmaceutical &
Biotechnology Companies, Research Institutes, and
Others)

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Abstracts

The lyophilization services for biopharmaceuticals market is expected to grow from US\$ 2.05 billion in 2022 to US\$ 3.58 billion by 2028; it is estimated to register a CAGR of 9.9% from 2023 to 2028.

The lyophilization services for biopharmaceuticals market growth is attributed to the rising demand for lyophilized products and rapidly growing contract manufacturing and lyophilization services across the world. However, the demerits associated with lyophilization process hinder the lyophilization services for biopharmaceuticals market growth.

Rising Demand for Lyophilized Products Drives Lyophilization Services for Biopharmaceuticals Market Growth

Lyophilization is a freeze drying method that removes water from the material to extend its stability and shelf life. The products processed under lyophilization are frozen under high vacuum that is majorly used for application in pharmaceutical industries to manufacture high quality and affordable products. Many new parenteral products,



including biotechnology-derived products, in-vitro diagnostics, and anti-infectives, are manufactured as lyophilized products. Many antibiotics such as some cephalosporins, semi-synthetic penicillin, erythromycin salts, chloramphenicol, and doxycycline are made by the lyophilization process. Low bioburden is expected when batching antibiotics formulations, which can be attained using lyophilization. Similarly, a few other dosage forms such as methylprednisolone sodium succinate, hydrocortisone sodium succinate, and many biotechnology-derived products are lyophilized.

Additionally, the number of biopharmaceuticals being developed and manufactured has increased considerably in recent years. Over ten novel biologics have been approved annually by the US Food and Drug Administration (FDA) in the last few years. According to the data published by FDA in February 2022, biologics continue to account for slightly more than 25% of all drugs accepted by the FDA. Most of these products are not stable as aqueous formulations, making it challenging to preserve them for longer durations. To achieve longer and commercially viable shelf lives, lyophilization is preferred for making dry biopharmaceutical formulations. According to the data published by Lubrizol Life Science, in October 2019, over 60% of biologics production in the market would not be possible without lyophilization, and market demand for lyophilization technology will increase due to the growing biosimilars and novel biologics development. The method proves to be beneficial when there is a stability issue while providing exact biologics dosage (for instance, very small and highly concentrated doses). Furthermore, it is suitable for biologics that are sensitive to heat, oxygen, and humidity.

Although lyophilization has been used for more than half a century in the drug product manufacturing industry owing to its ability to stabilize and extend the shelf life of pharmaceutical products, thus interest of biopharmaceutical manufacturers continues to grow, mainly due to the increasing number of biological drug development. Drug developers are focusing on adopting lyophilization as it can extend the shelf life of small and large-molecule drugs. The prevalence of formulation stability challenges for complex APIs and biologics has resulted in the adoption of lyophilization among most pharmaceutical and biotech manufacturers.

Further, lyophilization become important in the biotech industry, as several suppliers are introducing lyo-ready or pre-lyophilized products to the marketplace. As a result, the demand for lyophilization services is growing rapidly, which is driving the growth of the lyophilization services for biopharmaceuticals market.

The Report Segments of Lyophilization Services for Biopharmaceuticals Market are as



Follows.

Based on service type, the global lyophilization services for biopharmaceuticals market is segmented into commercial manufacturing, lyophilization cycle development, clinical manufacturing, and freeze drying analytical services. The commercial manufacturing segment held the largest market share in 2022. The lyophilization cycle development segment is expected to register the highest CAGR during the forecast period.

Based on end user, the global lyophilization services for biopharmaceuticals market is segmented into pharmaceutical and biotechnology companies, research institutes, and others. The pharmaceutical and biotechnology companies segment held the largest market share in 2022. The research institutes segment is expected to register the highest CAGR during the forecast period.

The World Health Organization (WHO), Food and Drug Administration (FDA), European Federation of Pharmaceutical Industry Associations, and Pharmaceutical Research, and Manufacturers of America are among the major primary and secondary sources referred to while preparing the report on the lyophilization services for biopharmaceuticals market.



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