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U.S. Plasma Derived Therapies Market: 2025-2035

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Abstracts

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This report will be delivered in 7-10 working days.Introduction to the U.S. Plasma Derived Therapies Market

Plasma-derived therapies involve the use of human plasma to produce critical therapeutic products, such as immunoglobulins, clotting factors, and albumin, for the treatment of various medical conditions like immune disorders, hemophilia, and liver diseases.

The U.S. Plasma-Derived Therapies Market is poised for significant growth between 2024 and 2035, driven by the increasing demand for immunoglobulins, coagulation factors, and albumin. These therapies are critical for treating conditions such as immune deficiencies, hemophilia, and autoimmune disorders, with the rising prevalence of these diseases contributing to market expansion. In 2024, the market is seeing growth due to advancements in plasma collection technologies, improved fractionation methods, and expanded donor participation programs. Key companies like CSL Behring, Grifols, and Takeda are enhancing plasma supply chain efficiency, ensuring a steady production of plasma-derived medicines. Additionally, regulatory support from the FDA, which has streamlined approval processes for plasma-derived therapies, is accelerating market penetration.By 2035, innovations in recombinant plasma alternatives and next-generation immunoglobulins are expected to transform the market. The integration of artificial intelligence and automation in plasma fractionation will further increase production efficiency and reduce dependency on manual processes. Moreover, the emergence of cell-based and gene therapies may complement traditional plasma-derived treatments, offering new therapeutic avenues.

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The growing prevalence of immune deficiencies, autoimmune diseases, and rare genetic disorders is a key driver of the U.S. plasma-derived therapies market. According to the Immune Deficiency Foundation (IDF), approximately 250,000 Americans are living with primary immunodeficiency diseases (PIDDs), which require lifelong immunoglobulin therapy. Additionally, autoimmune conditions such as Guillain-Barr? Syndrome, Myasthenia Gravis, and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) are leading to an increase in prescriptions for IVIG and SCIG treatments. The CDC and NIH are also funding research to explore new applications for plasma-derived immunoglobulins, particularly in neurodegenerative diseases. As diagnostic technologies improve disease detection and access to plasma therapies expands, the demand for these treatments is expected to grow significantly.

Moreover, the development of recombinant plasma alternatives and next-generation plasma therapies is reshaping the landscape of plasma-derived treatments. Companies like CSL Behring (Afstyla – recombinant Factor VIII) and Takeda (Advate – recombinant Factor VIII) are leading efforts to develop recombinant coagulation factors, reducing the reliance on plasma-derived therapies for hemophilia treatment. In addition, advancements in gene therapy are opening up the possibility for long-term, potentially curative treatments for plasma-dependent conditions such as hemophilia and primary immunodeficiencies. With increasing FDA support for recombinant biologics and cell-based therapies, the transition toward non-plasma alternatives presents a significant growth opportunity for biopharmaceutical companies.

Howeover, the ongoing shortage of plasma donations and the high cost of plasma fractionation is hindering the market growth. Producing plasma-derived therapies requires large quantities of plasma. for example, over 1,000 plasma donations are needed to produce a year’s supply of IVIG for a single patient. The COVID-19 pandemic exacerbated this issue, significantly disrupting plasma donations and leading to shortages in immunoglobulin and coagulation factor therapies. Although donation rates have since improved, the gap between supply and demand remains a concern. Additionally, plasma collection and fractionation processes are costly, with companies investing heavily in infrastructure, purification methods, and quality control. To address this, companies like Grifols and CSL Behring are expanding plasma collection centers, while biopharma firms are exploring recombinant and gene-based alternatives to reduce reliance on plasma.

Market players in the plasma-derived therapies market are actively enhancing their capabilities and expanding their reach to meet the growing demand for these essential treatments. For instance, Grifols has strategically expanded its global presence through

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acquisitions. In April 2022, the company acquired Biotest AG, a German-based plasma protein and biotechnology firm, for approximately ?318 million ($331.78 Million). This acquisition enhances Grifols' capacity to supply plasma-derived medicines, broadens its product portfolio, and strengthens its position in the market.

Key players in the market are Takeda Pharmaceutical Company Limited (BioLife), CSL Behring, Grifols, Octapharma, Kedrion Biopharma, Bio Products Laboratory, LFB Group, Emergent BioSolutions, RAAS Blood Products, etc.

Market Segmentation:

Segmentation 1: by Product Type

• Immunoglobulins (IGs)

• Coagulation Factors

• Albumin

• Alpha-1 Proteinase Inhibitors (A1PI)

• Others

Immunoglobulins to Lead the U.S. Plasma Derived Therapeis Market (by Product Type)

Immunoglobulins (IGs) holds the largest share in U.S. Plasma Derived Therapies Market, driven by their essential role in treating a wide range of conditions, including primary immune deficiencies, autoimmune disorders, and neurological diseases. Immunoglobulin therapies are particularly crucial for patients with conditions such as primary immunodeficiencies (PIDDs), where the body’s immune system is unable to produce enough antibodies. One of the major factors propelling market growth is the increasing adoption of subcutaneous immunoglobulin (SCIG) therapies, which offer greater convenience and improved patient adherence compared to traditional intravenous immunoglobulin (IVIG) treatments. SCIG products like Hizentra (CSL Behring) and Cuvitru (Takeda) allow for self-administration at home, reducing the need for hospital or infusion center visits, thus improving patient quality of life and enhancing overall treatment compliance.

Segmentation 2: by Application

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• Hemophilia

• Alpha-1 Antitrypsin Deficiency

• Immunodeficiency Diseases

• Autoimmune and Inflammatory Diseases

• Others

Immunodeficiency Diseases to Lead the U.S. Plasma Derived Therapeis Market (by Application)

Immunodeficiency diseases dominate the U.S. plasma-derived therapies market due to their high prevalence and reliance on plasma-derived immunoglobulin (IVIG) therapy for treatment. IVIG therapies like Privigen (CSL Behring) and Gamunex-C (Grifols) have become the standard treatment, providing essential immune support to patients with compromised immune systems. The increasing incidence of these conditions, along with the expanding availability of subcutaneous immunoglobulin (SCIG) options is driving market growth. Additionally, the FDA’s continuous support for the development of immunoglobulin therapies and improvements in the ease of administration, such as self-infusion options for patients, has enhanced treatment access and outcomes, further solidifying the dominance of immunodeficiency diseases in the plasma-derived therapies market.

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