

Recombinant Albumin Market Size and Forecast (2021 - 2031), Global and Regional Share, Trend, and Growth Opportunity Analysis Report Coverage: By Source (Human Recombinant Albumin, Bovine Recombinant Albumin, and Others), Application (Excipient in Biotherapeutics And Vaccines, Cell Culture, Drug Delivery, Diagnostics, and Others), and End User (Pharmaceutical and Biotechnology Companies, Research Institutes, Hospitals and Diagnostic Laboratories, and Others)

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Abstracts

According to our new research study on “Recombinant Albumin Market Forecast to 2031 –Global Analysis – by Application and End User,” the market is anticipated to grow from US\$ 392.50 million in 2024 to US\$ 767.54 million by 2031; the market is expected to register a CAGR of 10.1% from 2025 to 2031. The Recombinant Albumin Market growth is attributed to the increasing prevalence of liver diseases and associated conditions, advancements in biotechnological manufacturing and product development, and growing demand for albumin in critical care and emergency settings.

Recombinant albumin is a synthetic, non-animal-derived version of human serum albumin (HSA) produced through genetic engineering in host organisms such as yeast (*Pichia pastoris*, *Saccharomyces cerevisiae*), rice (*Oryza sativa*), or bacteria (*E. coli*). It is 100% identical in amino acid sequence to natural HSA but completely free of blood-borne pathogens, prions, and viral contaminants associated with plasma-derived albumin. Recombinant albumin is manufactured under cGMP conditions, offering

superior batch-to-batch consistency, scalability, and regulatory safety. It is widely used as a stabilizer/excipient in biotherapeutics and vaccines, a critical component in serum-free cell culture media for biologics and cell/gene therapies, and an emerging therapeutic for hypoalbuminemia, liver disease, and regenerative medicine applications.

The Recombinant Albumin market in North America is segmented into the US, Canada, and Mexico. The recombinant albumin market in North America is experiencing significant growth driven by increasing clinical demand for safer and more consistent plasma protein products. According to the U.S. FDA, the prevalence of conditions requiring albumin therapy—such as liver cirrhosis, burns, and shock—has increased significantly. The CDC reported an estimated 40,000 new cases of liver cirrhosis annually in the US as of 2023. The growing adoption of recombinant albumin is also supported by advancements in biotechnology, leading to the development of safer, scalable, and ethically sustainable products. Notably, in 2022, the FDA approved new recombinant albumin formulations that reduce the risk of pathogen transmission compared to plasma-derived options, aligning with increasing safety concerns. Ongoing research and product innovations, such as the launch of recombinant albumin-based therapies for critical care and oncology, fuel market expansion. Government initiatives, including funding for biotechnology research and stricter regulations on plasma-derived products, encourage the shift toward recombinant alternatives. The COVID-19 pandemic underscored the importance of reliable biopharmaceuticals, further accelerating market growth. As of 2024, regulatory agencies continued to endorse recombinant albumin as a safer option for albumin therapies.

The US witnesses a demand for safer biologic inputs, rising prevalence of liver disease, and evolving regulatory expectations. A recent study found the prevalence of cirrhosis to be 2.6% of the US adult population. Individuals with liver cirrhosis often develop hypoalbuminemia and require albumin administration. The Food and Drug Administration (FDA) issued a draft guidance in April 2024 titled “Considerations for the Use of Human-and Animal-Derived Materials in the Manufacture of Cell and Gene Therapy and Tissue-Engineered Medical Products.” In this draft, the agency highlighted concerns over the use of human- or animal-derived materials such as albumin and feeds in advanced therapies and encouraged manufacturers to justify alternatives. This regulatory momentum places recombinant human serum albumin (rHSA) and other non-plasma-derived albumin products in a favorable position as safer, defined alternatives.

Therapeutic Substitution of Plasma-Derived Albumin to Provide Market Opportunities in Future

A major opportunity for recombinant albumin lies in replacing plasma-derived human serum albumin (HSA) for therapeutic use, addressing safety and plasma-supply constraints. In China, human albumin demand exceeded 1,000 tons in 2024, with imports accounting for over 69% of total supply, according to the Wuhan Municipal Health Commission. To reduce reliance on plasma imports, the National Medical Products Administration (NMPA) approved the world's first rice-derived recombinant human albumin injection developed by Wuhan Healthgen Biotechnology in July 2025. In India, Shilpa Medicare Ltd. became the first domestic company to complete Phase I clinical trials for recombinant human albumin (20%) in August 2024, with Phase III trials authorized by CDSCO in November 2024. These regulatory milestones mark growing confidence in recombinant technology. With liver cirrhosis and hypoalbuminemia increasing globally, recombinant albumin presents a scalable, pathogen-free therapeutic substitute.

World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), National Center for Biotechnology Information (NCBI), American Chemical Society Publications, The U.S. Centers for Medicare & Medicaid Services (CMS), US Department of Health & Human Services, Public Health Agency of Canada (PHAC), French National Institute of Health and Medical Research (INSERM), Italian National Institute of Health (ISS), The Korean Journal of Internal Medicine, the Saudi Press Agency (SPA), UAE Ministry of Health and Prevention (MOHAP) are among the primary and secondary sources referred to while preparing the Recombinant Albumin market report.

Reason to buy

Save and reduce time carrying out entry-level research by identifying the growth, size, leading players and segments in the global Recombinant Albumin market.

Highlights key business priorities in order to assist companies to realign their business strategies

The key findings and recommendations highlight crucial progressive industry trends in the global Recombinant Albumin market, thereby allowing players across the value chain to develop effective long-term strategies

Develop/modify business expansion plans by using substantial growth offering developed and emerging markets

Scrutinize in-depth global Recombinant Albumin market trends and outlook coupled with the factors driving the market, as well as those hindering it.

Enhance the decision-making process by understanding the strategies that underpin commercial interest with respect to client products, segmentation, pricing and distribution

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