

US Bulk Lyophilization Services Market Size and Forecast (2021 - 2031), Country Share, Trend, and Growth Opportunity Analysis Report Coverage: By Lyophilization Format (Bulk Tray Lyophilization, Drum Lyophilization, Shelf Freeze-Drying, Tunnel or Conveyer Based Freeze Drying, and Hybrid Methods), Scale (Small Scale or Lab Scale, Pilot Scale, and Commercial and Industrial Scale), Service Type (Custom Process Development and Optimization, Pilot Scale and Research and Development Lyophilization, and Full Scale Commercial Bulk Lyophilization), and End User (Pharmaceutical and Biotechnology Companies, Research and Academic Institutes, and Others), and Geography

<https://marketpublishers.com/r/U4BA2FE36190EN.html>

Date: November 2025

Pages: 94

Price: US\$ 2,450.00 (Single User License)

ID: U4BA2FE36190EN

Abstracts

The US bulk lyophilization services market size is expected to grow from US\$ 340.37 million in 2024 and is projected to reach US\$ 573.30 million by 2031; it is expected to register a CAGR of 7.8% during 2025-2031. The robust growth in the biopharmaceutical sector, the increase in outsourcing demand, stringent regulatory compliance and technological advancements are noteworthy factors contributing to the expansion of the US bulk lyophilization services market size. focus on sustainability and green technologies, integration of AI, automation, and robotics are projected to bring new US bulk lyophilization services market trends in the coming years.

In the US, the bulk lyophilization services sector is experiencing a marked uptick in outsourcing as pharmaceutical and biotechnology companies increasingly turn to external providers for freeze-drying operations. As pharmaceutical and biotech firms grapple with escalating research and development costs, complex regulatory requirements, and capacity constraints, outsourcing bulk lyophilization to specialized contract development and manufacturing organizations (CDMOs) has become a strategic imperative. This shift allows companies to leverage external expertise, accelerate time-to-market, and mitigate risks associated with in-house production. Biopharma leaders are increasingly prioritizing innovation and core competencies—such as drug discovery—over capital-intensive manufacturing infrastructure. Outsourcing enables access to advanced lyophilization technologies, including continuous freeze-drying systems and robotic fill-finish lines, without the burden of upfront investments. Moreover, the rising complexity of biologics, which constitute a significant portion of new drug approvals, demands specialized handling that many firms lack internally. According to Industry Standard Research insights, two-thirds of pharmaceutical manufacturing activities are now outsourced, reflecting a norm rather than an exception. This figure underscores the market's maturity, with CDMOs stepping in to fill capacity gaps exacerbated by post-pandemic supply chain disruptions.

A 2024 CPHI trend report revealed that biologics account for 46% of total pharmaceutical spending, yet many developers outsource production to navigate biosimilar competition and scale-up challenges. US pharma and biotech firms increasingly outsource bulk lyophilization to CDMOs such as PCI Pharma Services to cut capital costs and focus on core research and development, fueled by trends in personalized medicine and clinical trials. Specialized CDMOs report a 20-30% year-over-year increase in lyophilization contracts, driven by demand for high-volume bulk services that ensure sterility and efficacy. This outsourcing boom is particularly evident in oncology and rare diseases, where personalized therapies require precise, scalable lyophilization to extend shelf life and enable global distribution.

By streamlining operations and bolstering supply chains, this driver not only sustains but also elevates the bulk lyophilization services market, ensuring innovative therapies reach patients faster and more reliably. Thus, the driving force of increasing outsourcing demand is powered by biopharma complexity, cost-efficiency, regulatory demands, and the maturity of the CDMO ecosystem. Firms positioning themselves as reliable outsourcing partners are well-placed to capitalize on this shift.

In the rapidly evolving US pharmaceutical landscape, lyophilization has become

indispensable for ensuring drug stability and extending shelf life. Bulk lyophilization services are witnessing heightened demand amid a surge in biopharmaceutical innovation. Central to this growth is the critical role of cycle development and optimization services, which refine freezing, primary drying (sublimation), and secondary drying stages to minimize processing time and uphold product quality. In 2025, the US FDA projects over 2 million new cancer cases alone, fueling the need for stable oncology therapeutics that rely on lyophilized formulations. This underscores the urgency for robust cycles to accelerate time-to-market.

Optimization services employ advanced tools such as computational fluid dynamics (CFD) modeling and Design of Experiments (DoE) to predict and fine-tune parameters, ensuring scalability from lab to commercial production. For instance, AbbVie Contract Manufacturing has leveraged CFD to shorten lyophilization cycles by 20-40% for monoclonal antibodies, minimizing drug substance use during scale-up and enhancing efficiency without compromising stability. These examples highlight how tailored cycle development mitigates risks, such as thermal variability, enabling consistent critical quality attributes (CQAs) like residual moisture below 1%. Also, over 82% of 2022 FDA-approved lyophilized drugs targeted oncology and infectious diseases, with optimization proving vital for their viability. As personalized medicine rises, US firms are prioritizing DoE-driven optimizations to handle liposomal nanoparticles and cell therapies.

This opportunity beckons service providers to invest in data-driven platforms, fostering partnerships that expedite regulatory approvals and bolster supply resilience. By embracing cycle optimization, the market can sustain its leadership, delivering life-saving therapies faster and more affordably.

In the US, the bulk lyophilization services market is undergoing a transformative shift toward sustainability, driven by escalating energy costs, stringent Environmental, Social, and Governance (ESG) mandates, and a commitment to eco-friendly biopharmaceutical production. As contract manufacturing organizations (CMOs) grapple with the demands of biologics, vaccines, and gene therapies—products that rely heavily on freeze-drying for stability—innovations in green technologies are redefining efficiency and reducing environmental footprints. This trend not only aligns with federal initiatives such as the Inflation Reduction Act, which incentivizes low-carbon manufacturing, but will also position US CMOs as global leaders in responsible scaling. A key focus is retrofitting existing lyophilizers with heat pump systems, which recapture waste heat during the drying cycle to preheat incoming air or water, slashing energy consumption. Such retrofits can cut operational energy use by 20-35% across facilities, a critical metric as electricity prices for industrial users rose 8.2% in 2024 per the US Energy Information

Administration. Companies such as PCI Pharma Services offer green lyophilization packages to attract sustainability-focused biotech clients.

Vacuum optimization represents another pillar of this green revolution. Advanced vacuum systems, equipped with variable-speed pumps and real-time pressure controls, minimize air leaks and optimize sublimation phases, reducing power draw. A prime example is the partnership between CryoDry and Pfeiffer Vacuum in June 2024, which introduced vacuum technologies tailored for bulk services. These enhancements are particularly vital for bulk operations, where processing thousands of vials per batch amplifies energy demands. Solvent recovery technologies bolster sustainability by capturing and recycling volatile organics such as acetonitrile used in formulations, mitigating hazardous waste.

Thus, as the biopharma pipeline swells, these advancements ensure the US market remains agile, cost-effective, and planet-positive. By prioritizing green tech, CMOs will meet mandates and pioneer a resilient future for bulk lyophilization thus becoming a notable trend in the US bulk lyophilization services market.

End User-Based Insights

Based on distribution channel, the US bulk lyophilization services market is segmented into Pharmaceutical and Biotechnology Companies, Research and Academic Institutes, Others. The pharmaceutical and biotechnology companies segment held the largest US bulk lyophilization services market share in 2024. Pharmaceutical and biotechnology companies represent the dominant end-user segment, leveraging these services to stabilize heat-sensitive biologics, vaccines, and parenteral drugs for extended shelf life and global distribution. These firms outsource lyophilization to specialized CDMOs to accelerate time-to-market while minimizing capital investments in in-house equipment. For instance, Moderna relies on these services for mRNA-based therapies, where freeze-drying preserves lipid nanoparticles against degradation. Growth in this segment is propelled by the exponential rise in biologic drug approvals, with the FDA greenlighting over 50 novel biologics annually in recent years, necessitating scalable preservation techniques for complex molecules like monoclonal antibodies and gene therapies. The shift toward personalized medicine further amplifies demand, as custom formulations require precise lyophilization cycles to maintain efficacy. Additionally, regulatory pressures for stringent quality control—such as compliance with cGMP standards—drive outsourcing, allowing pharma giants to focus on R&D. Supply chain disruptions, highlighted by the 2021-2023 global shortages, have underscored the value of domestic US providers for resilient manufacturing. Technological advancements,

including continuous lyophilization processes that reduce cycle times by up to 30%, attract biotech startups scaling from pilot to commercial batches. Environmental sustainability initiatives also contribute, as energy-efficient lyophilizers align with ESG goals, reducing carbon footprints in production. Overall, the convergence of innovation in immunotherapy and oncology drugs, coupled with a projected doubling of the US biologics pipeline by 2030, positions this segment for sustained expansion, fostering partnerships with CDMOs for customized solutions that enhance drug stability and bioavailability.

Investor presentation, company website is among the primary and secondary sources referred to while preparing the US bulk lyophilization services 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 US Bulk Lyophilization Services 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 US Bulk Lyophilization Services 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 US Bulk Lyophilization Services 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

The List of Companies - US Bulk Lyophilization Services Market

Hudson Valley Lyomac

Alcami Corporation

Affinity Life Sciences

OFD Life Sciences.

Quality BioResources

Symbiosis

Lyophilization Technology, Inc.

Attwill

PCI Pharma Services,

Catachem Inc.

Contents

1. INTRODUCTION

- 1.1 Report Guidance
- 1.2 Market Segmentation

2. EXECUTIVE SUMMARY

- 2.1 Analyst Market Outlook

3. US BULK LYOPHILIZATION SERVICES MARKET LANDSCAPE

- 3.1 Overview
- 3.2 Value Chain Analysis
 - 3.2.1 Bulk Lyophilization Services Market – Value Chain Analysis
 - 3.2.2 Raw Material Suppliers / Components
 - 3.2.3 Manufacturers Process / Technology
 - 3.2.4 Distribution Landscape
- 3.3 Supply Chain Analysis
 - 3.3.1 List of Service Providers
 - 3.3.2 List of Potential Customers
- 3.4 PEST Analysis
- 3.5 Impact of Artificial Intelligence (AI)
- 3.6 Technology Roadmap
- 3.7 Sustainability and ESG Trends
- 3.8 Regulatory Framework

4. COMPETITIVE LANDSCAPE

- 4.1 Heat Map Analysis by Key Players
- 4.2 Market Concentration Analysis, 2024
- 4.3 Company Market Share (%) Analysis, 2024

5. US BULK LYOPHILIZATION SERVICES MARKET – KEY MARKET DYNAMICS

- 5.1 US Bulk Lyophilization Services Market – Key Market Dynamics
- 5.2 Market Drivers
 - 5.2.1 Robust Growth in the Biopharmaceutical Sector

- 5.2.2 Increasing Outsourcing Demand
- 5.2.3 Stringent Regulatory Compliance and Technological Advancements
- 5.3 Market Restraints
 - 5.3.1 High Operational Costs
 - 5.3.2 Process Complexity and Optimization Challenges
 - 5.3.3 Supply Chain/Input Constraints
- 5.4 Market Opportunities
 - 5.4.1 Rise in Lyophilization for Advanced Therapies
 - 5.4.2 Growing Importance of Cycle Development and Optimization Services
 - 5.4.3 Shift Toward Continuous Lyophilization
- 5.5 Future Trends
 - 5.5.1 Adoption of Advanced Monitoring Systems
 - 5.5.2 Focus on Sustainability and Green Technologies
 - 5.5.3 Integration of AI, Automation, and Robotics
- 5.6 Impact of Drivers and Restraints:

6. US BULK LYOPHILIZATION SERVICES MARKET ANALYSIS

- 6.1 US Bulk Lyophilization Services Market Revenue (US\$ Million), 2021–2031
- 6.2 US Bulk Lyophilization Services Market Forecast and Analysis

7. US BULK LYOPHILIZATION SERVICES MARKET ANALYSIS – BY LYOPHILIZATION FORMAT

- 7.1 Bulk Tray Lyophilization
 - 7.1.1 Overview
 - 7.1.2 Bulk Tray Lyophilization: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)
- 7.2 Drum Lyophilization
 - 7.2.1 Overview
 - 7.2.2 Drum Lyophilization: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)
- 7.3 Shelf Freeze-Drying
 - 7.3.1 Overview
 - 7.3.2 Shelf Freeze-Drying: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)
- 7.4 Tunnel or Conveyer Based Freeze Drying
 - 7.4.1 Overview
 - 7.4.2 Tunnel or Conveyer Based Freeze Drying: US Bulk Lyophilization Services Market

– Revenue and Forecast, 2021–2031 (US\$ Million)

7.5 Hybrid Methods

7.5.1 Overview

7.5.2 Hybrid Methods: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

8. US BULK LYOPHILIZATION SERVICES MARKET ANALYSIS – BY SCALE

8.1 Small Scale or Lab Scale

8.1.1 Overview

8.1.2 Small Scale or Lab Scale: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

8.2 Pilot Scale

8.2.1 Overview

8.2.2 Pilot Scale: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

8.3 Commercial and Industrial Scale

8.3.1 Overview

8.3.2 Commercial and Industrial Scale: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

9. US BULK LYOPHILIZATION SERVICES MARKET ANALYSIS – BY SERVICE TYPE

9.1 Custom Process Development and Optimization

9.1.1 Overview

9.1.2 Custom Process Development and Optimization: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

9.2 Pilot Scale and R and D Lyophilization

9.2.1 Overview

9.2.2 Pilot Scale and R and D Lyophilization: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

9.3 Full Scale Commercial Bulk Lyophilization

9.3.1 Overview

9.3.2 Full Scale Commercial Bulk Lyophilization: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

10. US BULK LYOPHILIZATION SERVICES MARKET ANALYSIS – BY END USER

10.1 Pharmaceutical and Biotechnology Companies

10.1.1 Overview

10.1.2 Pharmaceutical and Biotechnology Companies: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

10.2 Research and Academic Institutes

10.2.1 Overview

10.2.2 Research and Academic Institutes: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

10.3 Others

10.3.1 Overview

10.3.2 Others: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

11. US BULK LYOPHILIZATION SERVICES MARKET INDUSTRY LANDSCAPE

11.1 Overview

11.2 Agreements, Collaborations, and Joint Ventures

11.3 Expansions and Other Strategic Developments

12. COMPANY PROFILES

12.1 Hudson Valley Lyomac

12.1.1 Key Facts

12.1.2 Business Description

12.1.3 Products and Services

12.1.4 Financial Overview

12.1.5 SWOT Analysis

12.1.6 Key Developments

12.2 Alcami Corporation

12.2.1 Key Facts

12.2.2 Business Description

12.2.3 Products and Services

12.2.4 Financial Overview

12.2.5 SWOT Analysis

12.2.6 Key Developments

12.3 Affinity Life Sciences, Inc.

12.3.1 Key Facts

12.3.2 Business Description

12.3.3 Products and Services

- 12.3.4 Financial Overview
- 12.3.5 SWOT Analysis
- 12.3.6 Key Developments
- 12.4 OFD Life Sciences
 - 12.4.1 Key Facts
 - 12.4.2 Business Description
 - 12.4.3 Products and Services
 - 12.4.4 Financial Overview
 - 12.4.5 SWOT Analysis
 - 12.4.6 Key Developments
- 12.5 Quality BioResources
 - 12.5.1 Key Facts
 - 12.5.2 Business Description
 - 12.5.3 Products and Services
 - 12.5.4 Financial Overview
 - 12.5.5 SWOT Analysis
 - 12.5.6 Key Developments
- 12.6 Symbiosis Pharmaceutical Services Ltd
 - 12.6.1 Key Facts
 - 12.6.2 Business Description
 - 12.6.3 Products and Services
 - 12.6.4 Financial Overview
 - 12.6.5 SWOT Analysis
 - 12.6.6 Key Developments
- 12.7 Lyophilization Technology, Inc.
 - 12.7.1 Key Facts
 - 12.7.2 Business Description
 - 12.7.3 Products and Services
 - 12.7.4 Financial Overview
 - 12.7.5 SWOT Analysis
 - 12.7.6 Key Developments
- 12.8 ATTWILL Medical Solutions
 - 12.8.1 Key Facts
 - 12.8.2 Business Description
 - 12.8.3 Products and Services
 - 12.8.4 Financial Overview
 - 12.8.5 SWOT Analysis
 - 12.8.6 Key Developments
- 12.9 PCI Pharma Services

- 12.9.1 Key Facts
- 12.9.2 Business Description
- 12.9.3 Products and Services
- 12.9.4 Financial Overview
- 12.9.5 SWOT Analysis
- 12.9.6 Key Developments
- 12.10 Catachem Inc.
- 12.10.1 Key Facts
- 12.10.2 Business Description
- 12.10.3 Products and Services
- 12.10.4 Financial Overview
- 12.10.5 SWOT Analysis
- 12.10.6 Key Developments

13. APPENDIX

- 13.1 About The Insight Partners
- 13.2 Glossary of Terms

14. RESEARCH METHODOLOGY

- 14.1 Secondary Research
- 14.2 Primary Research
 - 14.2.1 Hypothesis formulation:
 - 14.2.2 Macro-economic factor analysis:
 - 14.2.3 Developing base number:
 - 14.2.4 Data Triangulation:
 - 14.2.5 Country level data:
- 14.3 Assumptions and Limitations

List Of Tables

LIST OF TABLES

Table 1. US Bulk Lyophilization Services Market Segmentation

Table 2. List of Service Providers

Table 3. List of Potential Customers

Table 4. List of Regulatory Bodies and Organizations

Table 5. Heat Map Analysis by Key Players

Table 6. Company Market Share (%) Analysis, 2024

Table 7. US Bulk Lyophilization Services Market – Revenue, 2021–2024 (US\$ Million)

Table 8. US Bulk Lyophilization Services Market – Revenue Forecast, 2025–2031 (US\$ Million)

Table 9. Glossary of Terms, US Bulk Lyophilization Services Market

List Of Figures

LIST OF FIGURES

Figure 1. US Bulk Lyophilization Services Market Segmentation

Figure 2. PEST Analysis

Figure 3. Market Concentration Analysis, 2024

Figure 4. Impact Analysis of Drivers and Restraints

Figure 5. US Bulk Lyophilization Services Market Revenue (US\$ Million), 2021–2031

Figure 6. US Bulk Lyophilization Services Market Share (%) – by Lyophilization Format, 2024 and 2031

Figure 7. Bulk Tray Lyophilization: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 8. Drum Lyophilization: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 9. Shelf Freeze-Drying Tunnel or Conveyer Based: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 10. Freeze Drying: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 11. Hybrid Methods: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 12. US Bulk Lyophilization Services Market Share (%) – by Scale, 2024 and 2031

Figure 13. Small Scale or Lab Scale: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 14. Pilot Scale: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 15. Commercial and Industrial Scale: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 16. US Bulk Lyophilization Services Market Share (%) – by Service Type, 2024 and 2031

Figure 17. Custom Process Development and Optimization: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 18. Pilot Scale and R and D Lyophilization: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 19. Full Scale Commercial Bulk Lyophilization: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 20. US Bulk Lyophilization Services Market Share (%) – by End User, 2024 and

2031

Figure 21. Pharmaceutical and Biotechnology Companies: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 22. Research and Academic Institutes: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

Figure 23. Others: US Bulk Lyophilization Services Market – Revenue and Forecast, 2021–2031 (US\$ Million)

I would like to order

Product name: US Bulk Lyophilization Services Market Size and Forecast (2021 - 2031), Country Share, Trend, and Growth Opportunity Analysis Report Coverage: By Lyophilization Format (Bulk Tray Lyophilization, Drum Lyophilization, Shelf Freeze-Drying, Tunnel or Conveyer Based Freeze Drying, and Hybrid Methods), Scale (Small Scale or Lab Scale, Pilot Scale, and Commercial and Industrial Scale), Service Type (Custom Process Development and Optimization, Pilot Scale and Research and Development Lyophilization, and Full Scale Commercial Bulk Lyophilization), and End User (Pharmaceutical and Biotechnology Companies, Research and Academic Institutes, and Others), and Geography

Product link: <https://marketpublishers.com/r/U4BA2FE36190EN.html>

Price: US\$ 2,450.00 (Single User License / Electronic Delivery)

If you want to order Corporate License or Hard Copy, please, contact our Customer Service:

info@marketpublishers.com

Payment

To pay by Credit Card (Visa, MasterCard, American Express, PayPal), please, click button on product page <https://marketpublishers.com/r/U4BA2FE36190EN.html>