

Automated And Closed Cell Therapy Processing Systems Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Workflow (Separation, Expansion, Apheresis, Fill-Finish, Cryopreservation, Others), By Type (Stem Cell Therapy, Non-Stem Cell Therapy), By Scale (Pre-commercial/ R&D Scale, Commercial Scale), By Region, By Competition

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Abstracts

Global Automated And Closed Cell Therapy Processing Systems Market has valued at USD 910.65 million in 2022 and is anticipated to project impressive growth in the forecast period with a CAGR of 9.10% through 2028. The increasing appeal of regenerative medicine and cell therapies, along with the numerous advantages associated with automation technologies in their development, is projected to drive market expansion. Moreover, the increasing incorporation of software technologies into advanced therapy development procedures is also expected to stimulate market growth. Additionally, the rising investments made by biopharmaceutical manufacturers in the development of cellular therapy products, supported by multiple rounds of funding, are poised to provide attractive growth prospects for the market.

Key Market Drivers

Growing Popularity of Regenerative Medicine and Cell Therapies

Regenerative medicine and cell therapies represent a groundbreaking frontier in modern healthcare, offering new hope for treating a variety of challenging medical

conditions. As these therapies gain momentum and continue to demonstrate their effectiveness, they are poised to significantly impact the healthcare industry. One crucial factor enabling the scalability and efficiency of regenerative medicine and cell therapy production is the adoption of automated and closed cell therapy processing systems.

The increasing popularity of regenerative medicine and cell therapies has led to a surge in demand for these groundbreaking treatments. However, with greater demand comes the need for efficient, scalable, and consistent manufacturing processes. Automated and closed cell therapy processing systems offer a solution to this challenge. They can handle large-scale production while maintaining precise control over cell culture conditions. This scalability is essential to meet the growing global demand for these therapies.

One of the key factors driving the adoption of automated systems is their ability to enhance quality control and standardization. Manual cell therapy processing can be prone to human errors and variability, which can compromise product quality and safety. Automated systems, on the other hand, provide a controlled and reproducible environment, ensuring that each batch of cell therapy products meets stringent quality standards. This level of consistency is crucial for regulatory compliance and patient safety.

Automation technologies streamline complex cell therapy manufacturing workflows, significantly reducing production costs. These systems can perform tasks such as cell culture, harvesting, and processing with high precision and efficiency. The reduced need for manual labor not only cuts labor costs but also minimizes the risk of contamination and product loss, further boosting cost-effectiveness.

The rapid development of regenerative medicine and cell therapies requires streamlined and efficient manufacturing processes. Automated systems enable faster production and quicker turnaround times. This acceleration in development timelines can bring promising therapies to patients sooner, increasing their accessibility and potentially saving lives.

Regulatory bodies worldwide are recognizing the potential of regenerative medicine and cell therapies and are establishing clear guidelines for their development and production. Automated and closed cell therapy processing systems play a critical role in helping manufacturers adhere to these regulations. These systems provide the necessary documentation, traceability, and data integrity required for regulatory

approval, ensuring that therapies can reach the market faster.

As researchers and scientists continue to uncover the potential of regenerative medicine and cell therapies, new clinical applications are emerging. These therapies are no longer confined to a niche market but are being explored for a broader range of medical conditions, from cancer to degenerative diseases and beyond. The flexibility and adaptability of automated systems make them ideal for accommodating the diverse needs of this expanding field.

Benefits of Automation Technologies

In the rapidly evolving field of regenerative medicine and cell therapies, automation technologies are emerging as a driving force behind progress and innovation. These cutting-edge technologies offer a range of benefits that are not only transforming the way cell therapies are developed and manufactured but are also propelling the growth of the global automated and closed cell therapy processing systems market.

Automation technologies excel in providing precision and consistency throughout the cell therapy manufacturing process. These systems can execute complex tasks with the utmost accuracy, eliminating human error and variability. By ensuring a controlled and reproducible environment, they enhance the quality of cell therapy products, making them more reliable and effective. This precision is essential for both research and clinical applications, fostering trust among stakeholders and regulatory bodies.

The scalability and efficiency of automated systems are paramount in meeting the growing demand for cell therapies. As the popularity of regenerative medicine and cell therapies continues to rise, the need for large-scale production becomes apparent. Automation technologies enable manufacturers to scale up their operations while maintaining consistent product quality. This not only satisfies the increasing market demand but also reduces production costs, making therapies more accessible.

Automation technologies streamline and simplify complex cell therapy manufacturing workflows. These systems can perform a multitude of tasks, from cell culture and harvesting to processing and quality control, with minimal human intervention. This streamlining of workflows reduces the time and resources required for production, ultimately speeding up the development timeline and bringing therapies to patients sooner.

By automating labor-intensive processes, companies can significantly reduce labor

costs. Automated systems can work around the clock without the need for rest or breaks, contributing to cost-effectiveness. The reduction in labor costs translates into more affordable therapies for patients, widening access and increasing market penetration.

Automation technologies offer robust data management capabilities, allowing for real-time monitoring, data analysis, and documentation. This ensures complete traceability of the manufacturing process, a critical requirement for regulatory compliance. The ability to track and trace each step of production enhances product safety and quality, making it easier to obtain regulatory approvals and market access.

Integration of Software Technologies

In the fast-evolving landscape of regenerative medicine and cell therapies, the integration of advanced software technologies is emerging as a key driver of innovation and efficiency. These software solutions are not just streamlining processes; they are also playing a significant role in boosting the growth of the global automated and closed cell therapy processing systems market.

One of the most compelling advantages of software integration in cell therapy processing systems is the ability to provide real-time monitoring and control. Researchers and manufacturers can track critical parameters such as temperature, pH levels, and cell viability in real-time. Any deviations from the desired conditions can be swiftly addressed, ensuring that the cell therapy production process remains on track. This level of control enhances the quality and consistency of the final product.

Advanced software technologies enable in-depth data analysis, allowing researchers and manufacturers to gain valuable insights into their processes. These insights can be used to optimize production workflows, identify bottlenecks, and enhance yields. Data-driven decision-making is becoming increasingly crucial in the competitive cell therapy market, where efficiency and cost-effectiveness are paramount.

Integration of software technologies enables the automation of various aspects of cell therapy production, from cell culture to harvesting and quality control. This automation reduces the need for manual intervention, minimizing the risk of human errors and increasing overall efficiency. By streamlining workflows, software integration accelerates production timelines, allowing therapies to reach patients faster.

The regulatory landscape for cell therapy manufacturing is becoming more stringent.

Software solutions can facilitate compliance by providing comprehensive documentation and traceability throughout the production process. This documentation is invaluable when seeking regulatory approvals, ensuring that therapies meet the required safety and quality standards.

In an era where remote work and collaboration are becoming the norm, software integration offers the advantage of remote monitoring and accessibility. Researchers and manufacturers can monitor and control cell therapy processes from anywhere in the world, facilitating collaboration and reducing the need for physical presence in the manufacturing facility. This flexibility is particularly valuable in global supply chains and collaborations.

The field of regenerative medicine and cell therapies is constantly evolving, with new technologies and research findings emerging regularly. Software-integrated cell therapy processing systems are designed to be adaptable, allowing them to incorporate and integrate emerging technologies seamlessly. This adaptability ensures that manufacturers can stay at the cutting edge of innovation.

Increased Investment by Bio Manufacturers

The field of regenerative medicine and cell therapies has witnessed a surge in interest and optimism in recent years, promising groundbreaking treatments for a wide range of medical conditions. A critical enabler of this progress is the increased investment by bio manufacturers in the development and commercialization of these therapies. A noteworthy consequence of this surge in funding is the substantial growth of the global automated and closed cell therapy processing systems market.

The influx of investments from bio manufacturers has accelerated research and development efforts in the field of regenerative medicine and cell therapies. These funds are being used to explore new therapeutic approaches, conduct pre-clinical and clinical trials, and develop innovative cell therapy products. This surge in R&D activities has created a strong demand for automated and closed cell therapy processing systems, as these technologies are essential for efficiently translating promising therapies from the laboratory to commercial production.

To meet the growing demand for cell therapies, bio manufacturers are investing in the construction of state-of-the-art production facilities. These facilities are designed to handle large-scale manufacturing, producing cell therapy products at volumes that can cater to the global market. The adoption of automated cell therapy processing systems

is crucial in these facilities to ensure scalability, consistency, and cost-effectiveness in the manufacturing process.

The investment surge by bio manufacturers is also directed towards conducting extensive clinical trials to demonstrate the safety and efficacy of cell therapies. Successful trial outcomes pave the way for regulatory approvals and commercialization. Automated and closed cell therapy processing systems are indispensable in ensuring that therapies produced for clinical trials are of consistent quality and meet rigorous regulatory standards. They also enable a smooth transition from clinical trials to commercial-scale manufacturing.

As bio manufacturers diversify their cell therapy product portfolios, they require adaptable and versatile processing systems. Investments allow manufacturers to explore a broader range of cell therapy applications, from oncology to degenerative diseases and beyond. Automated systems can be tailored to accommodate various cell types and production requirements, making them an attractive choice for manufacturers pursuing diverse therapeutic avenues.

Increased investments by bio manufacturers contribute to market accessibility and affordability. By funding research, development, and production capabilities, these investments help bring cell therapies to a wider range of patients, addressing unmet medical needs. Automated processing systems play a crucial role in ensuring that cell therapies are both accessible and affordable, as they optimize production efficiency and reduce manufacturing costs.

Key Market Challenges

High Initial Costs

One of the most significant challenges in the adoption of automated cell therapy processing systems is the substantial upfront investment required. The cost of acquiring and implementing these sophisticated technologies can be prohibitive for smaller biotech companies and research institutions. The initial financial burden may deter some potential stakeholders from entering the market.

Technical Expertise

Operating and maintaining automated cell therapy processing systems requires a high level of technical expertise. Training staff and ensuring that they have the necessary

skills to operate these complex systems can be a time-consuming and resource-intensive endeavor. A shortage of skilled personnel in the field can pose a significant challenge for companies looking to adopt automated technologies.

Integration with Existing Workflows

Integrating automated systems into existing manufacturing workflows can be a complex process. Compatibility issues, process modifications, and potential disruptions during integration can be daunting for companies. Seamless integration is crucial to maximize the efficiency and benefits of automation, but it can be a major challenge to achieve.

Key Market Trends

Miniaturization and Modularization

Miniaturization of equipment and the development of modular processing systems are gaining traction. Smaller, more portable systems allow for greater flexibility in cell therapy manufacturing, making it easier to set up production facilities and conduct research in various settings. This trend supports scalability and adaptability in the field.

Advanced Sensor Technologies

The integration of advanced sensor technologies is becoming increasingly important. These sensors provide real-time monitoring and feedback on critical parameters such as cell viability, pH levels, and temperature. Enhanced sensors enable precise control over the manufacturing environment, ensuring consistent product quality and regulatory compliance.

Closed Systems for Improved Safety

Closed processing systems are becoming the gold standard for cell therapy manufacturing. These systems reduce the risk of contamination, ensuring the safety and purity of cell therapy products. As patient safety is paramount, the adoption of closed systems will continue to rise, particularly for commercial-scale production.

Segmental Insights

Workflow Insights

Based on the category of Workflow, the most substantial revenue share in 2022 came from the expansion segment. This growth can largely be attributed to the extensive range of products available within this segment. Furthermore, the proliferation of partnerships among market players, aimed at adopting and applying systems within this segment, has been a significant driver of its expansion. As an example, Angiocrine Bioscience has successfully integrated Terumo BCT's quantum cell expansion system to expedite its cell therapy research efforts.

Moving forward, it is anticipated that the separation segment will exhibit the highest CAGR during the forecast period. The cell separation process plays a pivotal role in various cellular experiments, including molecular analysis, cellular genetic modification, hybridoma production, and other cell research and analysis-related applications. The growth in this segment is expected to be bolstered by the increasing number of research activities in academic universities and other research settings for these applications.

In addition to expansion and separation, the workflow segment encompasses apheresis, fill-finish, cryopreservation, and other components. Cryopreservation and apheresis workflows are also poised for significant growth, thanks to the rising awareness and acceptance of regenerative medicines.

In February 2023, Cell and Gene Therapy Catapult, a UK-based company, made an announcement about its involvement in the development of an extensive new life science campus in Stevenage, for which the company has allocated a budget exceeding USD 900 million. This new campus is being established to meet the surging demand within the life sciences industry.

Type Insights

In 2022, the non-stem cell therapy sector captured the largest share of revenue and is projected to experience the most rapid CAGR in the coming forecast period. The expected boost in segment growth is primarily driven by a rising number of product launches targeting non-stem cell therapy applications. Additionally, the success of CAR-T therapies has led to increased investments in the development of non-stem cell therapies, further contributing to revenue growth.

In February, IASO Biotherapeutics, a clinical-stage biopharmaceutical company specializing in cutting-edge cell therapies, announced that the Food and Drug Administration (FDA) had granted Fast Track (FT) Designation and Regenerative

Medicine Advanced Therapy (RMAT) Designation to its novel BCMA CAR-T CT103A (Equecabtagene Autoleucel) drug. This medication has the potential to treat Relapsed/Refractory Multiple Myeloma (RRMM), an aggressive form of blood cancer that no longer responds to conventional cell treatments.

Companies are actively forming partnerships and collaborations to develop innovative regenerative medicines for the treatment of chronic conditions. These research endeavors primarily focus on non-stem cell applications, thereby propelling the growth of the non-stem cell therapy segment. Furthermore, the increasing emphasis on cell and tissue-based engineering, driven by its significant clinical potential, is expected to further accelerate segment growth in the forecast period.

Conversely, the stem cell therapy segment is also anticipated to experience substantial growth during the forecast period. This growth is driven by the growing awareness of the therapeutic benefits offered by stem cell therapies and the increasing research efforts aimed at enhancing drug effectiveness and understanding disease mechanisms.

Regional Insights

In 2022, North America asserted its dominance in the market, capturing the largest share of revenue. This commanding position was primarily attributed to the increased adoption of advanced technology for cell therapy processing and a strong focus on achieving high precision and production throughput. The regional market is poised to continue expanding steadily, maintaining a Compound Annual Growth Rate (CAGR) from 2023 to 2030. This growth is driven by the significant demand for regenerative medicines in the healthcare sector of the region. Furthermore, the substantial investments made by market players and research institutes are expected to be pivotal in fostering the region's growth.

In contrast, Europe and Asia Pacific are expected to witness substantial growth rates during the forecast period. The European market is anticipated to benefit from a robust facility network and a skilled workforce in various European countries, which is projected to fuel market expansion. In recent years, there has been a series of introductions of fully automated platforms in European countries capable of supporting the entire bioprocess workflow, from initiation to completion.

On the other hand, the notable growth of the market in the Asia Pacific region can be attributed to several key factors. These include increasing government and private investments, rising healthcare needs, and the establishment of expedited approval

pathways for medical products.

Key Market Players

Miltenyi Biotec Inc

Lonza Group AG

Fresenius Kabi AG

Cytiva Europe GmbH

Biospherix Ltd

Terumo Corp

Sartorius AG

ThermoGenesis Holdings Inc

Cellares Corporation

Thermo Fisher Scientific Inc

Report Scope:

In this report, the Global Automated And Closed Cell Therapy Processing Systems Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Automated And Closed Cell Therapy Processing Systems Market, By Workflow:

Separation

Expansion

Apheresis

Fill-Finish

Cryopreservation

Others

Automated And Closed Cell Therapy Processing Systems Market, By Type:

Stem Cell Therapy

Non-Stem Cell Therapy

Automated And Closed Cell Therapy Processing Systems Market, By Scale:

Pre-commercial/ R&D Scale

Commercial Scale

Automated And Closed Cell Therapy Processing Systems Market, By Region:

North America

United States

Canada

Mexico

Europe

Germany

United Kingdom

France

Italy

Spain

Asia-Pacific

China

Japan

India

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Kuwait

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Automated And Closed Cell Therapy Processing Systems Market.

Available Customizations:

Global Automated And Closed Cell Therapy Processing Systems market report with the

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given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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