

Global Isolator Market: Analysis By Tier (High-value & Low-value), By Type (Premium & Mid-tier), By Region (North America, Europe, Asia Pacific and ROW), Size and Trends with Impact of COVID-19 and Forecast up to 2028

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Abstracts

The global isolator market was valued at US\$1.63 billion in 2022 and is expected to be worth US\$3.14 billion in 2028. An isolator is a bacteriologically sealed enclosure used in the medical and pharmaceutical environment for toxic processes and aseptic filling process. It is made of a perfectly sterile main isolator where the products are handled, stored or packaged using shoulder high gloves placed on one of the walls. It also includes transfer systems that allow the entry and exit of the products and the elimination of waste without breaking aseptic conditions.

The market is projected to grow at a CAGR of 11.52% over the projected period of 2023-2028. Isolators, also known as isolation systems or isolator gloves, are specialized devices used to provide physical and/or microbiological isolation for handling hazardous substances or carrying out sensitive operations. They are commonly used in industries such as pharmaceuticals, biotechnology, healthcare, and research laboratories. The isolator market is growing due to increasing demand for high quality, contamination-free products across various industries. Furthermore, the growing preference for injectable medications and personalized medicines, accompanied by the movement towards re-shoring, is contributing to the higher demand for isolators. Consequently, cleanrooms and Restricted Access Barrier Systems (RABS) are being substituted, providing lucrative opportunities to the market.

Market Segmentation Analysis:

By Tier: The report identifies two segments based on tier: High-value and Low-value. The high-value isolator market refers to the sector of pharmaceutical manufacturing that has stringent regulatory standards. On the other hand, the low-value isolator market includes countries with lower manufacturing costs, where the use of isolators is not as widespread. The high-value segment is further classified in two types: premium and mid-tier. The share of high value isolators has grown significantly throughout the years due to the presence of standard quality in providing sterile environment. Within this segment, premium high value isolators are gaining high popularity due their increasing adoption by CDMOs (Contract Development Manufacturing Organizations).

By Region: In the report, the global isolator market is divided into four regions: North America, Europe, Asia Pacific, and ROW. North America accounted for the maximum share in the global market in 2022. This can be attributed to the region's well-established healthcare infrastructure, the presence of key pharmaceutical and medical device companies in the region, an increase in the burden of noncommunicable diseases, and increased awareness of cosmeceuticals and nutraceuticals. Furthermore, strict regulations governing the approval of healthcare products in this region, such as the US, have increased demand for isolators.

However, the market in Asia Pacific is expected to grow rapidly over the forecast period. Investment in healthcare development is also increasing in this region. The increase in generic drug production due to branded drug patent expirations, growing geriatric population, and increasing burden of noncommunicable diseases are the major factors driving the growth of the pharmaceutical industry in Asia Pacific, thereby attributing to the growth of the isolator market.

Market Dynamics:

Growth Drivers: One of the key drivers of the market's expansion is the growth in biopharmaceuticals industry. The growth of the biopharmaceuticals industry has fueled the demand for isolators, specialized containment systems used in pharmaceutical manufacturing. Biopharmaceuticals, derived from biological sources, require a controlled and sterile environment to ensure product safety and efficacy. Isolators meet this need by providing a closed system that prevents contamination and cross-contamination. The biopharmaceutical industry faces stringent regulatory requirements, and isolators help companies comply with these regulations by creating a controlled environment. Additionally, isolators ensure the quality of biopharmaceutical products by minimizing the risk of contamination from external sources. The rising demand for

personalized medicine, which involves small-scale production of specialized drugs, also drives the need for isolators. Other significant growth factors of the market include increasing prevalence of infectious diseases, growing demand from hospitals & ambulatory surgery centers, regulatory framework to support adoption of pharmaceutical isolators, rising demand for sterile products and increase in use of high potency active pharmaceutical ingredients.

Challenges: However, some challenges are impeding the growth of the market such as complex installation and maintenance, barriers to entry and limited flexibility. Installing isolators can be a complex process that requires expertise and specialized knowledge. The installation typically involves integrating the isolator system into existing infrastructure, such as cleanrooms or laboratories. This may require modifications to the facility, including HVAC (heating, ventilation, and air conditioning) systems, to ensure proper air filtration and pressure differentials. The installation process must also comply with regulatory guidelines and standards. Moreover, maintaining isolator systems is crucial to ensure their optimal performance and maintain the desired sterility levels. The complexity of maintenance and the need for trained personnel can increase the overall cost and time involved in managing isolator systems, thus hampering the market growth.

Trends: The market is projected to grow at a fast pace during the forecast period, due to explosive growth of cell & gene therapies in development, digital isolators, shift toward personalized medicine, and automation inside isolators. Digital isolators are a significant trend in the isolator market, offering numerous advantages over traditional optocouplers and other forms of isolation technology. Digital isolators use semiconductor-based technology to provide electrical isolation between input and output circuits, ensuring safety and data integrity in various applications. One key advantage of digital isolators is their superior performance and reliability. Unlike optocouplers, which rely on light-sensitive components, digital isolators use integrated circuits that are less prone to aging, temperature variations, and degradation over time. This results in improved long-term performance and stability. Digital isolators can operate at high data rates, enabling reliable communication in applications such as industrial automation, medical devices, and telecommunications.

Impact Analysis of COVID-19 and Way Forward:

The emergence of COVID-19 at the beginning of 2020 brought about unprecedented events. The pandemic highlighted the importance of isolators in preventing the spread of infectious diseases and protecting public health. The pharmaceutical and biotech

industries, in particular, have seen a surge in demand for isolators as they ramp up production of COVID-19 vaccines and treatments, thus driving the market upwards in 2020. Moreover, during the year, the CDER has approved several novel drugs and biologics, which also influenced the demand for isolators. The post-COVID environment also appears to be fortunate for the market. With the emergence of highly contagious diseases like COVID-19, there is a heightened emphasis on bio containment capabilities in isolators. Manufacturers are investing in developing isolators with enhanced biosecurity measures, such as negative pressure systems, multiple airlocks, and decontamination systems. These advancements aim to provide maximum protection to operators and prevent the release of harmful substances or pathogens. The post-COVID era has witnessed a rise in the adoption of advanced technologies in isolators. These include features such as HEPA (High-Efficiency Particulate Air) filtration systems, enhanced airflow management, and innovative sealing mechanisms. The integration of smart technologies and automation within isolators has also gained prominence to ensure efficient and safe operations.

Competitive Landscape:

Global isolator market is moderately consolidated across six companies: Skan, Syntegon, OPTIMA, FZ Franz Ziel, IMA and Comecer. SKAN is the global market leader in high-end aseptic manufacturing solutions that prevent contamination for the biopharmaceutical industry, with products ranging from customized and standard isolator solutions to automated aseptic filling stations.

The key players in the global isolator market are:

Azbil Corporation

Getinge AB

Hosokawa Micron Corporation

SKAN Group AG

ATS Automation Tooling Systems Inc. (Comecer)

Syntegon Packaging Technology GmbH

Franz Ziel GmbH

IMA (Industria Macchine Automatiche) S.p.A.

Optima Packaging Group

Germfree Laboratories Inc.

NuAire Inc.

HECHT Technologie Inc.

These players dominate the market due to product differentiation, financial stability, strategic developments, and diversified regional presence. The players are focused on investing in research and development. Furthermore, they adopt strategic growth initiatives, such as expansion, product launches, joint ventures, and partnerships, to strengthen their market position and capture a large customer base. Moreover, manufacturers are entering into agreements with biopharma/cell and gene therapy companies, academic & research institutes, hospitals, and contract research organizations for supply contracts. Therefore, manufacturers develop new products with refined features to increase favorability and stay ahead of their competitors.

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