

Bispecific Antibody Therapeutics Contract Manufacturing Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Indication (Cancer, Infectious Diseases, Autoinflammatory and Autoimmune Diseases, CNS Conditions, Others), By Route of Administration (Intravenous, Subcutaneous, Others), By End Use (Pharmaceutical Companies, Biopharmaceutical Companies, Others), By Region, By Competition Forecast & Opportunities, 2018-2028F

<https://marketpublishers.com/r/B2192F9FE45DEN.html>

Date: October 2023

Pages: 190

Price: US\$ 4,900.00 (Single User License)

ID: B2192F9FE45DEN

Abstracts

In 2022, the Global Bispecific Antibody Therapeutics Contract Manufacturing Market was valued at USD 5.02 billion, and it is expected to grow with a Compound Annual Growth Rate (CAGR) of 15.56% through 2028. The growth of the Global Bispecific Antibody Therapeutics Contract Manufacturing Market is substantial, driven by the increasing recognition within the biopharmaceutical industry of the potential of bispecific antibodies in treating complex diseases, including cancer and autoimmune disorders. Contract manufacturing organizations (CMOs) play a pivotal role in this market by offering their expertise and infrastructure for the efficient and cost-effective production of bispecific antibodies.

Several factors are propelling the market's growth, including the expanding pipeline of bispecific antibody candidates, the demand for specialized manufacturing capabilities, and the inclination to outsource production to focus on core competencies. As biopharmaceutical companies strive to advance novel therapeutic solutions, the

Bispecific Antibody Therapeutics Contract Manufacturing Market is poised to expand further, providing a wide range of services to support the development and production of these innovative therapies.

Key Market Drivers

Ongoing Research Activities in Bispecific Antibody Therapeutics

Ongoing research activities in Bispecific Antibody Therapeutics are instrumental in driving the Global Bispecific Antibody Therapeutics Contract Manufacturing Market. These activities are characterized by a relentless pursuit of innovative therapeutic solutions, resulting in an increasing number of bispecific antibody candidates in development. This surge in research fuels the demand for contract manufacturing services for bispecific antibodies, and here's how: The growing interest in bispecific antibodies is reflected in the expanding pipeline of drug candidates. Biopharmaceutical companies are investing heavily in research to develop bispecific antibodies targeting a wide range of diseases, from cancer to autoimmune disorders. The diversity of therapeutic indications drives the need for contract manufacturing partners with specialized expertise in producing these complex molecules.

Bispecific antibodies are highly complex molecules that often require advanced manufacturing technologies. Research efforts aim to optimize their design and functionality, resulting in the creation of novel bispecific formats. Contract manufacturing organizations (CMOs) are sought after to leverage their technical capabilities and infrastructure to produce these sophisticated therapeutics accurately. Ongoing research also contributes to advancements in biomanufacturing processes. Novel production methods, purification techniques, and cell line development strategies are continually refined to enhance the efficiency and scalability of bispecific antibody production. CMOs, at the forefront of these advancements, offer state-of-the-art manufacturing solutions to biopharmaceutical companies. Research activities explore novel therapeutic modalities and mechanisms of action for bispecific antibodies. This innovation leads to the development of groundbreaking therapies with improved efficacy and safety profiles. Contract manufacturing partners are indispensable for scaling up the production of these innovative bispecific antibodies for clinical trials and commercialization.

Collaborative research efforts between academia, biotech startups, and established pharmaceutical companies drive the discovery and development of bispecific antibodies. CMOs often collaborate with these entities, offering manufacturing support that enables research to progress swiftly from preclinical stages to clinical trials.

Research plays a pivotal role in advancing regulatory understanding of bispecific antibodies. Ongoing studies contribute to the development of robust regulatory guidelines for these complex therapeutics, providing clarity and consistency in manufacturing expectations. CMOs ensure compliance with these evolving regulations, facilitating successful product development. In conclusion, the dynamic landscape of bispecific antibody therapeutics, characterized by ongoing research and therapeutic innovation, propels the demand for contract manufacturing services. CMOs play a critical role in supporting the biopharmaceutical industry's quest for novel therapeutic solutions, making them integral partners in advancing the Global Bispecific Antibody Therapeutics Contract Manufacturing Market.

Rapid success of bispecific antibody therapeutics in cancer and non-cancer programs

The rapid success of bispecific antibody therapeutics in both cancer and non-cancer programs is a driving force behind the growth of the Global Bispecific Antibody Therapeutics Contract Manufacturing Market. Bispecific antibodies have emerged as a transformative class of biopharmaceuticals, and their versatile applications across various therapeutic areas are fostering a surge in research and development activities. Here's how the success of these therapeutics is fueling the contract manufacturing market. Bispecific antibodies have demonstrated remarkable success in cancer immunotherapy, particularly in redirecting immune cells to attack tumor cells. Approved bispecific antibodies like blinatumomab and emicizumab have set the stage for the development of new cancer treatments. As more biopharmaceutical companies invest in oncology programs, contract manufacturing organizations (CMOs) play a vital role in meeting the increasing demand for production capacity.

The success of bispecific antibodies in early-phase clinical trials has prompted a proliferation of programs across diverse therapeutic areas. Beyond cancer, these therapeutics are being explored for autoimmune diseases, infectious diseases, and more. CMOs are key partners in supporting these trials by providing the necessary expertise and infrastructure for manufacturing. With several bispecific antibody candidates advancing through late-stage clinical trials, the potential for commercialization is substantial. The successful launch of bispecific antibody products in the market drives biopharmaceutical companies to secure reliable manufacturing partners. CMOs offer the scalability and regulatory compliance required for large-scale production. The impressive clinical outcomes achieved by certain bispecific antibody therapeutics have attracted increased investment from both pharmaceutical companies and venture capitalists. This influx of capital accelerates the development of bispecific antibody pipelines, further driving the need for contract manufacturing services.

Bispecific antibodies often feature complex structures and unique manufacturing challenges. Success in developing and manufacturing these therapeutics requires specialized expertise. CMOs, with their experience in bispecific antibody production, become invaluable partners in navigating these complexities. As the success of bispecific antibodies transcends borders, the global market for these therapeutics expands. CMOs with a global presence are strategically positioned to offer manufacturing solutions to biopharmaceutical companies operating in different regions, promoting market growth. In conclusion, the rapid success of bispecific antibody therapeutics across cancer and non-cancer programs is a powerful catalyst for the Global Bispecific Antibody Therapeutics Contract Manufacturing Market. This success is driving increased research, clinical trials, investment, and demand for specialized manufacturing expertise. Contract manufacturing organizations are playing a pivotal role in supporting biopharmaceutical companies in realizing the full potential of bispecific antibodies, ensuring their timely and efficient production for the benefit of patients worldwide.

Bio manufacturing Advancements

Bio manufacturing advancements play a pivotal role in driving the Global Bispecific Antibody Therapeutics Contract Manufacturing Market by enhancing the efficiency, scalability, and cost-effectiveness of producing bispecific antibodies. These advancements are transforming the landscape of biopharmaceutical manufacturing, and their impact on the contract manufacturing sector is particularly significant. Firstly, innovations in single-use bioreactor technology have revolutionized the production of bispecific antibodies. Single-use systems eliminate the need for extensive cleaning and validation, reducing downtime between manufacturing runs. This enhances production agility, allowing contract manufacturing organizations (CMOs) to respond rapidly to changing client demands and expedite project timelines.

Secondly, process intensification techniques optimize bio manufacturing processes, resulting in higher yields and reduced production costs. These advancements are crucial for bispecific antibody production, as they help meet the growing demand for these complex molecules while keeping manufacturing expenses in check. CMOs at the forefront of process intensification can offer competitive pricing to their clients, further boosting their appeal. Automation and digitalization are also transforming bio manufacturing. Robotic systems, data analytics, and artificial intelligence are increasingly integrated into manufacturing processes, enhancing process control, data accuracy, and quality assurance. CMOs embracing these technologies ensure

consistent and high-quality bispecific antibody production, meeting stringent regulatory requirements. Furthermore, advances in cell line development and optimization contribute to higher expression levels and improved product quality. Contract manufacturers with expertise in cell line engineering can deliver superior yields and product attributes, making them preferred partners for biopharmaceutical companies.

Additionally, continuous manufacturing approaches are gaining traction in biomanufacturing. Continuous bioprocessing minimizes batch-to-batch variability and reduces production cycle times. CMOs adopting these methods can offer more efficient and sustainable manufacturing solutions for bispecific antibodies. The adoption of flexible and modular manufacturing facilities is another biomanufacturing advancement that benefits the contract manufacturing market. These facilities can be easily reconfigured to accommodate different production needs, enabling CMOs to efficiently produce bispecific antibodies with varying specifications. In conclusion, biomanufacturing advancements, including single-use systems, process intensification, automation, digitalization, cell line development, continuous manufacturing, and flexible facilities, are driving the Global Bispecific Antibody Therapeutics Contract Manufacturing Market. These innovations enhance the speed, cost-efficiency, and quality of bispecific antibody production, making contract manufacturing an indispensable partner for biopharmaceutical companies seeking to bring innovative therapies to market.

Evolving Healthcare Landscape

The evolving healthcare landscape is a significant driver behind the growth of the Global Bispecific Antibody Therapeutics Contract Manufacturing Market. As the healthcare industry undergoes transformative changes, the demand for innovative and personalized therapies, such as bispecific antibodies, is on the rise, and contract manufacturing organizations (CMOs) are playing a crucial role in meeting these evolving needs.

One of the key factors driving this market is the shift towards patient-centric care. In today's healthcare landscape, there is a growing emphasis on tailoring treatments to individual patient profiles, aiming for better outcomes and reduced side effects. Bispecific antibodies, with their ability to target multiple disease pathways or antigens simultaneously, align perfectly with this patient-centric approach. CMOs specializing in bispecific antibody manufacturing offer the flexibility needed to produce customized therapies that cater to individual patient requirements, ensuring that healthcare becomes more patient-focused. Additionally, healthcare systems worldwide are

grappling with the challenge of managing chronic and complex diseases. Bispecific antibodies, with their potential to address various therapeutic areas, including oncology, autoimmune diseases, and infectious diseases, provide a versatile solution. CMOs with expertise in manufacturing these complex molecules are well-positioned to support biopharmaceutical companies in developing therapies that tackle these healthcare challenges effectively.

Moreover, the evolving healthcare landscape is marked by a shift from traditional treatment modalities to novel, targeted biologics. Bispecific antibodies represent a cutting-edge approach to disease management, attracting significant attention from pharmaceutical companies and researchers. CMOs are instrumental in translating these innovative therapies from research and development into commercial production, ensuring that patients can access the latest advancements in healthcare. Furthermore, the demand for biologics, including bispecific antibodies, is driven by the need for effective treatments with fewer side effects. The evolving healthcare landscape is characterized by a growing awareness of safety and efficacy concerns associated with certain pharmaceuticals. Bispecific antibodies, known for their precise targeting, offer a safer alternative, and CMOs ensure their reliable and compliant production, aligning with the evolving healthcare quality standards. In conclusion, the evolving healthcare landscape, characterized by patient-centric care, the management of chronic diseases, the shift to targeted biologics, and a focus on safety and efficacy, is a major driver of the Global Bispecific Antibody Therapeutics Contract Manufacturing Market. CMOs that specialize in bispecific antibody production are poised to play a pivotal role in meeting the demands of this changing healthcare environment, ensuring that innovative and personalized therapies reach patients around the world.

Key Market Challenges

Challenges associated with manufacturing of bispecific antibody therapeutics The manufacturing of bispecific antibody therapeutics presents several complex challenges that require meticulous attention and innovative solutions. These challenges stem from the unique properties and design complexities of bispecific antibodies, making their production more intricate compared to traditional monoclonal antibodies. One of the primary challenges is the complexity of the bispecific antibody structure itself. These molecules typically combine two different antigen-binding specificities into a single entity, resulting in intricate molecular designs. This complexity demands precise control over the manufacturing process to ensure consistent quality and potency. Furthermore, bispecific antibodies often exhibit heterogeneity due to various post-translational modifications, such as glycosylation and oxidation. These variations can impact product

stability and efficacy, requiring manufacturers to employ advanced analytical techniques to monitor and control product quality. Scale-up and process development represent another set of challenges. As bispecific antibodies move from research and development to commercial production, manufacturers must establish scalable processes capable of meeting market demand while maintaining product consistency. Achieving this balance is particularly challenging given the complexities of bispecific antibody manufacturing.

Purification and separation are critical steps in bispecific antibody production. Separating bispecific antibodies from other impurities, including aggregates and host cell proteins, can be technically challenging due to the uniqueness of each bispecific antibody design. Manufacturers must develop customized purification strategies for each molecule, increasing the complexity of the manufacturing process. Additionally, manufacturing bispecific antibodies requires specialized equipment and facilities to accommodate their unique production needs. This includes bioreactors and chromatography systems tailored to bispecific antibody manufacturing, which can be cost-intensive to implement and maintain. Regulatory compliance is a constant challenge in biopharmaceutical manufacturing, and bispecific antibodies are no exception. Manufacturers must adhere to stringent quality and safety standards while navigating evolving regulatory guidelines specific to these innovative therapeutics.

Supply chain logistics present their own challenges. Bispecific antibodies often have short shelf lives, and their distribution must be carefully managed to maintain product integrity. This requires precise coordination between manufacturers, distributors, and healthcare providers. In conclusion, the manufacturing of bispecific antibody therapeutics poses several intricate challenges related to the unique structure of these molecules, process scalability, purification complexity, specialized equipment and facilities, regulatory compliance, and supply chain logistics. Overcoming these challenges requires ongoing innovation, advanced analytical methods, and a commitment to ensuring the consistent production of high-quality bispecific antibodies that meet the evolving needs of patients and the biopharmaceutical industry.

Scale-Up Challenges

Scale-up challenges represent a significant hurdle for the Global Bispecific Antibody Therapeutics Contract Manufacturing Market. The transition from laboratory-scale production to commercial-scale manufacturing is a complex process that demands careful planning, technical expertise, and meticulous execution. One of the primary issues in scaling up bispecific antibody manufacturing is the need for larger bioreactors

and production facilities. Laboratory-scale production often involves small bioreactors, which are insufficient to meet the demands of commercial production. The selection, installation, and validation of larger bioreactors are critical steps, and any errors can disrupt the manufacturing process. Moreover, process optimization is essential for maintaining product quality and yield during scale-up. Factors such as agitation, oxygen transfer, and nutrient supply must be carefully controlled to ensure that the cells producing bispecific antibodies perform consistently at larger scales. This involves not only adjusting parameters but also validating the scalability of the entire process.

Another challenge is the logistics of raw materials and consumables. Larger-scale production requires greater quantities of materials such as cell culture media, buffers, and purification resins. Ensuring a continuous supply chain for these critical components is essential to prevent disruptions in production. Purification of bispecific antibodies is inherently challenging due to their structural complexity and potential heterogeneity. Scaling up purification processes without compromising product purity and yield is a delicate task. Manufacturers must develop and validate purification strategies that are effective at larger scales while maintaining the quality of the final product. Regulatory considerations add another layer of complexity to scale-up efforts. Ensuring that the scaled-up process complies with regulatory standards and requirements is essential for obtaining approvals and commercializing bispecific antibody therapeutics. This includes validating the quality control methods and ensuring consistency in product attributes.

Furthermore, scale-up often involves technology transfer between different manufacturing sites or contract manufacturing organizations (CMOs). This process requires close collaboration, knowledge transfer, and comprehensive documentation to ensure that the product remains consistent and meets regulatory expectations. In conclusion, scale-up challenges in the Global Bispecific Antibody Therapeutics Contract Manufacturing Market are multifaceted and demand meticulous attention. Successful scale-up requires the integration of advanced technologies, process optimization, logistical planning, regulatory compliance, and seamless technology transfer. Overcoming these challenges is essential to meet the increasing demand for bispecific antibody therapeutics while ensuring product quality, safety, and regulatory adherence on a commercial scale. Collaborative efforts between biopharmaceutical companies and CMOs with expertise in bispecific antibody manufacturing are crucial to addressing these challenges effectively.

Key Market Trends

Increasing Demand for Bispecific Antibodies

The increasing demand for bispecific antibodies has emerged as a prominent and enduring trend driving the Global Bispecific Antibody Therapeutics Contract Manufacturing Market. This surge in demand is underpinned by several factors that collectively highlight the transformative potential of bispecific antibodies in addressing unmet medical needs across a spectrum of diseases. First and foremost, the unique capabilities of bispecific antibodies to simultaneously target two different antigens or pathways have sparked enthusiasm within the biopharmaceutical industry. This enthusiasm has led to a significant expansion of bispecific antibody pipelines, with numerous biopharmaceutical companies actively developing and advancing these molecules into clinical trials and commercialization. In oncology, bispecific antibodies, such as bispecific T-cell engagers (BiTEs), have demonstrated impressive clinical outcomes by harnessing the immune system to combat cancer cells. This success has fueled the development of bispecific antibodies for various cancers, creating a high demand for contract manufacturing services. Beyond oncology, bispecific antibodies show promise in addressing autoimmune disorders, infectious diseases, and other therapeutic areas, broadening their applicability. As researchers explore new disease targets and indications, the demand for contract manufacturing support in producing these diverse bispecific antibody formats continues to grow.

Furthermore, the trend towards personalized medicine is driving the customization of bispecific antibodies to suit specific patient populations or disease subtypes. This trend necessitates contract manufacturing partners capable of producing tailored therapies, contributing to the overall demand for specialized manufacturing expertise. In conclusion, the increasing demand for bispecific antibodies is a prevailing trend that propels the Global Bispecific Antibody Therapeutics Contract Manufacturing Market forward. As biopharmaceutical companies recognize the potential of these innovative therapeutics, the need for contract manufacturing services to support their development and production is expected to remain robust, making bispecific antibodies a focal point in the biopharmaceutical industry's quest for transformative therapies.

Technological Advancements

Technological advancements are at the forefront of the evolving trend within the Global Bispecific Antibody Therapeutics Contract Manufacturing Market. These advancements play a pivotal role in reshaping and enhancing the manufacturing landscape for bispecific antibodies, making them more accessible, cost-effective, and efficient to produce. One key facet of this trend is the continuous innovation in biomanufacturing

technologies. New and improved bioreactor designs, such as single-use systems, are revolutionizing the production of bispecific antibodies by offering flexibility and scalability. These systems reduce the time required for equipment preparation and validation, enabling contract manufacturing organizations (CMOs) to respond swiftly to changing client demands. Process intensification is another crucial aspect. Advanced techniques are optimizing bioprocessing, resulting in higher yields and reduced production costs. Process intensification not only enhances productivity but also helps meet the growing demand for bispecific antibodies without compromising quality. Automation and digitalization are also driving this trend. Robotics, artificial intelligence, and data analytics are increasingly integrated into manufacturing processes, enhancing control, data accuracy, and quality assurance. These technologies are instrumental in maintaining the consistency and reliability of bispecific antibody production. Furthermore, advancements in cell line development and optimization are contributing to higher expression levels and improved product quality. CMOs equipped with expertise in cell line engineering are well-positioned to deliver superior yields and product attributes.

The adoption of continuous manufacturing approaches is gaining momentum. Continuous bioprocessing minimizes batch-to-batch variability and reduces production cycle times. CMOs exploring these methods can offer more efficient and sustainable manufacturing solutions for bispecific antibodies. In summary, technological advancements are a driving force behind the trend in the Global Bispecific Antibody Therapeutics Contract Manufacturing Market. These innovations, including bioreactor advancements, process intensification, automation, digitalization, cell line development, and continuous manufacturing, are collectively enhancing the speed, cost-efficiency, and quality of bispecific antibody production. Contract manufacturing organizations that embrace these technologies are poised to meet the growing demand for bispecific antibodies with state-of-the-art manufacturing capabilities.

Segmental Insights

Indication Insights

In 2022, the cancer segment dominated the market, capturing a substantial market share. Cancer remains a global health challenge as the leading cause of death, driving significant research efforts. Within the realm of cancer immunotherapy, bispecific antibodies (bsABs) have gained prominence due to their remarkable clinical efficacy in cancer patients. This has spurred intensive efforts to translate bsABs into effective therapies. For example, in June 2022, Roche received conditional marketing

authorization from the European Commission for Lunsumio (mosunetuzumab), a CD20xCD3 T-cell binding bsAB used to treat relapsed or refractory follicular lymphoma patients who have undergone two prior systemic therapies.

Conversely, the segment focused on autoinflammatory, and autoimmune diseases is expected to maintain a steady growth rate throughout the forecast period. This is driven by the widespread adoption of novel bsAB therapeutics, which offer the potential to significantly enhance treatment efficacy. The prevalence of autoimmune diseases is substantial, with an estimated 14 million affected individuals in the U.S., encompassing 80 to 100 recognized autoimmune-related conditions. Notably, around 80% of those diagnosed are women, underscoring the importance of bsABs in addressing these health challenges.

End Use Insights

In 2022, the intravenous (IV) segment claimed the largest market share for global revenue. IV therapies play a crucial role in supporting the immune system to effectively combat cancer cells, representing a promising breakthrough in the treatment of certain cancer types. Moreover, antibody drugs have emerged as a hopeful avenue for patients with specific cancer conditions. According to the American Society of Hematology (ASH), bsAB therapy achieved a success rate of 73% among patients in a Phase I clinical trial involving 232 participants from various cancer centers worldwide, conducted between January 2018 and November 2021.

Concurrently, the subcutaneous segment is poised to experience the swiftest Compound Annual Growth Rate (CAGR) of 36.8% during the forecast period. Subcutaneous administration of bsABs demonstrated a significant positive response among patients dealing with relapsed or refractory multiple myeloma. The growing preference for subcutaneous delivery routes is expected to contribute significantly to market expansion in the foreseeable future. These factors collectively drive the segment's growth.

Regional Insights

In 2022, North America emerged as the dominant force in the market, commanding the largest share of revenue. The region's growth can be attributed to its well-established market, the increasing prevalence of cancer and infectious diseases, which necessitate advanced solutions. Additionally, the escalating research endeavors, a growing number of clinical trials, and substantial investments contribute significantly to the region's

expansion. Among North American countries, the United States stands out as the largest market for bsAB therapeutics contract manufacturing, primarily driven by the surge in clinical trials, research and development activities, and increased investments by companies.

Conversely, the Asia Pacific region is poised to witness the most rapid Compound Annual Growth Rate (CAGR) during the forecast period. The region's growth is underpinned by various factors, including the substantial burden of cancer and the pressing need for novel drugs, particularly in countries like Japan and China. Furthermore, increased market demand and a rising number of collaborative partnerships among companies are expected to fuel growth throughout the forecast period.

Key Market Players

Lonza Group AG

Creative Biolabs Inc

Amgen Inc

Johnson & Johnson

Wuxi Biologics Cayman Inc

Roche Holding AG

Sino Biological Inc

IQVIA Inc

Janssen Pharmaceuticals Inc

AbbVie Inc

Report Scope:

In this report, the Global Bispecific Antibody Therapeutics Contract Manufacturing Market has been segmented into the following categories, in addition to the industry

trends which have also been detailed below:

Bispecific Antibody Therapeutics Contract Manufacturing Market, By Indication:

Cancer

Infectious Diseases

Autoinflammatory and Autoimmune Diseases

CNS Conditions

Others

Bispecific Antibody Therapeutics Contract Manufacturing Market, By Route of Administration:

Intravenous

Subcutaneous

Others

Bispecific Antibody Therapeutics Contract Manufacturing Market, By Route of Administration:

Pharmaceutical Companies

Biopharmaceutical Companies

Others

Bispecific Antibody Therapeutics Contract Manufacturing Market, By Region:

North America

United States

Canada

Mexico

Europe

France

United Kingdom

Italy

Germany

Spain

Asia-Pacific

China

India

Japan

Australia

South Korea

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Kuwait

Turkey

Egypt

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Bispecific Antibody Therapeutics Contract Manufacturing Market.

Available Customizations:

Global Bispecific Antibody Therapeutics Contract Manufacturing market report with the 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).

Contents

1. PRODUCT OVERVIEW

2. RESEARCH METHODOLOGY

3. EXECUTIVE SUMMARY

4. VOICE OF CUSTOMERS

5. GLOBAL BISPECIFIC ANTIBODY THERAPEUTICS CONTRACT MANUFACTURING MARKET OUTLOOK

5.1. Market Size & Forecast

5.1.1. By Value

5.2. Market Share & Forecast

5.2.1. By Indication (Cancer, Infectious Diseases, Autoinflammatory and Autoimmune Diseases, CNS Conditions, Others)

5.2.2. By Route of Administration (Intravenous, Subcutaneous, Others)

5.2.3. By End Use (Pharmaceutical Companies, Biopharmaceutical Companies, Others)

5.2.4. By Company (2022)

5.2.5. By Region

5.3. Market Map

6. NORTH AMERICA BISPECIFIC ANTIBODY THERAPEUTICS CONTRACT MANUFACTURING MARKET OUTLOOK

6.1. Market Size & Forecast

6.1.1. By Value

6.2. Market Share & Forecast

6.2.1. By Indications

6.2.2. By Route of Administration

6.2.3. By End Use

6.2.4. By Country

6.3. North America: Country Analysis

6.3.1. United States Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

6.3.1.1. Market Size & Forecast

- 6.3.1.1.1. By Value
- 6.3.1.2. Market Share & Forecast
 - 6.3.1.2.1. By Indications
 - 6.3.1.2.2. By Route of Administration
 - 6.3.1.2.3. By End Use
- 6.3.2. Mexico Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook
 - 6.3.2.1. Market Size & Forecast
 - 6.3.2.1.1. By Value
 - 6.3.2.2. Market Share & Forecast
 - 6.3.2.2.1. By Indications
 - 6.3.2.2.2. By Route of Administration
 - 6.3.2.2.3. By End Use
- 6.3.3. Canada Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook
 - 6.3.3.1. Market Size & Forecast
 - 6.3.3.1.1. By Value
 - 6.3.3.2. Market Share & Forecast
 - 6.3.3.2.1. By Indications
 - 6.3.3.2.2. By Route of Administration
 - 6.3.3.2.3. By End Use

7. EUROPE BISPECIFIC ANTIBODY THERAPEUTICS CONTRACT MANUFACTURING MARKET OUTLOOK

- 7.1. Market Size & Forecast
 - 7.1.1. By Value
- 7.2. Market Share & Forecast
 - 7.2.1. By Indications
 - 7.2.2. By Route of Administration
 - 7.2.3. By End Use
 - 7.2.4. By Country
- 7.3. Europe: Country Analysis
 - 7.3.1. France Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook
 - 7.3.1.1. Market Size & Forecast
 - 7.3.1.1.1. By Value
 - 7.3.1.2. Market Share & Forecast
 - 7.3.1.2.1. By Indications
 - 7.3.1.2.2. By Route of Administration
 - 7.3.1.2.3. By End Use

7.3.2. Germany Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

7.3.2.1. Market Size & Forecast

7.3.2.1.1. By Value

7.3.2.2. Market Share & Forecast

7.3.2.2.1. By Indications

7.3.2.2.2. By Route of Administration

7.3.2.2.3. By End Use

7.3.3. United Kingdom Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

7.3.3.1. Market Size & Forecast

7.3.3.1.1. By Value

7.3.3.2. Market Share & Forecast

7.3.3.2.1. By Indications

7.3.3.2.2. By Route of Administration

7.3.3.2.3. By End Use

7.3.4. Italy Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

7.3.4.1. Market Size & Forecast

7.3.4.1.1. By Value

7.3.4.2. Market Share & Forecast

7.3.4.2.1. By Indications

7.3.4.2.2. By Route of Administration

7.3.4.2.3. By End Use

7.3.5. Spain Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

7.3.5.1. Market Size & Forecast

7.3.5.1.1. By Value

7.3.5.2. Market Share & Forecast

7.3.5.2.1. By Indications

7.3.5.2.2. By Route of Administration

7.3.5.2.3. By End Use

8. ASIA-PACIFIC BISPECIFIC ANTIBODY THERAPEUTICS CONTRACT MANUFACTURING MARKET OUTLOOK

8.1. Market Size & Forecast

8.1.1. By Value

8.2. Market Share & Forecast

8.2.1. By Indications

8.2.2. By Route of Administration

8.2.3. By End Use

8.2.4. By Country

8.3. Asia-Pacific: Country Analysis

8.3.1. China Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

8.3.1.1. Market Size & Forecast

8.3.1.1.1. By Value

8.3.1.2. Market Share & Forecast

8.3.1.2.1. By Indications

8.3.1.2.2. By Route of Administration

8.3.1.2.3. By End Use

8.3.2. India Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

8.3.2.1. Market Size & Forecast

8.3.2.1.1. By Value

8.3.2.2. Market Share & Forecast

8.3.2.2.1. By Indications

8.3.2.2.2. By Route of Administration

8.3.2.2.3. By End Use

8.3.3. South Korea Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

8.3.3.1. Market Size & Forecast

8.3.3.1.1. By Value

8.3.3.2. Market Share & Forecast

8.3.3.2.1. By Indications

8.3.3.2.2. By Route of Administration

8.3.3.2.3. By End Use

8.3.4. Japan Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

8.3.4.1. Market Size & Forecast

8.3.4.1.1. By Value

8.3.4.2. Market Share & Forecast

8.3.4.2.1. By Indications

8.3.4.2.2. By Route of Administration

8.3.4.2.3. By End Use

8.3.5. Australia Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

8.3.5.1. Market Size & Forecast

8.3.5.1.1. By Value

8.3.5.2. Market Share & Forecast

8.3.5.2.1. By Indications

8.3.5.2.2. By Route of Administration

8.3.5.2.3. By End Use

9. SOUTH AMERICA BISPECIFIC ANTIBODY THERAPEUTICS CONTRACT MANUFACTURING MARKET OUTLOOK

9.1. Market Size & Forecast

9.1.1. By Value

9.2. Market Share & Forecast

9.2.1. By Indications

9.2.2. By Route of Administration

9.2.3. By End Use

9.2.4. By Country

9.3. South America: Country Analysis

9.3.1. Brazil Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

9.3.1.1. Market Size & Forecast

9.3.1.1.1. By Value

9.3.1.2. Market Share & Forecast

9.3.1.2.1. By Indications

9.3.1.2.2. By Route of Administration

9.3.1.2.3. By End Use

9.3.2. Argentina Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

9.3.2.1. Market Size & Forecast

9.3.2.1.1. By Value

9.3.2.2. Market Share & Forecast

9.3.2.2.1. By Indications

9.3.2.2.2. By Route of Administration

9.3.2.2.3. By End Use

9.3.3. Colombia Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

9.3.3.1. Market Size & Forecast

9.3.3.1.1. By Value

9.3.3.2. Market Share & Forecast

9.3.3.2.1. By Indications

9.3.3.2.2. By Route of Administration

9.3.3.2.3. By End Use

10. MIDDLE EAST AND AFRICA BISPECIFIC ANTIBODY THERAPEUTICS CONTRACT MANUFACTURING MARKET OUTLOOK

10.1. Market Size & Forecast

10.1.1. By Value

10.2. Market Share & Forecast

10.2.1. By Indications

10.2.2. By Route of Administration

10.2.3. By End Use

10.2.4. By Country

10.3. MEA: Country Analysis

10.3.1. South Africa Bispecific Antibody Therapeutics Contract Manufacturing Market

Outlook

10.3.1.1. Market Size & Forecast

10.3.1.1.1. By Value

10.3.1.2. Market Share & Forecast

10.3.1.2.1. By Indications

10.3.1.2.2. By Route of Administration

10.3.1.2.3. By End Use

10.3.2. Saudi Arabia Bispecific Antibody Therapeutics Contract Manufacturing Market

Outlook

10.3.2.1. Market Size & Forecast

10.3.2.1.1. By Value

10.3.2.2. Market Share & Forecast

10.3.2.2.1. By Indications

10.3.2.2.2. By Route of Administration

10.3.2.2.3. By End Use

10.3.3. UAE Bispecific Antibody Therapeutics Contract Manufacturing Market Outlook

10.3.3.1. Market Size & Forecast

10.3.3.1.1. By Value

10.3.3.2. Market Share & Forecast

10.3.3.2.1. By Indications

10.3.3.2.2. By Route of Administration

10.3.3.2.3. By End Use

11. MARKET DYNAMICS

11.1. Drivers

11.2. Challenges

12. MARKET TRENDS & DEVELOPMENTS

- 12.1. Recent Developments
- 12.2. Product Launches
- 12.3. Mergers & Acquisitions

13. PESTLE ANALYSIS

14. PORTER'S FIVE FORCES ANALYSIS

- 14.1. Competition in the Industry
- 14.2. Potential of New Entrants
- 14.3. Power of Suppliers
- 14.4. Power of Customers
- 14.5. Threat of Substitute Product

15. COMPETITIVE LANDSCAPE

- 15.1. Business Overview
- 15.2. Company Snapshot
- 15.3. Product & Services
- 15.4. Financials (In case of listed companies)
- 15.5. Recent Developments
- 15.6. SWOT Analysis
 - 15.6.1. Lonza Group AG
 - 15.6.2. Creative Biolabs Inc
 - 15.6.3. Amgen Inc
 - 15.6.4. Johnson & Johnson
 - 15.6.5. Wuxi Biologics Cayman Inc
 - 15.6.6. Roche Holding AG
 - 15.6.7. Sino Biological Inc
 - 15.6.8. IQVIA Inc
 - 15.6.9. Janssen Pharmaceuticals Inc
 - 15.6.10. AbbVie Inc

16. STRATEGIC RECOMMENDATIONS

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