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Oral Solid dosage (OSD) Contract Manufacturing Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Product (Tablets, Capsules, Powders, Granules, Others), By End User (Large-size companies, Small & medium size companies, Startups and generic pharmaceutical companies), By Region and Competition

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Abstracts

Global Oral Solid dosage (OSD) Contract Manufacturing Market has valued at USD 33.45 billion in 2022 and is anticipated to project impressive growth in the forecast period with a CAGR of 6.24% through 2028. Oral Solid Dosage (OSD) Contract Manufacturing is a vital segment of the pharmaceutical industry where specialized Contract Manufacturing Organizations (CMOs) provide comprehensive services for the production of solid dosage forms such as tablets, capsules, powders, and granules. Pharmaceutical companies outsource OSD manufacturing to these CMOs for numerous reasons, including cost-efficiency, allowing them to focus on core competencies like research and marketing. OSD CMOs offer scalability, adhering to rigorous regulatory standards like Good Manufacturing Practices (GMP), ensuring quality and compliance. They enable speedier product development and market entry, with capabilities encompassing various dosage forms and formulation types. As the pharmaceutical landscape evolves, this competitive and dynamic market continues to grow, fostering collaboration, innovation, and global expansion opportunities for both pharmaceutical companies and OSD contract manufacturers. The Oral Solid Dosage (OSD) Contract Manufacturing Market refers to the pharmaceutical industry segment where specialized contract manufacturing organizations (CMOs) produce a wide range of solid dosage

forms, such as tablets, capsules, powders, and granules, on behalf of pharmaceutical companies. This outsourcing of manufacturing is driven by various factors and offers several advantages. Cost Efficiency: OSD contract manufacturing allows pharmaceutical companies to reduce production costs significantly. CMOs often have specialized facilities and expertise, resulting in cost savings compared to in-house production. Focus on Core Competencies: By outsourcing OSD manufacturing, pharmaceutical firms can concentrate on research, development, and marketing of drugs while leaving the production process to experts. Scalability: CMOs can accommodate various production scales, from small batches for clinical trials to large-scale commercial production, providing flexibility to pharmaceutical companies. Regulatory Compliance: Reputable OSD CMOs adhere to strict quality and regulatory standards, ensuring compliance with Good Manufacturing Practices (GMP) and other regulations, reducing regulatory risks for their clients. Speed to Market: Contract manufacturers often have streamlined processes and established infrastructure, allowing for faster product development and market entry. Diverse Capabilities: OSD contract manufacturers offer a wide range of formulation development and manufacturing services, including controlled release, immediate release, and oral sustained-release dosage forms. Global Expansion: Companies can leverage the global presence of CMOs to access new markets and benefit from their established international regulatory expertise. The OSD contract manufacturing market is highly competitive and dynamic, driven by the pharmaceutical industry's need for efficiency, cost-effectiveness, and regulatory compliance. As pharmaceutical companies continue to seek strategic partnerships with CMOs, this market is expected to grow, providing opportunities for innovation and collaboration within the pharmaceutical manufacturing sector.

Key Market Drivers

Cost Efficiency

Cost efficiency in the context of the Oral Solid Dosage (OSD) Contract Manufacturing Market is a pivotal driver that refers to the ability of pharmaceutical companies to produce oral solid dosage forms in a manner that maximizes value while minimizing expenses. OSD contract manufacturing offers several cost-efficient advantages to pharmaceutical firms. Firstly, Contract Manufacturing Organizations (CMOs) typically possess specialized infrastructure and equipment optimized for OSD production, leading to economies of scale and reduced operational costs. This enables pharmaceutical companies to avoid substantial upfront capital investments in facilities and technology. Secondly, CMOs often benefit from bulk purchasing power, procuring

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raw materials and components at lower costs, which can translate into cost savings for their clients. Additionally, the expertise of OSD CMOs in optimizing manufacturing processes and adhering to regulatory requirements helps prevent costly errors and regulatory setbacks, further enhancing cost-efficiency. The ability to scale production up or down quickly, depending on market demand, minimizes excess inventory costs and wastage. Furthermore, pharmaceutical firms can direct their financial resources and focus on core competencies such as research, development, and marketing, rather than allocating substantial budgets to in-house manufacturing facilities. Overall, cost efficiency is a critical consideration for pharmaceutical companies when choosing OSD contract manufacturing, as it offers a means to control production expenses while ensuring high-quality, compliant, and timely delivery of oral solid dosage products to the market.

Focus on Core Competencies

In the Oral Solid Dosage (OSD) Contract Manufacturing Market, the concept of 'Focus on Core Competencies' underscores the strategic advantage gained by pharmaceutical companies when they entrust specialized Contract Manufacturing Organizations (CMOs) with the production of oral solid dosage forms, allowing the companies to concentrate their resources and expertise on areas where they excel. By outsourcing OSD manufacturing, pharmaceutical firms can shift their focus to their core competencies, which typically encompass research and development (R&D), regulatory affairs, and marketing. This strategic redirection of resources is significant for several reasons. Firstly, it enables pharmaceutical companies to allocate more time, talent, and financial resources to their R&D efforts, accelerating the development of new drug formulations and enhancing their competitive edge in the market. Secondly, by relying on OSD CMOs' manufacturing expertise and state-of-the-art facilities, pharmaceutical companies can ensure the consistent and cost-effective production of their products without the need for substantial investments in manufacturing infrastructure. This not only reduces capital expenditure but also allows for greater agility in responding to market dynamics. Additionally, the outsourcing of manufacturing to specialists enhances regulatory compliance and quality control, mitigating risks associated with production errors or regulatory non-compliance. Ultimately, focusing on core competencies and leveraging the capabilities of OSD CMOs empowers pharmaceutical companies to streamline operations, drive innovation, and optimize their market strategies, resulting in increased efficiency, profitability, and competitiveness in the dynamic pharmaceutical landscape.

Increasing Drug Development

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Increasing Drug Development' is a significant driver within the Oral Solid Dosage (OSD) Contract Manufacturing Market, reflecting the growing pipeline of pharmaceutical products, including generic drugs and novel therapies, that require manufacturing services. This driver is fueled by several factors. Firstly, the pharmaceutical industry is continually advancing, with ongoing research and development efforts aimed at addressing various medical conditions. As a result, there is a constant need for OSD contract manufacturing services to produce these new drug formulations efficiently and cost-effectively. Secondly, the emergence of biopharmaceuticals and specialty drugs has expanded the scope of drug development, leading to a broader range of therapeutic options that require OSD manufacturing expertise. Additionally, the expiration of patents for many blockbuster drugs has led to an increase in generic drug development, boosting the demand for OSD contract manufacturing services to produce these cost-effective alternatives. Furthermore, the globalization of pharmaceutical markets and the need to comply with various regulatory standards across regions necessitate partnerships with OSD CMOs that have the expertise and infrastructure to navigate complex regulatory requirements. The OSD CMOs' role in ensuring consistent and compliant manufacturing processes is pivotal in facilitating the efficient development and commercialization of new drugs, making them indispensable partners in the pharmaceutical industry's quest for innovation and market competitiveness. As a result, the increasing pace of drug development serves as a driving force in the growth and importance of the OSD Contract Manufacturing Market.

Technological Advancements

'Technological Advancements' are a crucial driver in the Oral Solid Dosage (OSD) Contract Manufacturing Market, playing a pivotal role in shaping the industry's growth and capabilities. The pharmaceutical manufacturing landscape has witnessed significant advancements in recent years, which have had a profound impact on OSD contract manufacturing. Firstly, advancements in automation and robotics have revolutionized OSD manufacturing processes, enhancing precision and efficiency while reducing the risk of errors. Automated equipment can accurately measure, dispense, blend, and compress raw materials, ensuring consistency in dosage forms and minimizing batch-to-batch variations. Secondly, the implementation of process analytical technology (PAT) and quality by design (QbD) principles has led to more robust and streamlined manufacturing processes. PAT allows for real-time monitoring and control of critical manufacturing parameters, ensuring product quality and reducing the likelihood of batch failures or deviations. Thirdly, continuous manufacturing has gained prominence in OSD production, replacing traditional batch processes with continuous,

integrated systems. This approach offers improved control, reduced production times, and enhanced flexibility, aligning with the industry's push for efficiency and cost-effectiveness. Fourthly, advancements in analytical techniques, such as spectroscopy, chromatography, and particle size analysis, enable thorough product characterization and quality control, ensuring that manufactured OSD products meet stringent regulatory requirements. Fifthly, 3D printing technology is emerging as a disruptive force in OSD manufacturing, enabling the rapid production of complex dosage forms with precise drug release profiles. This technology holds promise for personalized medicine and novel drug delivery systems. Overall, technological advancements in the OSD Contract Manufacturing Market are driving increased efficiency, product quality, and innovation. Pharmaceutical companies seek out contract manufacturers that incorporate these advancements into their operations, ensuring that they can meet evolving industry standards and maintain a competitive edge in the dynamic pharmaceutical landscape.

Key Market Challenges

Quality Control and Assurance

Quality Control (QC) and Quality Assurance (QA) are paramount in the Oral Solid Dosage (OSD) Contract Manufacturing Market, ensuring that pharmaceutical products meet stringent quality standards throughout the manufacturing process. QC encompasses the systematic inspection and testing of raw materials, in-process samples, and finished dosage forms to verify their compliance with predetermined specifications. This involves a series of analytical techniques, such as chromatography, spectroscopy, and dissolution testing, to assess attributes like potency, purity, and dissolution rates. Simultaneously, QA focuses on the overarching systems, procedures, and processes that safeguard product quality from the initial development phase to the final delivery of the product to the market. This includes establishing and maintaining robust quality management systems, implementing GMP guidelines, conducting audits, and overseeing compliance with regulatory requirements. In the OSD Contract Manufacturing Market, ensuring QC and QA is critical for several reasons. Firstly, pharmaceutical products must consistently meet safety and efficacy standards to protect patient health and maintain regulatory compliance. Secondly, pharmaceutical companies rely on contract manufacturers to maintain high-quality standards to safeguard their reputation and prevent regulatory penalties. Thirdly, the global nature of pharmaceutical markets means that products manufactured by OSD CMOs may need to meet different regulatory requirements in various regions, making comprehensive QA and QC systems indispensable. Finally, the complexity of OSD manufacturing processes, the multitude of dosage forms, and the evolving regulatory landscape

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necessitate a commitment to ongoing QA and QC improvements, including the implementation of cutting-edge analytical technologies and process controls to ensure the highest quality standards are met. Ultimately, QC and QA play a pivotal role in the OSD Contract Manufacturing Market by guaranteeing the safety, efficacy, and consistency of pharmaceutical products, fostering trust between contract manufacturers and pharmaceutical companies, and facilitating compliance with global regulatory standards.

Intellectual Property Issues

Intellectual Property (IP) issues in the Oral Solid Dosage (OSD) Contract Manufacturing Market pertain to the protection of proprietary information, formulations, and technologies during the outsourcing of manufacturing processes to Contract Manufacturing Organizations (CMOs). Pharmaceutical companies often possess valuable IP related to drug formulations, manufacturing methods, and other critical processes. When outsourcing OSD production to CMOs, there is a risk of unintentional IP exposure or infringement if adequate safeguards are not in place. Securing IP rights and managing these issues are essential challenges. One major concern is the protection of confidential information and trade secrets. Pharmaceutical firms must ensure that sensitive data, including proprietary formulations and production techniques, is not disclosed or misappropriated during the manufacturing process. Non-disclosure agreements (NDAs) and confidentiality clauses in contracts are common tools used to address this concern. Another aspect of IP issues is patent protection. Pharmaceutical companies hold patents on drug formulations and processes, and outsourcing OSD manufacturing requires careful consideration of patent rights. Contract manufacturers need access to patented information to carry out production but must do so within the bounds of licensing agreements. Additionally, there are concerns related to data exclusivity and regulatory data protection. Some countries provide exclusivity periods during which the original drug manufacturer has exclusive rights to the data submitted for regulatory approval. Contract manufacturers must adhere to these exclusivity periods when working with clients' proprietary data. Dispute resolution mechanisms and clear contractual agreements are vital to addressing IP issues. Contracts should define ownership of IP developed during the manufacturing process and outline procedures for dispute resolution in case of IP-related conflicts. Overall, navigating intellectual property issues in OSD contract manufacturing requires a delicate balance between sharing necessary information for production and safeguarding valuable IP rights. Careful legal and contractual considerations are essential to protect the interests of both pharmaceutical companies and contract manufacturers.

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Key Market Trends

Biopharmaceuticals and Complex Formulations

Biopharmaceuticals and Complex Formulations' refer to a significant trend where pharmaceutical companies increasingly seek contract manufacturing services for intricate and specialized drug formulations beyond traditional small molecule drugs. This trend encompasses several key aspects: Firstly, the demand for OSD contract manufacturing of biopharmaceuticals is on the rise. Biopharmaceuticals are therapeutic products derived from biological sources, such as proteins, antibodies, and nucleic acids. These complex molecules often require specific expertise and advanced technologies to formulate them into oral solid dosage forms like tablets or capsules. OSD contract manufacturers with the capabilities to handle biopharmaceuticals, including handling sensitive biologics, are becoming sought-after partners. Secondly, complex formulations extend beyond biologics to include drugs with unique delivery systems, controlled-release mechanisms, or multiple active ingredients. For example, extended-release tablets, multiparticulate dosage forms, and combination therapies that incorporate different APIs (Active Pharmaceutical Ingredients) present manufacturing challenges that necessitate specialized knowledge and equipment. OSD CMOs are adapting to meet these demands, offering solutions for the formulation and production of such complex drug products. This trend reflects the pharmaceutical industry's evolving landscape, with a growing focus on innovative therapies, personalized medicine, and specialty drugs. Pharmaceutical companies are seeking OSD contract manufacturers capable of handling these complex formulations, ensuring precise dosage, controlled release, and the preservation of drug efficacy. As a result, OSD CMOs are investing in state-of-the-art facilities and R&D capabilities to meet the demand for biopharmaceuticals and complex oral solid dosage forms, further expanding their role in the pharmaceutical supply chain.

Sustainability and Green Manufacturing

'Sustainability and Green Manufacturing' in the context of the Global Oral Solid Dosage (OSD) Contract Manufacturing Market represent a growing trend towards environmentally responsible and resource-efficient practices within the pharmaceutical manufacturing sector. OSD contract manufacturers are increasingly adopting sustainability initiatives and green manufacturing processes for several reasons. Firstly, environmental consciousness and corporate social responsibility have become more significant factors for both pharmaceutical companies and their customers. OSD CMOs are responding to these demands by minimizing their environmental footprint. This

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includes reducing water and energy consumption, minimizing waste generation, and using eco-friendly materials in packaging. Secondly, sustainable practices can lead to cost savings and operational efficiencies. By optimizing resource utilization and reducing waste, OSD contract manufacturers can lower production costs, enhancing their competitiveness in the market. Thirdly, regulatory agencies are increasingly emphasizing sustainability in their guidelines. OSD CMOs must adhere to environmental regulations and demonstrate compliance with sustainability standards to maintain their reputation and meet the requirements of pharmaceutical clients. To implement sustainable and green manufacturing, OSD CMOs are investing in technologies that improve energy efficiency and reduce emissions. They are also adopting cleaner and more efficient production processes, such as solvent-free manufacturing and the use of renewable energy sources. Additionally, they are actively engaging in recycling and waste reduction programs to minimize their environmental impact. Overall, sustainability and green manufacturing are integral trends in the OSD Contract Manufacturing Market, reflecting the pharmaceutical industry's commitment to responsible production practices and environmental stewardship. These efforts not only align with global sustainability goals but also enhance the appeal of OSD CMOs to environmentally conscious pharmaceutical clients and consumers.

Segmental Insights

Product Type Insights

In 2022, the Oral Solid dosage (OSD) Contract Manufacturing Market was dominated by Tablets segment and is predicted to continue expanding over the coming years. This is attributed because tablets are the most common OSD form. This form contains an Active Pharmaceutical Ingredient (API), which is also known as a dry powder ingredient and a drug substance.

Regional Insights

In 2022, the Global Oral Solid dosage (OSD) Contract Manufacturing Market was dominated by the North America segment and is predicted to continue expanding over the coming years. This is ascribed due to rising cases of chronic diseases, rising development of cancer technology, and the growing healthcare infrastructure.

Key Market Players

AbbVie Inc.

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Acino International AG

Aenova Holding GmbH

Beximco Pharmaceuticals Ltd

Boehringer Ingelheim International GmbH

Catalent Inc.

Corden Pharma International GmbH,

PerkinElmer Inc.

Pyramid Laboratories Inc.

Siegfried AG.

Report Scope:

In this report, the Global Oral Solid dosage (OSD) Contract Manufacturing Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Global Oral Solid dosage (OSD) Contract Manufacturing Market, By Product:

Tablets

Capsules

Powders

Granules

Others

Global Oral Solid dosage (OSD) Contract Manufacturing Market, By End User:

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Large-size companies

Small & medium size companies

Startups and generic pharmaceutical companies

Global Oral Solid dosage (OSD) 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

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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 Oral Solid dosage (OSD) Contract Manufacturing Market.

Available Customizations:

Global Oral Solid dosage (OSD) 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).

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8. ASIA-PACIFIC ORAL SOLID DOSAGE (OSD) CONTRACT MANUFACTURING MARKET OUTLOOK

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9. SOUTH AMERICA ORAL SOLID DOSAGE (OSD) CONTRACT MANUFACTURING MARKET OUTLOOK

10. MIDDLE EAST AND AFRICA ORAL SOLID DOSAGE (OSD) CONTRACT MANUFACTURING MARKET OUTLOOK

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