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Downstream Processing Market Research Report—Global Forecast till 2027

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Description:

Downstream Processing Market Overview:

The global downstream processing market is expected to cross ~USD 61,174.53 million by 2027 at a CAGR of ~16.09%. Downstream processing refers to the series of operations required to derive pure and homogeneous protein products from biological materials such as cells, tissue culture fluid, or plant tissues.Downstream processing is one of the vital stepsin the manufacturing process for pharmaceuticals,biopharmaceuticals, industrial enzymes, and natural fragrance &flavor compounds. There is a high demand for the end products extracted by downstream processing, owing to its increasing application in biopharmaceutical products.Thus, the downstream processing market is anticipated to observe significant growth during the forecast period.

COVID-19 Analysis:

The rising prevalence of COVID-19 is projected to influence positively on market growth over the forecast period. As the coronavirus outbreak continues, the majority of pharmaceutical and biopharmaceutical companies experienced a significant loss, thereby hampering the downstream processing market. Many companies had restricted or halted their manufacturing and supply operations in the initial phase of the pandemic.In addition, the supply shortage of raw materials has further impacted the downstream processing market. Social distancing guidelines and resource reallocation in the course of the COVID-19 pandemic have led to significant disruption of pharmaceutical and biopharmaceutical industriesglobally.

However, owing to the increasing demand for the COVID-19 vaccine, there has been a sudden increase in demand for downstream processing products.The key players in the downstream processing market have increased their production to meet the demand for the products. For instance, In February 2021, Rentschler Biopharma, a Germany-based contract development and manufacturing organization (CDMO), announced the ramping up of the production of CVnCoV COVID-19 candidate vaccine by CureVac N.V. (Germany).Rentschler Biopharma (Germany)is responsible for manufacturing,downstream processing, and formulation of the vaccine.Furthermore, to avoid shortages for the necessary downstream processing products, the Food and Drug Administration (FDA) and European Commission proposed and published regulations focusing on-demand optimization and rational supply. These regulation revisions included several regulations to enhance imports to maintain integration of the supply chain.

Market Dynamics:

Drivers

- **Growing biopharmaceutical industry and increasing spending in medical research**

In recent years, the biopharmaceutical industry has witnessed robust growth. Biopharmaceutical companies are involved in the development of various innovative and effective regenerative therapies, which are playing a vital role in the growth of the biopharmaceutical industry. Moreover, increasing public-private investments and R&D expenditure in biopharmaceutical & life science researchare further driving the growth of the biopharmaceutical industry, which is likely to propel the growth of the global downstream processing market in the coming years. For instance, according to Research!America, in 2018, total estimated theUS medical and health R&D expenditures accounted for about USD 194,175 million. Out of this, USD 129,488 million was invested by the industrysector,including biopharmaceutical and medical technology R&D firms, companies in the health care services arena, and others, and USD 43,016 million by the federal government.

Moreover, there was a 35.65% growth in the totalUS Medical and Health R&D expenditures between 2013 and 2018. Thus, the growing biopharmaceutical industry and increasing spending in medical research are anticipated to drive the growth in the downstream processing market.

- **Increasing number of CMOs in the market for downstream processing**
- **Rising adoption of single-use technology in bioprocessing**

Restraints

- **Shortage of skilled professionals**

There isan impending shortage of trained professionals for the downstream processing industry. Bioprocess engineering is one of the core skills required forthe downstream processing industry. Owing to the increasing demand for biosimilars, an increasing number of Contract Manufacturing Organizations (CMOs) have entered the market. However, a shortage of skilled workforce is anticipated to restrain the market growth. The companies have to spend a significant amount of time training the staff with the necessary skills required for handling the operations. Furthermore, a high attrition rate in the bioprocessing industry is also anticipated to restrain the market growth.

- **Growing regulatory scrutiny on the cleaning validation of downstream purification processes**

Opportunities

- **Advances in downstream processing**

Technological advancements for downstream operations are crucial for maintaining efficiency and driving innovation in bioprocessing. Recent advances in downstream processing, including remote monitoring, membrane chromatography technology, single-use sensors, anddata analytics, are anticipated to provide significant growth opportunities for the global downstream processing market. Furthermore, a rise in R&D activities in advanced bioprocess technologies has led to high-throughput process development and high-resolution membrane systems. Thus, advances in bioprocessing technologies are anticipated to provide significant growth opportunities for the market.

- **Increasing demand for monoclonal antibodies**

Value Chain Analysis

The global downstream processing market is growing steadily due to the rising number of players coming forward with new and better products. The value chain analysis of the downstream processing market comprises four major components starting with the R&D and designing, followed by manufacturing the products, distribution & sales, and ends with post-sales services.

R&D and designing start with conceptualizing, followed by design, then development, and lastly, testing. The R&D segment comprises 25-30% of the value chain. After the product designs are final, the manufacturing of the product starts. Manufacturing consists of 45-50% of the value chain. The sourcing of raw material is the initial phase in the manufacturing of the products. The manufacturing components are sometimes outsourced. Outsourcing eliminates manufacturing process activities of some parts and helps to improve the efficiency of the process. Then comes distribution and sales, which is involved in creating awareness about the products to get interested customers for the product. It consists of 10-15% of the value chain. Lastly comes post-sales services, which account for around 5-10% of the value chain. In this step, customer feedback is taken into consideration to improve upon their existing product portfolio.

Segment Overview

By Technique

- **Cell Disruption**

Cell disruption is the process of lysing of cells and is an importanttechnique in downstream processing related to the manufacturing of biological products. Cell disruption is used forthe extraction and retrieval of the desired products.Cell disruption includes several methods such as mechanical methods, non-mechanical methods, and chemical methods. The method used may vary depending on the type of cell and its cell wall composition.

- **Solid-Liquid Separation**

Solid-liquid separation is one of the most common separation requirements in the downstream processingindustry, and many techniques are used,including sedimentation, centrifugation, filtration, and flocculation.

- **Clarification/Concentration**

There are several techniques,including evaporation, liquid-liquid extraction, membrane filtration, precipitation, and adsorption,that are used to concentrate the desired biological products. The techniques are chosen based on the nature of the desired product and the cost factor.

- **Purification Techniques**

Purification techniques can further be sub-segmented into Ion-Exchange chromatography, affinity chromatography, hydrophobic interaction chromatography, size exclusion chromatography, and others. Ion exchange chromatography is a process that separates ions and polar molecules based on their affinity to the ion exchanger. It works on almost any charged molecule, including small nucleotides, large proteins, and amino acids.Affinity chromatography is unique among separation methods as it is the only technique that permits the purification of proteins based on biological functions rather than individual physical or chemical properties.Hydrophobic interaction chromatography is a separation technique for purifying proteins while maintaining biological activity due to the use of conditions and matrices that operate under less denaturing conditions.Size-exclusion chromatography is a chromatographic method in which molecules in solution are separated by their size, and in some cases, molecular weight. Others include crystallization, sublimation, distillation, and other such purification techniques.The rising adoption of chromatography in the analysis of pharmaceutical drugs and its identification is fueling the growth of this segment.

- **Formulation**

The formulationis the process that transitions a drug substance into a formulated drug product. This brings the product molecule into a form suitable for clinical administration.

By Product

- **Chromatography Columns &Resins**

A chromatography column is a unit used in chromatography to separate chemical compounds. There isa wide range of products available for chromatography columns and resins.Several companies also provide customized products based on the requirement.

- **Filters**

Filtration is a method of separating suspended particles from a liquid or gas using a porous medium thatretains the particles but allows the liquid or gas to pass through. A variety of filters are used, such asrotary vacuum filters, depth filters, plate frame filters, tangential filters, centrifugal filters and, surface filters.

- **Membrane Adsorbers**

Membrane adsorbers are synthetic, thin, microporous, or macroporous membranes.There is a wide range of scalable formats available to be used in a variety of purification processes. Membrane adsorbers offer a cost-effective andflexible solution in antibody manufacturing and are gaining acceptance as an alternative to traditional resin-based chromatography,

- **Others**

Other include filters, evaporators, centrifuges, and other downstream processing products

By Application

- **Antibiotic Production**

Antibiotics are antimicrobial agents produced naturally by other microbes.Antibiotic production is one of the core applications of downstream processing.

- **Hormone Production**

Hormone therapy has gained significantimportance in the medical field. Several of the hormones can be produced through downstream processing, including insulin.

- **Antibodies production**

Antibody-based therapeuticsisone of the largest sectors of the biopharmaceutical industry. Increasing demand for antibody-based therapeutics is driving the market for antibodies production.

- **Vaccine Production**

Owing to the current pandemic, several new market players have entered into vaccine production. Moreover, due to the imminent demand for the COVID-19 vaccine, all the key players have ramped up their production for vaccine production.

- **Others**

Others include enzyme production, food-grade chemical production, nutraceutical productions, and other such applications.

By End User

- **Biopharmaceutical Manufacturers**

The biopharmaceutical manufacturers segment is expected to hold the largest market share in 2021 due to increased R&D activities and biologics productionon a largescale, along with the rapidly growing biopharmaceutical industry.

- **Contract Manufacturing Organizations**

The increasing number of contract manufacturing organizations and increasing demandfor biopharmaceuticals in pharma and biopharma companies through outsourcing activities is boosting the market growth.

- **Others**

The other end users ofdownstream processing are research and academic institutes, medical device manufacturers industrial enzyme manufacturers.

By Region

- **North America:**

The North American market accounted for the largest share in 2020, owing to the presence of well-established research organizations involved in research activities, the presence of a large number of CMOs, and pharmaceutical &biopharmaceutical companies. The presence of major market players in this region and their contribution through mergers& acquisitions and product launches is also boosting the market growth. North America is expected to continue dominating the global downstream processing market during the forecast period owing to a rise in R&D investments by public and private players in the healthcare sector.

- **Europe:**

The European downstream processing market is driven by the rising R&D expenditure by biopharmaceutical companies, increasing investment in the R&D sector, and market players playing a significant role in contributing to the market growth. For instance, in November 2019, ThermoFisherScientific, Inc. announced that it is investing nearly USD 24 million in its Inchinnan, Scotland, site to expand global bioproduction capabilities with additional large-volume liquid manufacturing capacity for cell culture media.In April 2020, Sartorius (Germany), a leading international partner of life science research and the biopharmaceutical industry, acquired selected life science businesses of Danaher Corporation (US). The acquisition will promote innovative protein analysis instruments, biosensors, and reagents that are used in drug discovery.

- **Asia-Pacific:**

The Asia-Pacific downstream processing market is expected to be the fastest-growing due to rapidly growing and improving healthcare infrastructure, the establishment of research organizations, and increasing investments in biotechnology. In addition, factors such as theincreasing skilled workforce, growing biopharmaceutical industry, significant investments by key market players, and expanding R&D infrastructure are supporting the growth of this market. For instance, in Apri 2021, Asahi Kasei Corporation, a solution provider to the biologics manufacturing industry, expanded its business in China with the launch of Asahi Kasei Bioprocess (Shanghai) Co., Ltd (AKBC), which will facilitate business expansion in China by localizing inventory management and order processing for shorter delivery times.

- **Rest of the World:**

Rising per capita expenditure of the population in the healthcare sector and increasingadoption rate of the bioprocessing technology by biopharmaceutical companies, booming biotechnology sector, and advancements in chromatographic techniques are major factors contributing to the growth of the downstream processing market in this region.

Competitive Landscape

The downstream processing market is profitable, both for existing players as well as new entrants. A substantial level of rivalry is observed among the existing manufacturers in the market. Our analysis revealed that market players have adopted different strategies and innovative R&D techniques to expand their business and secure their position in the global downstream processing market. For instance, in April 2021, Thermo Fisher Scientific, Inc. (US) launched the Thermo Scientific KingFisher Apex Purification System. This system is a high-throughput sample purification instrument.

Thermo Fisher Scientific, Inc. has a robust industry experience and is one of the leading companies in the life science industry. Furthermore, a high customer satisfaction level, exceptional performance in new markets, and a strong product portfolio add to the company’s competitive advantage. The company also has a strong clientele and is well established in the industry. Also, it is continuously involved in seminars, conferences, and trade fairs in several countries to generate awareness about its products.

List of Key Companies Covered in this report:

- Thermo Fisher Scientific Inc. (US)
- Sartorius Stedim Biotech S.A. (France)
- Merck Millipore (Germany)
- Danaher Corporation (US)
- 3M Company (US)
- Boehringer Ingelheim (Germany)
- Lonza Group AG (Switzerland)
- Eppendorf AG (Switzerland)
- Corning Incorporated (US)
- Asahi Kasei Corporation (Japan)

Recent Developments

- In July 2021, ThermoFisherScientific, Inc. (US) launched a set of solutions to support Adeno-associated Viral (AAV) manufacturing to decrease manufacturing costs and increase the viability of gene therapies as treatment options for patients. This included media panel, gene kit, and advanced purification resins.
- In March 2020, Danaher Corporation (US) completed the acquisition of the Biopharma business of General Electric Company's (US) Life Sciences division and rebranded it as Cytiva.
- In 2019, Sartorius AG (France) entered into an agreement to acquire parts of Danaher's Life Science portfolio, which complemented the portfolio of Sartorius' laboratory and bioprocess business.

Report Overview: The study covers the existing short-term and long-term market effects, as well as helping decision-makers to draught short-term and long-term plans for businesses by region. The report covers major regions in North America, Europe, Asia-Pacific, and the Rest of the World. The report analyzes market drivers, restraints, opportunities, challenges, Porter's Five Forces, Value Chain, and impact of COVID-19 on the market.
Scope of the Report

The scope of the global downstream processing market study includes a market size analysis and a detailed analysis of the manufacturer's products and strategies. The market has been segmented based on technique, product, application, end user, and region.

Market Segmentation

Global Downstream Processing Market, by Technique

- Cell Disruption
- Solid-Liquid Separation
- Clarification/Concentration
- Purification Techniques
    - Ion Exchange
    - Affinity Exchange
    - Hydrophobic Interaction
    - Size Exclusion Chromatography
    - Others
- Formulation

Global Downstream Processing Market, by Product

- Chromatography Columns &Resins
- Filters
- Membrane Adsorbers
- Others

Global Downstream Processing Market,by Application

- Antibiotic Production
- Hormone Production
- Antibodies Production
- Vaccine Production
- Others

Global Downstream Processing Market, by End User

- Biopharmaceutical Manufacturers
- Contract Manufacturing Organizations
- Research & Academic Institutes
- Others

Global Downstream Processing Market, by Region

- North America
  - US
  - Canada
- Europe
  - Germany
  - France
  - UK
  - Italy
  - Spain
  - Rest of Europe
- Asia-Pacific
  - China
  - Japan
  - India
  - Australia
  - South Korea
  - Rest of Asia-Pacific
- Rest of the World
  - Middle East&Africa
  - Latin America

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