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BIOSEPARATION SYSTEMS FOR GLOBAL BIOPHARMACEUTICAL MARKETS

(SAMPLE COPY, NOT FOR RESALE)

Trends, Industry Participants, Product Overviews and Market Drivers

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1. Overview

1.1 Statement of Report

Bioseparations Systems can be categorized into three types: chromatography, membranes/filters, and centrifuges. In this report, each is examined in detail including market size, drivers and restrictors, competitors and technology. In [redacted], chromatography will contribute $[redacted] to the global bioseparations market, membrane/filters will contribute $[redacted], and centrifuges will contribute $[redacted].

1.2 About this Report

The demand for single use products is increasing and fueling growth of the Global bioseparations market. New biosimilars are driving the increase in global biomanufacturing capacity. Blockbuster biologics are going off patent leaving the market open for development and manufacture of low cost biosimilars. Asian countries of India, Singapore, South Korea and China are fast becoming biomanufacturing hubs producing biosimilars for their large populations and Southeast Asia. Contract manufacturing organizations are increasing, providing biomanufacturing "capacity on demand" for biopharmaceutical and new development stage companies.

The main objectives of this analysis are:

- For the general Bioseparations testing market:
  - The size of the market and distribution between different market segments.
  - The expected growth over the next [redacted] years within each market segment.
  - A comprehensive overview of the main Bioseparations players. What kind of equipment do they have and what is the capacity of manufacturing.
  - Which sectors in bioseparations for the biopharmaceutical manufacturing area are expected to experience high growth in going forward.
- Identifying viable technology drivers through a comprehensive look at platform technologies for bioseparations Systems for the pharmaceutical industry.
- Understanding the different sectors of bioseparations, looking at a description of the instruments, reagents and supplies marketed by major companies in each segment.
- Obtaining a complete understanding of the individual bioseparations tests, from their basic principles to their clinical applications.
- Discovering feasible market opportunities by identifying high-growth applications in different analytical areas, emphasizing the biggest and expanding markets.
- Focusing on global industry development through an in-depth analysis of the major world markets for bioseparations technology, including growth forecasts.
- Presenting bioseparations market figures regarding the market's current value, market projections, market share, key players and sector growth rates, using the most current data derived from the global diagnostic industry.

This study contains:

- A detailed analysis of recent trends in the bioseparations marketplace.
- In-depth profiles of the leading companies with bioseparations tools and technologies.
- A forecast for the bioseparations market in the biotechnology and diagnostic industries.
- Views and principles on the bioseparations industry from leading industry experts.
- An analysis of potential new bioseparations applications in the pharmaceutical sector.
- Market predictions and trends analysis concerning U.S. expenditures on bioseparations solutions.
- Projections of bioseparations market sizes for European and Asian markets.
- Analysis of commercial bioseparations business strategies.
- The latest news and merger and acquisition developments in the bioseparations marketplace.
- A comprehensive overview of and insight into bioseparations business strategies.
- An in-depth examination of the subsections of each market segment.

Analysis includes charts and graphs measuring product growth and trends within the marketplace. Company-specific information, including sales figures, product pipeline status and research and development (R&D) trends, is provided. This review will also:

- Assess bioseparations market drivers and bottlenecks from medical and scientific community perspectives.
- Discuss the potential benefits of bioseparations for various sectors of the medical and scientific community.
- Establish the current total market size and future growth of the bioseparations market and analyze the current size and growth of individual segments.
- Provide current and forecasted market shares by company.
- Discuss profit and business opportunities by segment.
- Provide strategic recommendations for near-term business opportunities.
- Assess current commercial uses of the bioseparations market.

The following questions will also be addressed in this analysis:

- What are the near-term business opportunities in the bioseparations market?
- What are the current and forecasted bioseparations market sizes in the U.S., the European Union (E.U.), Japan and other key country markets?
- What are the business models currently used by companies in the bioseparations market?
- How will manufacturers, researchers, physicians and patients influence this market?
- What are the drivers and restraints influencing the bioseparations market?
- What are the technologies used in bioseparations?
- Who holds the proprietary rights to the bioseparations market technology platforms?
- In the U.S., Japan and the E.U., what regulatory processes apply to bioseparations technologies?

The report includes:

- A comprehensive overview of the several categories of bioseparations technology platforms that are or will be revolutionizing the use of diagnostic tests in hospitals.
- A chapter on each of the important bioseparations categories and applications.
- Full descriptions of the technologies involved and how they differ from existing and emerging technologies.
- Analysis of the technological approaches undertaken by various competitors, as well as industry and end-user responses to these products.
- Regulatory issues and legislation affecting the use and marketing of bioseparations products.
- Market forecasts for each category of product, including profiles of selected competitors.

1.3 Objectives

This report provides market revenue size and growth rate from [redacted] through [redacted] for North America, Europe, Asia-Pacific (Japan, South Korea, Singapore), and the emerging BRIC countries (Brazil, Russia, India, China). It analyzes the competitive landscape including key player's strengths and weaknesses, opportunities, gaps and industry trends. Applications and downstream bottlenecks are identified by separations product type for purification of monoclonal antibodies (MAb), recombinant proteins and peptides, vaccines and plasma fractionation. This report includes a comprehensive analysis of manufacturing capacity organized by biopharmaceutical company, contract manufacturing organization (CMO) and region.

1.4 Scope of the Report

This report covers:

- Single-use products.
- Manufacturing capacity.

- Applications of bioseparations in downstream processing.
- Downstream processing bottlenecks.
- Emerging bioseparations technologies.

1.5 Methodology

The writer of this report holds a M.S. in biochemistry from the University of Nebraska and has many decades of experience in pharmaceutical manufacturing and marketing, and as a medical industry analyst.The editor of this report holds a Ph.D. in biochemistry from the University of Minnesota and has had post-doctoral experience at the University of Connecticut School of Medicine. He has taught at Quinnipiac University and the Tufts School of Medicine and has been a senior scientist at Pfizer Pharmaceutical Laboratories in drug development. He also has many decades of experience in science writing and as a medical industry analyst, as well as extensive experience in senior-level management positions in biotech and medical service companies.

Company-specific information is obtained mainly from industry trade publications, academic journals, news and research articles, press releases and corporate websites as well as from annual reports for publicly-held firms. Additional sources of information include non-governmental organizations (NGOs) such as the World Health Organization (WHO) and governmental entities such as the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Where possible and practicable, the most recent data available have been used.

Some of the statistical information was taken from Biotechnology Associates' databases and from TriMark's private data stores. The information in this study was obtained from sources that we believe to be reliable, but we do not guarantee the accuracy, adequacy or completeness of any information or omission or the results obtained from the use of such information. Key information from the business literature was used as a basis to conduct dialogue with and obtain expert opinion from market professionals regarding commercial potential and market sizes. Senior managers from major company players were interviewed for part of the information in this report.

Primary Sources

TriMark collects information from hundreds of Database Tables and many comprehensive multi-client research projects, as well as from Sector Snapshots that it publishes annually. TriMark extracts relevant data and analytics from its research as part of this data collection.

Secondary Sources

TriMark uses research publications, journals, magazines, newspapers, newsletters, industry reports, investment research reports, trade and industry association reports, government-affiliated trade releases and other published information as part of its secondary research materials. The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations.

TriMark Publications Report Research and Data Acquisition Structure

The general sequence of research and analysis activity prior to the publication of every report includes the following items:

- Completing an extensive secondary research effort on an important market sector, including gathering all relevant information from corporate reporting, publicly available databases, proprietary databases, direct meetings and personal interviews with key personnel.

- Formulating a study outline with the assigned writer, including the following:

    - Market and product segment grouping and evaluating their relative significance.

- Key competitors' evaluations, including their relative positions in the business and other relevant facts to prioritize diligence levels and assist in designing a primary research strategy.
- End-user research to evaluate analytical significance in market estimation.
- Supply chain research and analysis to identify any factors affecting the market.
- New technology platforms and cutting-edge applications.

- Identifying the key technology and market trends that drive or affect these markets. Assessing the regional significance for each product and market segment for proper emphasis of further regional/national primary and secondary research.

- Launching a combination of primary research activities, including two levels of questionnaires and executive-direct focused, company-specific and region-specific communications to qualified and experienced senior executives worldwide.

- Completing a confirmatory primary research assessment of the report's findings with the assistance of Expert Panel Partners from the industry being analyzed.

The information is then analyzed and translated by the Industry Research Group into a TriMark study. The Editorial Group reviews the complete package with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations.

1.6 Executive Summary

Biomanufacturing is an expensive and complex industry. The manufacturing process requires scale up of a living system producing a biomolecule, then stringent purification of that biomolecule to ensure safety for administration to humans. Biomolecules produced from recombinant technology are variable in structure depending on the cells used to produce the biologic and the downstream purification process. The manufacturing process must be extensively validated as any changes can actually alter the structure of a protein and affect the biological activity or potency.

The capital investment in constructing a new factory to produce these complex biodrugs ranges from $[redacted] to $[redacted]. Reduction of the cost of manufacturing a biological is now a high priority for biopharmaceutical and pharmaceutical companies. Competition in the pharmaceutical and biopharmaceutical industry is increasing as more biologics go off patent, opening the door to new, lower cost biosimilars. Asia is becoming a biomanufacturing hub, with the potential to produce biosimilars at a lower cost, and then export its products to other countries.

Biomanufacturing is in a dynamic state of change. The biomanufacturing plant of the future will be more efficient, have higher throughput and greater flexibility. New single-use technology has reduced the need for high cost capital investment in big stainless steel facilities with [redacted] L bioreactors. The biomanufacturing industry is moving toward "plug and play" modules with single use upstream and downstream processing trains. These "plug and play" factories can be operational and cGMP compliant in [redacted] to [redacted] months, compared to years for a traditional, stainless steel factory.

Bioseparations products and systems are essential in the biomanufacturing of all biologicals. These highly specialized separations systems are integral components of the downstream process. They enable the separation of the target biomolecule from a thick, cellular soup-like material, containing proteins from the culture media and host cells, cellular debris, DNA, bacteria and virus and purification to meet the high purity required for administration of the biodrug to humans. Chromatography, membranes, filters and centrifuges are used in the multitude of steps required to purify a biologic. These high value separation systems provide the highest purity required for human use.

The global market for these high value separations products is growing from $[redacted] in [redacted] to $[redacted] in [redacted] at a compound annual rate of [redacted]%. North America and Western Europe account for [redacted]% of the global market. A significantly higher growth rate of [redacted]% is projected for the Asian markets.

Chromatography is the most costly separations method, and is $[redacted], or [redacted]% of the Bioseparations Product Market. Membranes and filters are $[redacted] ([redacted]% of the market), and centrifuges are $[redacted] ([redacted]% of the market).

The market is dominated by five companies: GE Healthcare Life Sciences, Pall Corporation, Merck Millipore, Sartorius and 3M Cuno. These companies collectively own [redacted]% share of the global bioseparations market. There are over [redacted] companies who manufacture and distribute separations systems and products globally and are competing for share of this rapidly growing market. Companies in this market are developing new single use products, innovative separations technologies to improve downstream processing, and producing "turn-key" systems with specific bioprocessing platforms. They are focusing marketing and sales efforts in Asia and emerging BRIC countries.

TriMark believes that the global bioseparations market will be driven by a number of key favorable industry trends.

- The demand for single use products is increasing and fueling growth of the global bioseparations market. Single use products have shifted the manufacturing cost structure from capital to operating expense. This is allowing rapid start up of biomanufacturing and reduction of millions of dollars in capital costs for expensive stainless bioreactors, holding tanks, and buffer tanks.

- Asian countries of India, Singapore, South Korea and China are fast becoming biomanufacturing hubs producing biosimilars for their large populations. India and China are increasing healthcare coverage, investing in treatments for chronic diseases and cancer. Singapore is a biomanufacturing center for major pharmaceutical and biopharmaceutical companies, producing biologics for the Southeast Asian market. South Korean is becoming a leader in contract manufacturing as well as production of biosimilars.

- New biosimilars are driving the increase in global manufacturing capacity. Blockbuster biologics are going off patent leaving the market open for development and manufacture of low cost biosimilars. Europe is leading in approval and marketing of biosimilars, followed by the emerging BRIC countries.

- Contract manufacturing organizations are increasing capacity to meet the demand from pharmaceutical and biopharmaceutical companies. CMOs are offering "capacity on demand," a cost-effective alternative to constructing new or expansion of existing biomanufacturing facilities.

- Bioseparations companies are investing in new innovative technologies for chromatography and membrane filtration making the downstream process more efficient. As these technologies are validated, they will replace existing process trains that have become a bottleneck in large biomanufacturing plants.

