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The Changing Face of Chromatography

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From cutting-edge gene therapies to groundbreaking mRNA vaccines, innovative approaches hold tremendous promise for treating and preventing diseases. However, their development and production pose unique challenges that demand equally innovative solutions. Let's look at how chromatography, a foundational technique in biopharmaceutical manufacturing, is keeping pace with these new therapies and explore the latest developments in the chromatography market.



The global chromatography market was worth $11.19 billion in 2021, and is projected to reach $15.33 billion by 2030, as per SkyQuest Technology Consulting. Increased investment in Research and Development (R&D), rise of new therapies, etc. all driving the growth of chromatography market.

Increased investment: Increased investment in R&D activities within the pharmaceutical and biotechnology sectors has resulted in a significant uptick in the utilisation of chromatographic techniques for downstream testing, contributing substantially to market expansion.

Rise of new therapies: Emerging therapies like cell and gene therapies, mRNA, biosimilars, proteomics, genomics, and monoclonal antibodies (mAb) are all advancing innovation in chromatography. Leading players in the field are introducing specific solutions for these therapies. In August 2023, Waters launched XBridge Premier GTx BEH size exclusion chromatography (SEC) columns to enhance gene therapy analysis, particularly for adeno-associated viral (AAV) vectors. Similarly, in 2021 Cytiva introduced HiScreen Fibro PrismA, a new tool for early monoclonal antibody purification process development, complementing their HiTrap Fibro PrismA platform designed for research applications.

Mergers and collaborations: Key market players are focusing on new product launches and partnerships to expand their global product offerings. For example, in 2023, Gamma Biosciences, a global life sciences platform formed by KKR to address the advanced therapy market with best-in-class bioprocessing solutions, entered into an agreement with Swedish life sciences company Biotage AB, whereby Biotage will acquire Gamma's operating company, Astrea Bioseparations, in exchange for newly issued shares in Biotage, creating a global chromatography leader with an attractive mix of products and services across multiple end-markets globally. In 2021, Sartorius Stedim Biotech acquired Novasep's chromatography equipment division.

What's new?

Major industry players are investing strategically to grow their market share and constantly working to develop new products that meet changing consumer demands.

High-Performance Liquid Chromatography (HPLC): Waters Corporation introduced the Alliance iS intelligent HPLC System to enhance compliance and error detection, in March 2023. When used with Empower Chromatography Software and eConnect HPLC Columns, it reduces common errors by up to 40 per cent, ensuring QC laboratories meet quality, safety, compliance, and delivery goals.

Shimadzu Corporation unveiled their cutting-edge 'Advanced i-Series' HPLC in 2020, a flagship liquid chromatography machine that can be operated remotely. In 2022, Bio-Rad Laboratories launched its EconoFit Low-Pressure Prepacked Chromatography Column Packs. The EconoFit columns are designed for resin screening, allowing customers that are developing protein purification workflows to select the optimal chemistry for different targets.

Portable HPLCs are an emerging technology in this segment. An example is PolyLC's Smart LifeLC, a complete, portable HPLC System designed for A1C testing (a diabetes marker) and screening of inherited blood disorders. Another notable example is the SIELC Technologies Chromite Analyzer, which represents a new generation of affordable and user-friendly HPLC instrumentation designed for educational institutions, including schools, colleges, and universities.

Emerging entrants are partnering with established companies to innovate and enhance existing solutions. Telescope Innovations' Direct Inject Liquid Chromatography (DILC) is swiftly establishing itself as a crucial tool for supporting process development in the market. One year post-launch, Telescope reports that DILC units have been adopted by 13 of the world's top 20 pharmaceutical companies (ranked by revenue).

Multi-column chromatography (MCC): In 2022, Tosoh Bioscience has introduced the Octave BIO Multi-Column Chromatography system, complemented by SkillPak BIO columns for efficient pre-clinical biomolecule development. This launch marks the first in a series of MCC instruments, with Octave PRO for GMP manufacturing expected by Q3 2023. The initiative aims to enhance biomanufacturing productivity, process flexibility, product quality, and cost efficiency. Last year, Merck Millipore also unveiled the Mobius Multi Column Capture System, offering a comprehensive solution for more efficient monoclonal antibody production, reducing resin and buffer usage by up to 99 per cent through continuous loading of multiple columns, thus enhancing productivity. It caters to bioreactor volumes ranging from 50 to 2000 L, operating in fed-batch and perfusion mode, with automated features for improved reproducibility and minimal operator intervention.

Notable collaborations in the field include Waters Corporation and Sartorius' announced in June 2023. They are integrating software and hardware between the Waters PATROL UltraPerformance Liquid Chromatography (UPLC) Process Analysis System and the Sartorius Resolute BioSMB multi-column chromatography platform. This integration empowers bioprocess engineers by providing comprehensive analytical data for downstream batch and continuous manufacturing, resulting in improved yields, reduced waste, and decreased manufacturing costs.

LC/MS: In June 2023, Agilent Technologies introduced two new liquid chromatography mass spectrometry (LC/MS) systems, the Agilent 6495D LC/TQ, and the Agilent Revident LC/Q-TOF. Alongside the Revident LC/Q-TOF, Agilent launched the Agilent MassHunter Explorer Profiling software and the Agilent ChemVista library manager software, enhancing high-end performance. In September 2023, Waters Corporation also made a significant advancement by integrating its BioAccord LC-MS system with the Waters Andrew+ robot using new OneLab software protocols. This integration creates user-friendly bioprocess walk-up solutions, facilitating critical quality attribute (CQA) data acquisition for drug product and cell culture media analysis. Direct data capture at the bioproduction laboratory aims to enhance process understanding, leading to more robust manufacturing processes and faster development timelines.

Thermo Fisher Scientific and Newomics are collaborating to develop an advanced native LC-MS platform, enhancing microflow LC-MS for proteomics and biopharmaceutical applications. This partnership announced in 2021 combines Thermo Fisher's cutting-edge LC-MS systems with Newomics' expertise, enabling high-sensitivity, high-throughput analysis of bioorganic complexes while maintaining their native state.

Affinity chromatography: The success of the mRNA vaccine against COVID-19 has skyrocketed the development of RNA therapies.Thermo Fisher Scientific has developed a novel affinity chromatography resin with a poly(styrene-*co*-divinylbenzene) backbone and with through pores to isolate and purify mRNA at various scales. Because the POROS Oligo dT(25) affinity resin binds mRNA through a simple adenine–thymine base-pairing mechanism, it can serve as a purification platform for all mRNA molecules containing a poly-A tail.

In 2021, Purolite announced the commercialisation of two novel affinity chromatography resins tailored to meet the diverse needs of today's biomolecule pipelines, including antibodies, vaccines, and gene therapy. In January 2023, Repligen launched AAV affinity resins for gene therapy purification.

Pharmaceutical R&D, new therapies, evolving customer demands and collaborations will continue to drive innovation and enhance chromatography capabilities.

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