By Dr. John Gebler, Director Strategic Biopharma Business Development

The impact of novel biologic modalities on the biopharmaceutical industry as well as on the popular belief of "what's possible" in science and healthcare have been monumentous. Extraordinary events have made terms such as mRNA and CRISPR a part of our common social vocabulary outside scientific circles. Before the unprecedented COVID-19 pandemic in 2020, very few within the scientific community could fathom or predict the successful commercialization and effectiveness of mRNA vaccines. These vaccines have helped more than 5.5 billion people avoid serious COVID illness (Our World in Data). However, new generations of biologics are far from one-hit wonders. Since the recent commercial success and cost-effectiveness at scale of mRNA vaccines, new vaccine modalities are now being used to develop next-generation flu vaccines that are able to cover all possible strains. (A multivalent nucleoside-modified mRNA vaccine against all known influenza virus subtypes, 2022) Despite economic challenges we see across other industries, new drug modalities, including gene- and cell-based therapies, are experiencing rapid and robust growth (Katsnelson, 2022).

As new biologic modalities continue to advance rapidly, especially with increased investments, the analytical lab will need to evolve its capabilities to address new analytical characterization challenges to seize this historic moment in biopharma. The increased molecular size, the complexity of new biologics, and the evolving regulatory expectations place new burdens on core traditional analytical capabilities. At the same time, expectations to create and adopt robust, reproducible methods are required to mitigate risks and consistently deliver high-quality drugs.

Modern High Performance Liquid Chromatography (HPLC) and Ultra High-Performance Liquid Chromatography (UHPLC) columns have significantly improved over the past 15 years. The continued innovation is vital to addressing the challenges of complex characterization and the ability to deliver high-quality biologic drugs. Chromatographic column improvements substantially reduce waste and sample consumption, avoid repeat analysis, and ultimately reduce the time-to-market timeline. Phenomenex is committed to developing quality columns and sample preparation devices for emerging biologics like mRNA and gene therapy and growing its strong portfolio for traditional biologics such as recombinant proteins and peptides, monoclonal antibodies, antibody drug conjugates, and oligonucleotides.

Click here to read about Phenomenex’s pioneering journey in biopharma and how they set the bar for oligonucleotide extraction and purification, as well as their approach for the future.

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