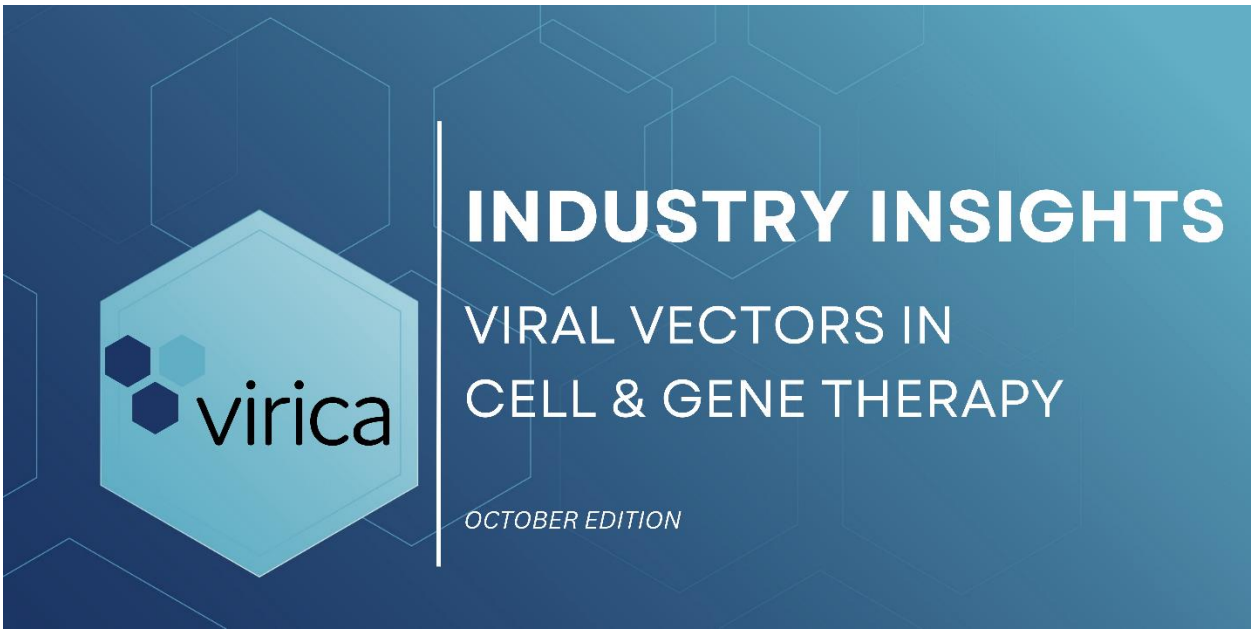

Report Overview:

- Virica's Insights
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Virica's Insights

The cell & gene therapy industry is re-calibrating following the strong years of economic investments due to COVID-19. The economic downturn makes focusing on core competencies and product differentiation imperative, alongside judicious allocation of investments. The need for differentiation is particularly pronounced in the CDMO space with several new entrants in 2023 including Lifera, eXmoor pharma, Kincell and NewBiologix. The market correction, however, has not deterred novel therapies, with several cell and gene therapies pending approval in 2023, a few notable therapies already cleared by the FDA.

The cell & gene therapy sector continues to experience production bottlenecks due to high manufacturing costs and limited capacity for viral vector manufacturing. To meet the challenge, the industry continues to innovate on upstream process development,

automation and downstream analytical technologies. The recent BioProcess International conference highlighted the complexity of cell and gene therapy manufacturing and the need to tackle the challenge from multiple angles using complementary and synergistic technologies. The 2023 Cell and Gene Meeting on the Mesa echoed the focal point of manufacturing, emphasizing capacity, stability, purity and quality control.

Top Headlines:

FDA green lights Intellia Therapeutics for first pivotal trial of in vivo gene editing treatment.

The FDA green lights Intellia Therapeutics, Inc. to conduct phase III clinical trials for transthyretin (ATTR) amyloidosis. This serves as the first & pivotal study of an in vivo gene editing treatment in the US. Intellia's ATTR amyloidosis treatment, NTLA-2001, is meant to be a one-time treatment for gene editing within the body, delivered via blood infusion to reduce the levels of misfolded proteins.

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Oxford Biomedica bolsters viral vector capacity by acquiring ABL Europe.

Oxford Biomedica is expanding its CDMO network by acquiring ABL Europe from Institut Mérieux in a deal worth €15 million. The partnership provides additional GMP-compliant viral vector facilities and ABL Europe's client portfolio. The expansion enhances Oxford Biomedica's CDMO capabilities and capacity to meet growing demand.

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Novo Nordisk to establish cell therapy manufacturing 'hub' to address manufacturing gaps in the cell therapy ecosystem.

Novo Nordisk Foundation invests $136 million in the Cellerator, a cell therapy hub at the Technical University of Denmark (DTU). The objective is to bridge manufacturing and workforce gaps in the cell therapy ecosystem by focusing on consistent, large-scale manufacturing for early clinical trials. Cellerator's services range from process development and manufacturing to product release and regulatory support for academia, biotech and pharmaceutical clients.

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News at a Glance

- Kincell Bio, a cell therapy CDMO, emerges from stealth. The company offers a suite of services targeted towards early-stage GMP production of cell therapies.

- Excellos opens a cell therapy manufacturing facility in San Diego, US amid growing manufacturing demands.

- Moderna follows Astrazeneca's lead, discontinues 4 mRNA based clinical assets. The pipeline changes follow after Moderna's announcement of phase 3 success on its mRNA flu vaccine, mRNA-1010.