SOLVING THE CHALLENGES IN VIRAL VECTOR SUPPLY:

A REPORT ON THE MARKET OUTLOOK FOR CELL & GENE THERAPY

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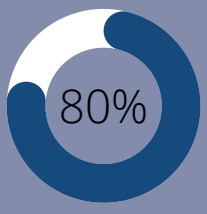
WHAT ARE THE CHALLENGES?

The capacity challenges in viral vector manufacturing cannot be understated. For more than 5 years, Cell and Gene Therapy's (CGT's) explosive growth has fueled a dramatic surge in demand. The Alliance for Regenerative Medicine's recent 2021 annual report shows over 2400 clinical trials. As these trials advance through the pipeline, larger patient populations will precipitously increase demand for AAV, LV, and other vectors. By 2025, the FDA expects approvals of 10-20 new commercial CGT drugs a year. The underlying demand trends show no slowdown in sight. Compounding the situation, the global pandemic has driven a surge in AV for viral vaccines. The timing of these unprecedented events has resulted in a multi-year deficit whereby therapeutic developers are paying advance reservation fees to hold capacity a year or more out.

THERAPEUTIC DEVELOPMENTS: IN HOUSE OR MANUFACTURED

While a few therapeutic developers have brought their viral vector supply in-house, the vast majority rely on contract manufacturing. Market dynamics strongly favor outsourcing. Large scale production offers massive economies of scale. And scaling up these processes requires critical technical expertise.



CDMOs continue to provide over 80% of supply – a trend expected to continue for years to come.

CGT TECHNOLOGIES:
KEY INDUSTRY PLAYERS

Alternative technologies have gained traction and show future promise for cell engineering. Novel gene-edited therapies use electroporation and mechanical methods for engineering. Gene therapies can use Lipid Nanoparticles. And mRNA has shown great promise for a wide range of applications, particularly in vaccines for cancer and infectious disease. But viral approaches remain the most common with established manufacturing methods, robust safety data, and proven regulatory pathways. The forecast for viral vectors demand remains bullish for several years to come.

The industry has responded with huge investments in manufacturing capacity. The large strategics have led the charge, including:

ThermoFisher SCIENTIFIC

CATALANT

MilliporeSigma

charles river

WuXi Biologics
Global Solution Provider

Mid-size players have also aggressively expanded, such as Andelyn and Vibologics. And a new wave of players is taking a new approach, combining proprietary technologies with investment funding, real estate, and CDMO capabilities. Companies like Resilience, Elevate Bio, and Center for Breakthrough Medicine have raised billions of dollars to support the emerging industry.

CELL & GENE THERAPY OUTLOOK

While aggressive expansion is helping to address the capacity crunch, the real promise lies in new technologies with the promise to boost productivity. Over the past 24 months, Perkin Elmer has made two such acquisitions in Oxgene and Sirion. CEVEC and Invitria have pivoted from biologics to apply their proprietary tools for gene therapy. And from recent start-ups, a new crop of “better mousetrap” components include Asimov’ cell lines, Virica’s viral sensitizers, and Xell’s (now Sartorius) culture media.

These novel technologies substantially boost productivity to provide critical supply of viral vectors with fewer production lots and reduced volumes. They promise to go far beyond what is possible than methods focusing solely on “brute force” expansion. In the medium-to-longer term, these technical advances will play a critical role in balancing the capacity constraints for viral vector manufacturing.

The industry outlook remains bright. Cell and Gene Therapies are slowly progressing towards more prevalent indications.In time, they will move to second and first-line treatments. As the modality becomes more mainstream, cost pressures will continue to mount. Novel technologies hold great promise to address the supply challenges in viral vector manufacturing and enable the broader application of CGTs to advance human health.

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