Viral vector one-stop-shop for gene and cell therapy

VIRAL VECTORS Many CDMOs have taken actions to meet the growing demand of viral vector development and manufacturing services for clinical trials, as well as for commercial scale production. While capacity is important, there are only a few companies who provide services across the entire supply and value chain. So, what should you expect when choosing a true One-Stop-Shop as a CDMO partner in the gene therapy space?

› Dr. Knut Ringbom, CEO, Biovian Oy, Turku, Finland

Currently, global biopharmaceutical companies are facing increasing pressure to develop innovative drugs in faster time and at lower cost. Thus, partnering with a CDMO that offers a comprehensive range of services can be the best policy for the drug developers seeking increased efficiency.

Many manufacturing organisations have adopted a phrase "one-stop-shop" to define their way to operate. However, a deeper look at the processes and operations may bring up some substantial differences between service providers, despite supposedly similar positioning. While there is no one-size-fits-all answer for gene therapy developers, a reflective, mutually transparent gap analysis is an important exercise between any developer and manufacturer when looking for the right CDMO for the specific needs.

Benefits of a true One-Stop-Shop

Biovian's definition of a one-stop-shop, is to provide clients with services across the supply and value chain. This is facilitated by Biovian's fully integrated infrastructure of resources and capabilities.

Within the supply chain, we cover services all the way from GMP cell bank manufacture to aseptic fill and finish of final products. Further, labelling and warehousing of the drug products at −80°C can be provided within the comfort of our EMA-certified, FDA-inspected facility. When it comes to the value chain, Biovian fully covers the life cycle from pre-clinical, to clinical, to commercial GMP supply of plasmid DNA and viral vectors.

Our new GMP production area includes 200 L scale, single-use bioreactors, which enable efficient manufacturing of viral vectors at a sufficiently large scale for more advanced clinical trials and support of commercial strategies. With this current facility extension, we will more than double our capacity in the production of adenovirus, AAV, and lentivirus, building on over a decade of experience in the viral vector field.

A key part of the value chain is, of course, quality and regulatory support from expert teams. We are very proud to have four Qualified Persons who ensure that clients' investigational, medicinal products are released smoothly for clinical trial use or for sale.

Keeping an eye on the future

To summarise, it is important to keep an eye on the future of the product from the very beginning of the project. When partnering with a qualified, dynamic One-Stop-Shop CDMO, like Biovian, that accompanies the entire supply chain and value chain, there is no need to change providers, which is often a time-consuming and costly hurdle. We eagerly look forward to Viral Vector-based gene therapy to step out of its niche, and we are ready to serve our new, current, and returning clients with Nordic consistency, reliability, and efficiency. ■

Pictures: Biovian Oy