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Biovian: a true one-stop-shop CDMO with gene therapy capacity and a Nordic ethos

Covering the whole production chain from the supply end to the value end, Nordic Biovian delivers a comprehensive and reliable manufacturing service, enabling the development of medical therapies.

Biovian is clearing bottlenecks in gene therapy production with its complete one-stop-shop service. Guided by its Nordic ethos, the contract development and manufacturing organization (CDMO) has built a reputation for delivering high-quality work on time and on budget to a global client base. Having done so, Biovian is continuing to expand its operation, adding scale and capabilities to support the development of breakthrough therapies.

'One-stop shop' is a term frequently used in the CDMO space, yet it is often poorly defined. Biovian views the concept along two axes, the supply chain and the value chain. To be a true one-stop shop, a CDMO needs to offer the full breadth of services along both the supply chain and the value chain.

Biovian meets that definition (Fig. 1). On the supply chain, Biovian's services span from master cell banking to qualified person release of the final labelled drug product.

Similarly, on the value chain Biovian's services run from preclinical supply up to commercial supply or manufacturing, enabling it to continue supporting clients as they take molecules through development and onto the market. At each stage, Biovian adheres to good manufacturing practice (GMP) and works out of fully inspected, fully certified facilities.

The breadth of Biovian's offering along both the supply and value chains differentiates it from some other CDMOs, which present themselves as one-stop shops but have gaps in their offerings that force clients to enlist other service providers for some work. Biovian is a true one-stop-shop CDMO.

How Nordic values guide Biovian

The clear definition of one-stop shop is in keeping with Biovian's straightforward, transparent approach to all communications and interactions with clients. As a Finnish CDMO, Biovian's approach is informed by the culture and world-leading education system of the Nordic region. Words such as quality, honesty and reliability that are inextricably linked to the Nordic region are embedded deep in Biovian's ethos.

That ethos can be boiled down to a simple statement: "We do what we say we will do." Those eight words capture the essence of Biovian's approach to clients, an approach that has enabled it to build a global customer base since it began operating in 2003. If Biovian says it will provide a deliverable by a particular date for a particular price, clients can be confident it will do everything in its power to do so.

Biovian's ability to live up to those expectations rests on its employees, who have the expertise and scientific skills needed for challenging projects. As importantly, having come through the Finnish



Fig. 1 | Biovian offers clients a true one-stop-shop good manufacturing practice (GMP) contract development and manufacturing organization (CDMO) service, with modularity available from gene to finished vial.

education system, Biovian's staff share its focus on quality, honesty and reliability, values that are reinforced through the nature of interactions between the company and its employees.

By taking a straightforward, human-centric approach to internal and external relationships, Biovian has built a culture that prioritizes customer satisfaction and employee fulfillment equally. The result is a CDMO that is institutionally driven to deliver on its promises.

Investing to serve changing client needs

Biovian's strong relationships with employees and clients alike help it stay abreast of changes in the type of services biopharma companies need. Such insights helped Biovian to foresee the ongoing surge in demand for gene therapy manufacturing services and invest accordingly. Having done so, Biovian is easing two critical bottlenecks in gene therapy production today: viral vectors and plasmids.

In 2020, Biovian opened an expanded GMP viral vector manufacturing plant, more than doubling its capacity to make adeno-associated viruses, adenoviruses and other viral vectors vital to the delivery of gene therapies. Through the expansion, Biovian added a 200 l bioreactor, equipping it to continue to serve clients as they take gene therapies into late-phase clinical trials and onto the market.

Reflecting Biovian's definition of one-stop shop, that expansion along the supply chain was accompanied by an expansion along the value chain.

Specifically, Biovian moved into the production of the plasmids that form the building blocks of viral vectors, making it a true one-stop shop for gene therapies.

Biovian is continuing to add to its capabilities. In 2021, the CDMO will open an aseptic filling line for recombinant proteins and plasmid DNA, adding to its existing biosafety level 1 and 2 viral vector fill-and-finish capabilities. The new fully automated filling line, which supports batches of up to 10,000 vials, features a restricted-access barrier system to ensure aseptic quality without sacrificing process flexibility.

The investments in viral vectors and fill-and-finish capacity are in line with the approach that has established Biovian as a premium CDMO. In a competitive market, Biovian has differentiated itself by pairing leading-edge production capabilities with its Nordic ethos, enabling it to deliver the materials clients need, when they need them, at the agreed quality.

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