

June 28, 2021



# BioConnection receives from the Dutch Healthcare Inspectorate (IGJ) the GMP certification and manufacturing license for their new large scale filling line

BioConnection B.V., an independent CMO (Contract Manufacturing Organization) based in Oss, The Netherlands, specialized in the production of sterile drug products for medicinal use in humans, has been given permission from the Dutch Healthcare and Youth Inspectorate (IGJ) to produce sterile drug products on their new large scale filling line. The receipt of this manufacturing license landmarks the go-ahead for BioConnection and their customers to now produce sterile drug products on a larger scale in their facility. The company is now also in a good position to fill a gap in the worldwide shortage of fill & finish production capacity for vaccines, for example.

In April 2019, BioConnection announced its plans to invest 12 million euros in a new production line to significantly increase its production capacity and to ensure future company growth. Construction started in December 2019. The construction was spot-on-track and within 18 months, the new line now is approved and licensed for GMP productions.

## EMA and US-FDA requirements

The new production line has an annual production capacity of up to 40 million vials for liquid products and up to 4 million vials for freeze-dried products. It features a fully automated filling line (by Groninger, Germany) coupled to a fully automated 10 m<sup>2</sup> freeze dryer (by HOF, Germany). The new production line is built to meet the highest quality requirements in the (bio) pharmaceutical industry which enabled BioConnection to have the line validated as per the EMA and US-FDA quality guidelines.

Due to the expansion, BioConnection is now able to service its clients from four different production lines within one facility in production scales ranging from 0,1L to 1.000L per batch.

“We are extremely proud of our new large-scale filling line and its significance for the Dutch pharmaceutical manufacturing industry. We can make an important contribution to fill a gap in the worldwide shortage of production capacity for sterile medicines”, says Alexander Willemse, CEO at BioConnection.

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## About BioConnection

BioConnection B.V. is an independent contract manufacturer for the GMP production of sterile drug products (in vials or syringes) for clinical trial programs and commercial purposes. Its state-of-the-art GMP manufacturing facility is EMA and US-FDA certified. BioConnection has more than 15 years of experience and a global customer base. BioConnection offers complete drug product service packages including: filling and freeze drying, technology transfer, scale-up, process validation, analytical support, stability studies, label & pack (incl. serialization) and final GMP release. Learn more at [www.bioconnection.eu](http://www.bioconnection.eu)

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