

Polyplus expands GMP offer with protein production and adds GMP capacity in Belgium

March 6, 2024 | News

New GMP certification for protein manufacturing covers the production of recombinant proteins



Polyplus (part of Sartorius) company, Xpress Biologics, has received a good manufacturing practice (GMP) certification for recombinant protein production and renewed the January 2023 GMP certification for DNA production at the facility located in Belgium.

In parallel to the new certification, an additional GMP clean room for the production of GMP cell banks has been added and the addition of a GMP production line is planned at the Belgium facility to increase capacity.

“This is a great time at Polyplus, as we continue to grow our footprint and capabilities under the Sartorius umbrella, fulfilling promises made to support customers. These certifications and extra capacity enable our Xpress Biologics team to offer research and development (R&D) into clinical phase support for any type of protein or DNA project, which can be hard to find,” said Mario Phillips, Head of Polyplus.

The new GMP certification for protein manufacturing covers the production of recombinant proteins including antibody fragment using microbial expression systems like *E. coli* and *P. pastoris* under certification number BE/GMP/2023/093 and MIA 2100 IMP.

The certification was performed by the Belgian Federal Agency of Medicines and Health Products (FAMHP) and is recognized by the FDA and EMA for recombinant plasmid and protein manufacturing including antibody fragments.

“We have already made great progress in just a year working with the DNA GMP certification. So far we have completed GMP release of 13 pDNA batches and Master Cell banks for different cell and gene therapy (CGT) and mRNA vaccine applications,” said Marc Daukandt, General Manager of Xpress Biologics.