

# Opportunities for biologics manufacturing

EU-based GMP manufacturing DS/DP facilities for biologics



# Bilthoven Biologicals provides a full-cycle biologics GMP infrastructure

## Introduction

BBio is an end-to-end vaccine manufacturing company in the EU, with a comprehensive commercialisation & distribution infrastructure.

With its' end-to-end GMP vaccine operations and approx. 500 employees, BBio is supplying more than 300M doses in bulk and 100M doses of vaccines globally.

BBio has recently expanded its commercial GMP infrastructure with two newly established manufacturing facilities:

1. **Drug Substance:** multi-purpose, single-use facility for (viral vector) vaccines and biologics, capability for adherent and suspension , cell culture (2x trains), USP with **3x 2,000L** scale SUBs and DSP (2x trains) with single-use technology
2. **Drug Product:** multi-purpose filling line for syringes and vials

These are new state-of-the-art facilities with much flexibility for **viral vector**, **vaccines** and **other biologicals**, fully supported by **QA/QC/QP**.

This GMP infrastructure could be made available for interested partners in search for GMP biologics manufacturing capacity in EU.

As a strategic partner to BBio, you will receive the following benefits:

- ✓ Access to fully operational GMP facilities for DS and DP in EU
- ✓ Flexibility to manufacture clinical and commercial material in EU
- ✓ Support with QA/QC/QP infrastructure of BBio for release of clinical and commercial material
- ✓ Lease GMP facilities with GMP trained staff, without substantial CAPEX investment required to establish GMP certified infrastructure
- ✓ A long-term strategic collaboration, with GMP manufacturing infrastructure in EU ensured

# Bilthoven Biologicals provides GMP biomanufacturing facilities



## Drug Substance facility (new)

- Drug Substance facility for biologics
- Single-use technology
- Cell culture area, USP/DSP area
- 3x 2,000L single-use bioreactors
- **GMP certified**
- Pandemic Preparedness facility



## Drug Product facility (new)

- Drug Product facility for biologics
- Filling line with isolator
- Vials and syringes (RTU)
- Single-use mixing
- **GMP certified**
- Pandemic Preparedness facility

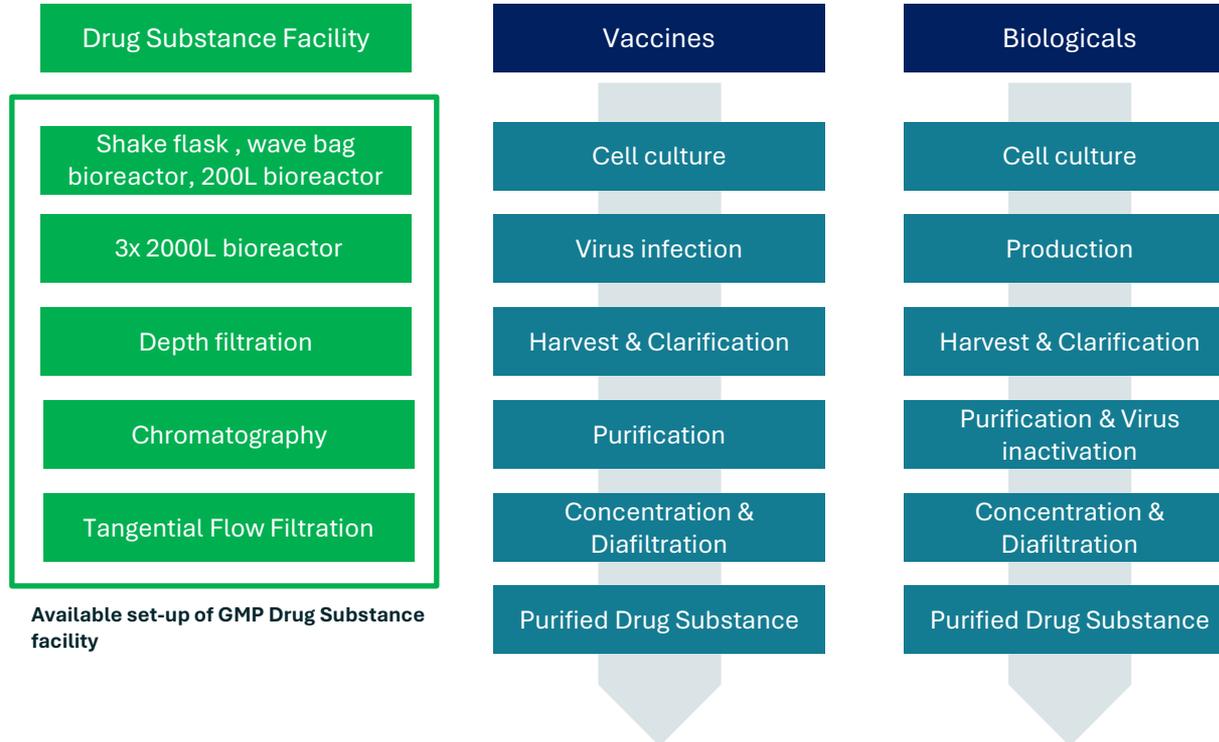


## High-containment manufacturing facility (new)

- BSL-3 facility
- Grade C cleanrooms
- Multi-purpose use
- All utilities in place
- Suitable for clinical material manufacturing
- **Ready for GMP certification**

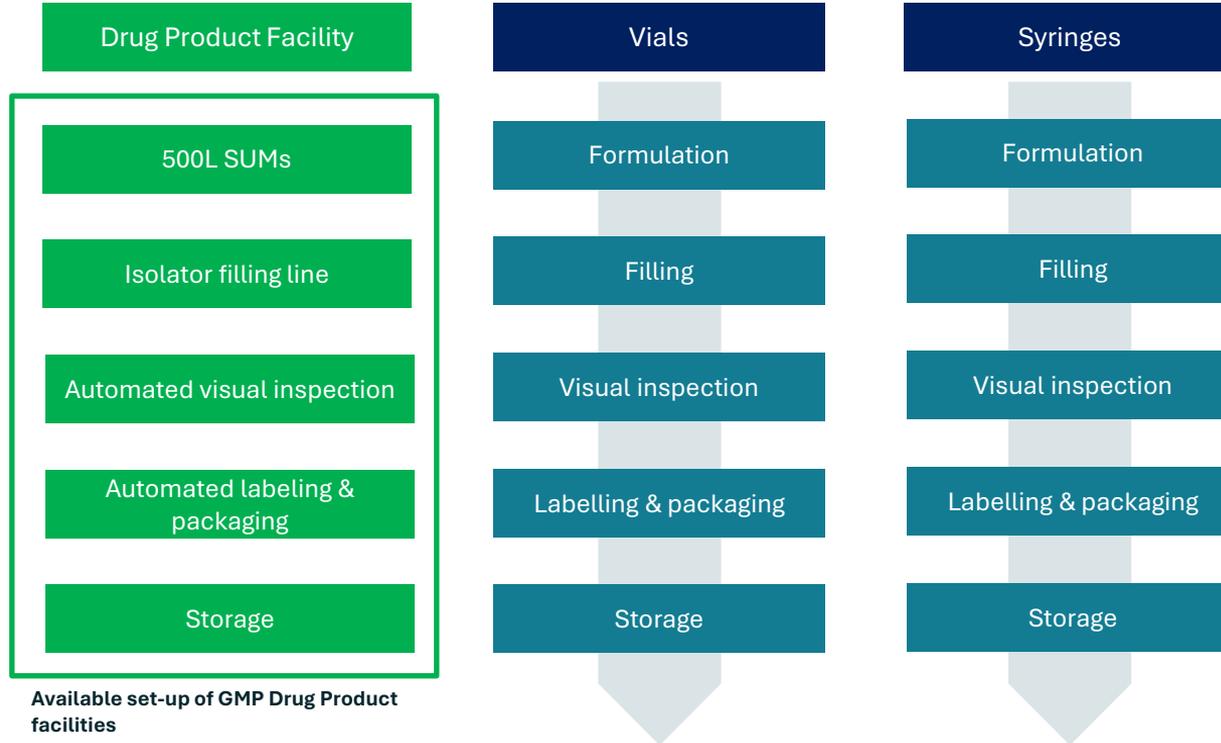
*GMP facilities available for flexible collaboration models (from CMO to sublease)*

# Bilthoven Biologicals state-of-the-art GMP Drug Substance facility



Available set-up of GMP Drug Substance facility

# Bilthoven Biologicals state-of-the-art GMP Drug Product facilities



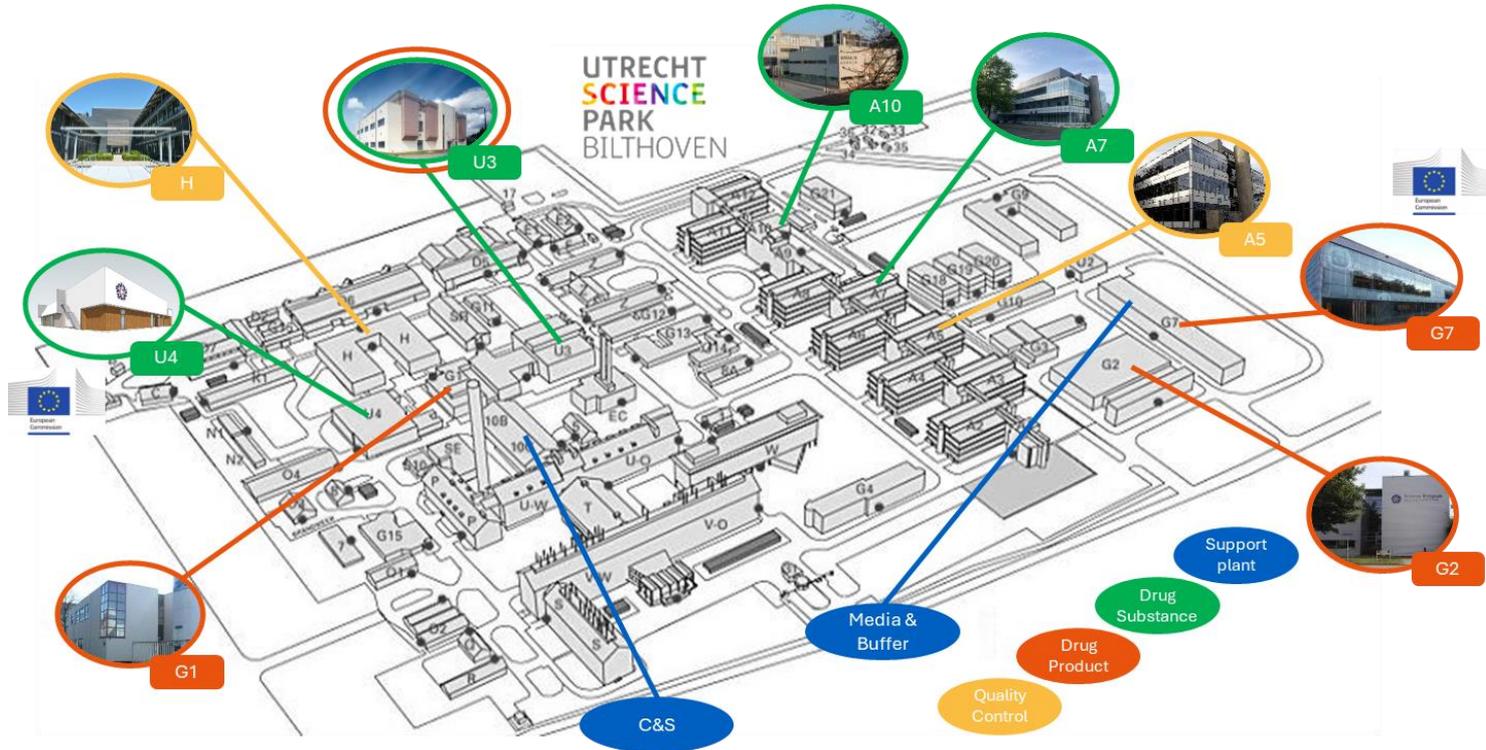
# Bilthoven Biologicals provides supporting biomanufacturing services

Occupants of DS and DP facilities can further benefit from GMP biomanufacturing services:

- **QC labs** for in-process and release testing
- **QA/QP and Regulatory** services for EU supply
- **Media and buffer preparation** services
- **Storage and warehousing**
- **Cleaning and sterilisation** services

Bilthoven Biologicals provides an integrated infrastructure for **large-scale biomanufacturing** within EU

# Bilthoven Biologicals newly established DS and DP facilities part of full cycle operations



Private and Confidential

Bilthoven Biologicals is located at **USP Bilthoven** a leading Dutch biomanufacturing hub



UTRECHT  
SCIENCE  
PARK  
BILTHOVEN

Private and Confidential

# Let's connect – Bilthoven Biologicals and USP Bilthoven offer a lot of opportunities for partners in search of biomanufacturing capacity



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