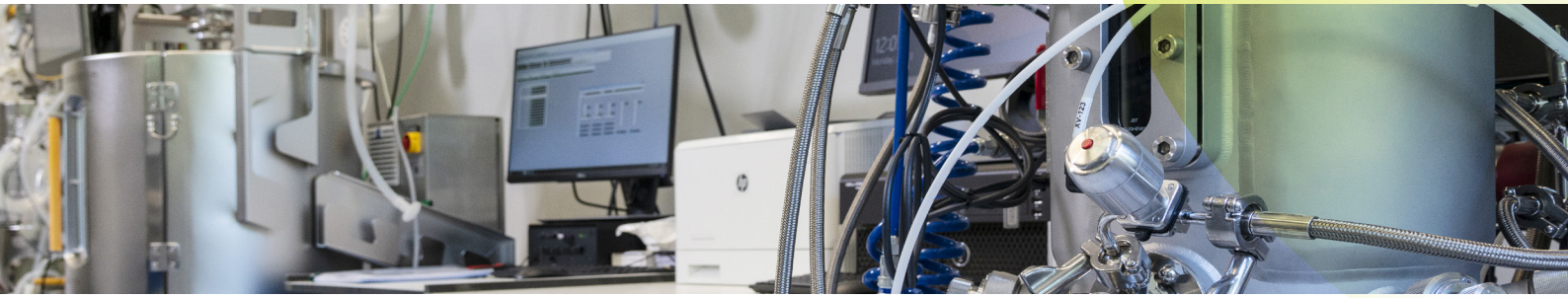
Vaccsheet

GMP facilities



At Intravacc we have two GMP facilities on the campus, Intravacc and BuildingX. We offer pilot GMP production of both viral, bacterial and cancer vaccines. A variety of production technologies are available in both single-use or stainless steel bioreactors.

At Intravacc, the GMP cleanrooms (class c) and quality control span 230 sqm. In BuildingX four labs are available for BSL3 activities (165 sqm). Two of these labs can be used for GMP activities. Through our partnership network we can produce up to 100 million doses of vaccine.

GMP plant capacities:

- 1 to 200 L single-use bioreactors and bag systems
- 20 to 70 L stainless steel bioreactors
- 1000 L stainless steel bioreactor can be used in collaboration with one of our GMP partners

All capacities include corresponding downstream process equipment.

Track record:

- RSV master and working seed lot and (pre)clinical trial material
- Neisseria seed lots and Outer Membrane Vesicles
- Polio type 1, 2 and 3 master and working seedlots and clinical trial material
- Vero-G: master and working cell bank
- Master and working seed lots of new attenuated poliovirus vaccine strains
- CTM production of a semi-synthetic Shigella conjugate vaccine
- CTM production of coxsackie B vaccine

Quality Control

Quality Control is responsible for release testing of GMP batches, sampling and testing of raw materials and the management and execution of stability programs. Furthermore, the QC department performs Intravacc's environmental monitoring program and routine monitoring of the purified water system.

At Intravacc, Quality Control (QC) utilizes dedicated labs under GMP regime. Release and stability testing is performed under GMP regime by qualified QC technicians. Product specific, in house developed, analytical techniques that are performed within QC include:

- virus titration
- pH, osmolality and appearance
- immunoassays (ELISA)
- qPCR
- protein content
- HPLC
- Mass Spectrometry
- NMR
- FFF-MALS

General (microbiological) analytical techniques that are outsourced to one of our partners include:

- Sterility
- Bioburden
- Endotoxin
- Mycobacteria and Mycoplasma
- Particulate Matter Subvisible
- TOC and Nitrates
- DNA fingerprinting and deep sequencing

In addition, Quality Control is involved in the validation of product specific analytical techniques that is performed in close collaboration with the department Product Characterization according to ICH Q2 (R1) guideline.

Intravacc.
Innovating vaccines

The Netherlands-based Intravacc is one of the world's leading organizations with many years of experience in translational vaccinology. As an established independent clinical development and manufacturing organization (CDMO) in the vaccine industry, Intravacc has transferred its technology and know-how world-wide, including oral polio vaccines, measles vaccines, and DPT, Hib and influenza vaccines. Intravacc offers a wide range of expertise and is the bridge between discovery and pilot scale GMP biomanufacturing up to phase I/II clinical trials for partners such as academia, public health organizations (WHO, BMGF), and biotech and pharmaceutical companies.

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