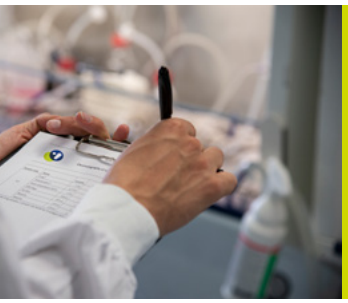
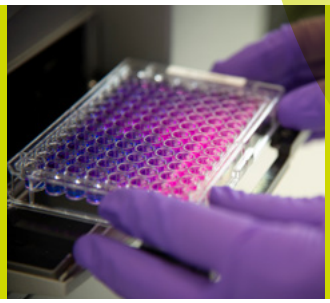
Vaccsheet

GMP Manufacturing






Intravacc is a market leader in vaccine development. We offer a wide range of services and vaccine development platforms, bridging the gap between discovery and pilot scale GMP manufacturing up to Phase I/II clinical trials.

Integral GMP production services

Our expertise spans a multitude of production processes towards, but not limited to, our vaccine development platforms entailing viral (attenuated and inactivated), bacterial (whole cell and OMV) and conjugated (cancer) vaccines. In our top-of-the-line clean rooms we manufacture both drug- substances and products all in compliance with GMP.

Key GMP capabilities

- BSL-2 clean rooms (class C)
- Sterile drug product manufacturing
- 1 to 200 L single-use bioreactors and bag systems
- 70 L stainless steel bioreactors
- DSP equipment matching mentioned production size
- Technology transfer
- CMC writing for IND/IMPD

Quality Control (QC) testing and stability studies

Our QC expertise includes assay validation, sampling and testing of raw materials, and management and execution of stability and release testing of your vaccine in compliance with GMP.

Key QC capabilities

- GMP compliant QC laboratories
- Qualified QC technicians
- GMP compliant sample management
- In-house developed validated analytical techniques include virus titration, protein content, immunoassays (ELISA), qPCR, HPLC, Mass Spectrometry, NMR and SEC- and FFF-MALS
- Compendial assays that include pH, osmolality, and appearance

Accessible QC capabilities

General (microbiological) analytical techniques that are outsourced to one of our selected and qualified partners include: Sterility, Bioburden, Endotoxin, Mycobacteria and Mycoplasma, Particulate Matter Subvisible, TOC and Nitrates and DNA fingerprinting and deep sequencing.

Assay validation services

QC includes support on the development and validation of product specific analytical techniques at the highest quality level. Validation of assays is performed according to current ICH Q2 (R2) guidelines.

Tailor-made GMP production capabilities

Our state-of-the-art manufacturing facilities and wide range of analytical techniques allow us to offer focused and customized support to your vaccine development program. Furthermore, our clinical, quality affairs and regulatory teams have extensive expertise to comply to the latest GMP standards.

References

- Press release: *Intravacc announces completion of formulation and manufacturing process development of PRV-101 vaccine candidate for Provention Bio*
- Publication: *Verdijk et al., 2020, First-in-human administration of a live-attenuated RSV vaccine lacking the G-protein assessing safety, tolerability, shedding and immunogenicity: a randomized controlled trial*
- Publication: *Van der Put et al., 2022, The First-in-Human Synthetic Glycan-Based Conjugate Vaccine Candidate against Shigella*

Want to know more?

- Want to know how we can help you with manufacturing and quality control and stability testing of your candidate vaccine? Please contact us at: BD@intravacc.nl

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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Platform Vaccsheet

Intravacc - innovating vaccines

Netherlands-based global CDMO
- Founded in 2013
- HQ at Utrecht Science Park Bilthoven
- Private company since 2021
- ~100 FTEs
- Leading OMV company

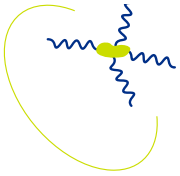
State-of-the-art facilities
- 1500+ m2 laboratories, incl. BSL-2 & GMP
- GMP certified
- ISO 14001:2015 certified
- In-house QA, QC and QP

Business focus
- Offering specialized CDMO services
- One-stop-shop for vaccine development
- Platforms & vaccines for partnering
- Bridge between bench- and large-scale manufacturing

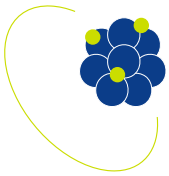
Our proprietary scalable platform technologies

OMV
- Bacterial
- Viral

Cell-based viral
- Vero and HEK293
- Viral (vector)



Conjugation
- Infectious diseases
- Combination with OMV



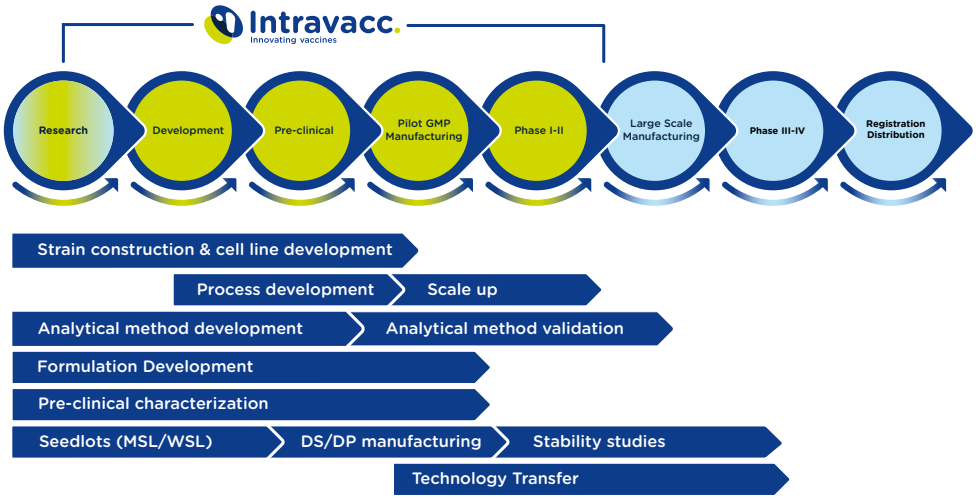
Adjuvant
- OMV
- LPS

Distinctive technology
- 4 proprietary vaccine platforms
- 11 patent families
- Viral rescue
- Mass spectrometry
- Intranasal vaccine development

In addition we offer
- Medium design
- Higher order structural analysis
- Physiochemical and immunological analysis
- Bench- and pilot-scale GMP

Stellar track record
- 2 OMV vaccines licensed
- 1 conjugate AMR vaccine licensed
- 3 cell-based viral vaccines licensed
- 300+ scientific publications
- 50+ customers worldwide
- >10 partnerships

Our services - from discovery to clinical proof of concept



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