

## GMP facility

### Pilot production for vaccine development



Intravacc has years of experience in production of GMP batches for phase 1 and 2 clinical studies of viral as well as for bacterial vaccines.

Intravacc is home to a GMP facility for production of vaccines on pilot scale. For Upstream Processing, we have bioreactors up to 100 liter; for Downstream Processing, we have all the required equipment at our disposal.

The GMP facility of Intravacc consists of a 100 m<sup>2</sup> class C/MLII cleanroom for active processes and 25 m<sup>2</sup> class C cleanroom for inactive processes. These cleanrooms are fully adaptable and can be equipped to comply to the required processes. A dedicated Cleaning & Sterilization department supports this pilot plant.

#### Benefits

- Highly experienced partner for pilot scale GMP productions
- Own cleanrooms and cleaning and sterilization department
- Own QC, QA/QP and Regulatory Affairs departments
- ISO 9001 and ISO 14001 certified

#### Quality Control

At Intravacc, Quality Control (QC) utilizes dedicated labs under GMP regime to perform validation of product specific analytical techniques. Our qualified QC technicians perform release and stability testings of GMP batches.



Assays performed within QC include:

- virus titration
- immunoassays (ELISA)
- qPCR
- protein content
- HPLC
- Mass Spectrometry
- NMR

In addition, the QC department is involved in Intravacc's environmental monitoring program.

### Track record:

In recent years, our GMP facility was used for such processes as:

- RSV master and working seed lot
- production, testing and release of clinical trial material of RSV vaccine
- Neisseria seed lots for Outer Membrane Vesicle production
- Polio seed lots type 1, 2, 3 Master and Working, pre-clinical and clinical lots
- Vero-G cell bank Master and Working
- New attenuated poliovirus vaccine strains master and working seed lot
- Shigella conjugate clinical trial material

### Intravacc

Intravacc is a renowned, not-for-profit R&D organization. With our unique capabilities and infrastructure, we are able to optimize vaccines, vaccine processes and vaccine technologies. Our aim is to increase equality in access to vaccines throughout the world in order to contribute to public health. We achieve this by transferring our knowledge and technologies to public and private partners worldwide and through collaborative R&D. A team of 150 professionals is at your disposal at Utrecht Science Park Bilthoven in The Netherlands.

### Contact

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