

## Process development Viral Vaccines



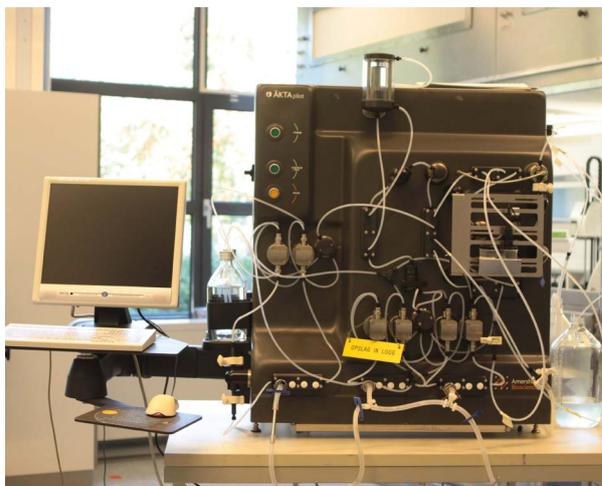
Intravacc designs and improves production processes for viral vaccines and prepares drug substances to enable pre-clinical and clinical studies at cGMP-level. Processes are designed using mathematical models, and are scalable from lab to high-volume production-scale bioreactors. Rationally designed processes are tested in our BSL-2/BSL-3 laboratory facilities using latest ICH-guidelines and insights. We have long-standing, extensive experience and capabilities in viral vaccine development, which can be applied to different vaccine concepts. Recently, Intravacc set up a scalable viral production process for Sabin-IPV, RSV, a new OPV and current HFMD vaccine.

### In silico

Production processes are controlled and characterized using statistical and mathematical computer models. This expertise enables Intravacc to design a rational and modelled process together with clients. Using these models and building on past experiences, fewer experiments are required as they are designed with more focus, for example by using cost of goods analysis and Design of Experiments approaches.

### Benefits

- Established cGMP Vero cell line
- Highly qualified BSL-2/GxP trained people
- Scalable from 2 mL to commercial manufacturing scale
- Process Models based on comprehensive and exhaustive data sets
- Tested processes to assure process robustness and reproducibility



## Cell and virus culture: process design

Intravacc's Upstream Processing (USP) expertise uses several cell lines such as the well-established Vero Cell line, and uses specific cell culture techniques in order to improve cell quality and virus yield per cell. Using exome sequencing, these processes are optimized and characterized. Furthermore, our extensive experience in culturing adherent cells on micro carriers from lab to production-scale can complement your vaccine concept. We are constantly improving processes, and are currently developing a virus culture production process using both Animal Component Free and Chemically Defined media.

## Bioreactors: technical selection

Intravacc's USP expertise allows us to design of scalable, and robust and reproducible USP processes. Our knowledge of parameters such as oxygen transfer and specific consumption rates can assist you in selecting the matching type of bioreactor. Our technical expertise enables to apply single-use technologies and analytical process technologies.

## High throughput process development

The capability to screen process conditions on a miniature scale enables Intravacc to test multiple conditions in parallel, enabling fast track process development and a reduction of resources used for an optimal process. A large dataset can be generated on a small scale, supporting development to larger production volume. For this we use multiple parallel miniaturized bioreactors, multiwell plates, miniature chromatographic columns and a liquid handling robot.

## Downstream processing

Intravacc's Downstream Processing (DSP) expertise encompasses all technologies required to process viruses in order to obtain a pure and stable vaccine or drug substance. From filtration (NFF/TFF), gradient centrifugation and ultracentrifugation, and selective precipitation to chromatographic separations and viral inactivation - the best and most cost effective methods are available to support development, intensification or improvements from lab to pilot-scale and beyond.

## Integrated Process development

As a translational institute Intravacc has in-house knowledge to develop analytical assays in order to verify production processes. Furthermore our clinical and regulatory team has extensive expertise to comply to the latest cGMP standards.

### Intravacc

Intravacc is a renowned, not-for-profit R&D organization. With unique capabilities and infrastructure, we are able to optimize vaccines, vaccine processes and vaccine technologies. We aim to increase equality by 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 programs with you. A team of 150 professionals can help you at Utrecht Science Park Bilthoven in The Netherlands.

### Contact

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