

## **PROCESS DEVELOPMENT FOR A FLEXIBLE VACCINE VECTOR PLATFORM BASED ON RECOMBINANT LIFE VIRUS**

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Vaccines are one of the most important, safe and efficient interventions to protect people from illness, disability and death. In recent years several new viral outbreaks where no vaccines are currently available were reported worldwide. Therefore, the development of flexible processes for the production of vaccines is urgently needed. This project aims at developing a platform process for the production of different viral vaccines. The core technology is based on the fact that large recombinant genes coding for selected, foreign antigens can be inserted into the genome of a well-established virus vaccination vector. The vaccine delivers the selected antigens directly to macrophages and dendritic cells, the most potent and effective antigen-presenting cells, thereby triggering a specific immune response to the selected antigens. As a replicating vector, the vaccine continuously expresses antigens even after immunization. This setup results in a powerful, antigen-focused immune response, which is expected to confer long-term immunity as shown for the measles vaccine.

The challenges in production process design for such a vaccine are the establishment of a robust cell expansion and infection strategy as well the development of efficient downstream processing methods including several chromatography principals, ultra-diafiltration and employment of bio recognition principles. The implementation of a meaningful real-time process monitoring/characterization concept furthermore serves as a basis for reliable in-process control strategies (e.g. the prediction of the optimal infection/harvesting time point).