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Advanced characterization of viral vectors for gene therapy using a combination of different analytical techniques

Field of use

Biotechnology, virus vector production and purification

Current state of technology

Technology is offered as a service with possibility of tech-transfer.

Patent status

NA

Publication

TBA

Developed by

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Background

Viruses for gene therapy and virus-like particles as vaccines are being evaluated is several clinical trials. Regulatory standards (e.g. from FDA and ICH) require control of safety, purity, concentration, identity, potency, and stability also for the virus related products. The technological progress in analytical methods for quality control assays enabled parallel development of new approaches. Quantification of target biomolecule in process development and final production, presents a specific challenge. Newly emerged analytical techniques can give results that are more informative, and complement or even outperform other methods that are used in parallel. Exact correlation between results of different techniques still needs to be established.

Description of offered Technology

We developed and applied different technological approaches for characterization of viral vectors for gene therapy or vaccines. Quantification of viral genomes is performed by molecular methods such as quantitative real-time PCR (qPCR) and digital PCR (dPCR) that enable relative and absolute quantification of the viral nucleic acid, respectively. We complement these results with Transmission Electron Microscopy (TEM) that is used for direct observation of the virus particles and impurities. Moreover, the use of High throughput sequencing (HTS) enables us to evaluate the nucleic acid content in the sample. As experts in all of the mentioned technologies, we can interpret results from more perspectives and connect them into a coherent whole.

Main Advantages

- dPCR offers accurate, robust, and repeatable absolute quantification.
- dPCR is most suitable method for direct virus quantification in up- or downstream process samples.
- HTS can identify production cell line contaminants, virus product mutations, presence of adventitious agents or other nucleic acid impurities.
- TEM offers evaluation of viral structure, ratio of full and empty capsids, and presence of other biological impurities.