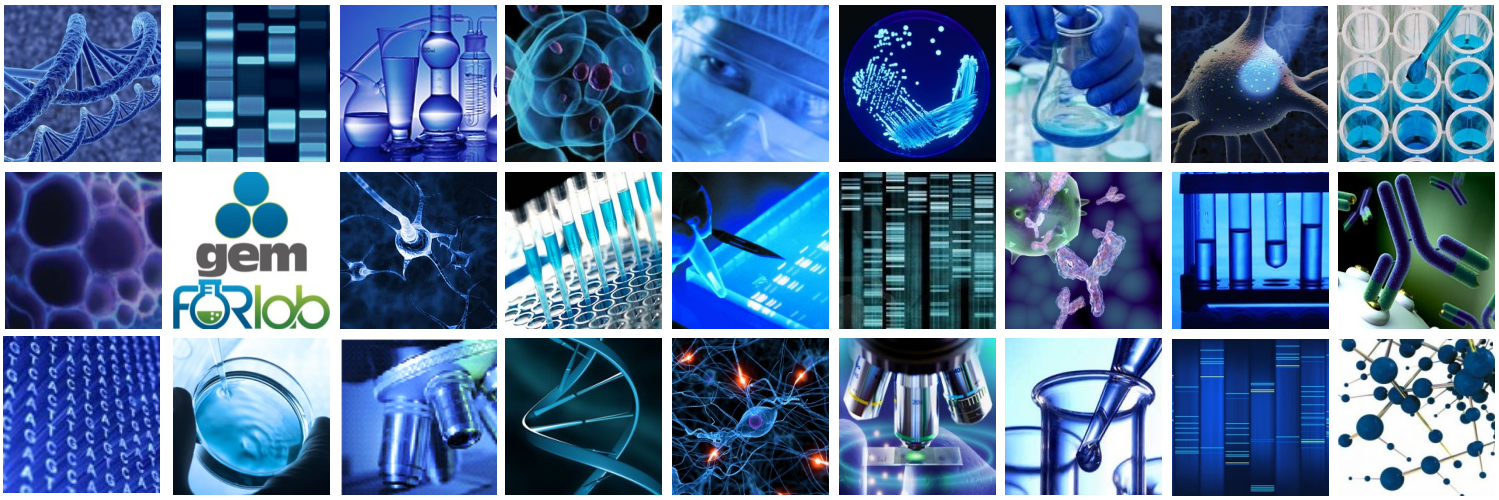

Biodistribution of a viral vaccine by Real Time PCR quantification

Aim of the study

Validation and application of an analytical qPCR method under GLP in a safety study by quantification of a viral vaccine in 13 different tissues for assessment of tissue distribution over time.

Analyte

Modified viral vector

Methodology

Biodistribution studies are essential for the evaluation of safety and efficacy of gene therapy protocols. Quantitative PCR offers a highly sensitive quantitative method for determining the presence, amount and persistence of a DNA target in various tissues after administration.

System Mouse organs

Therapeutic area Infectious disease

Development stage Preclinical

Customer A biotech company focused on the development of genetic vaccines

Results

DNA extraction using high throughput technologies can result in low yields or problematic reproducibility, especially if the same method is to be applied to many different tissue samples. Therefore, a method was set-up and optimized to obtain high and reproducible yields of DNA from extraction.

For reliable quantification of the DNA target after extraction from 13 different mouse tissues, a validation study was performed assessing LOQ, amplification efficiency, dynamic range, within-run and between-run accuracy and variability of samples spiked prior to extraction or prior to amplification. Moreover, potential inhibition of the qPCR reaction was assessed by spiking the DNA extracted from each type of tissue with known amounts of reference DNA. To assure recovery of both naked DNA and DNA contained in viral particles, tissues were spiked with both forms of DNA and quantification accuracy was calculated.

The analytical method was then succesfully applied in a multi-site study under GLP guidelines, for assessment of the biodistribution of a viral DNA vaccine administered by different routes.

Advantage of the methodology

For innovative therapies such as therapies based on nucleic acids, standard analytical techniques are often not available. Sensitivity, accuracy and reproducibility of the assays are highly dependent on assay design and methods must be adapted to the target and to the type of samples to be processed. Extraction and amplification of DNA by Real Time PCR can be optimized to fit the demand for highly sensitive qualitative or quantitative results.

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