generi biotech

DNA testing company

CRO Outsourcing Case Study

GLP-compliant Biodistribution Study of Vaccinia Virus in Mice by qPCR

Customer Need

Biodistribution (BD) studies are critical components when assessing the preclinical safety evaluation of cell and gene therapy molecules. BD analysis is performed to determine the distribution and the persistence of the vector/virus to target and non-target tissues following direct in vivo administration in animals.
BD analysis is generally conducted at the molecular level using a methodology that provides high sensitivity. The current "gold standard" for BD studies is a quantitative polymerase chain reaction (qPCR) assay that detects vector/virus genomes in biological fluids and tissue samples.
The request for a BD study by qPCR came from a now long-established client, a clinical research organization with a large animal breeding facility which focuses on preclinical and toxicology services. As they do not have laboratory capacity to perform molecular testing, they decided to leverage our experience, expertise and excellence and to outsource nucleic acid-based analysis to GENERI BIOTECH.

The Solution

The BD studies consisted of four steps:

1. DNA extraction from the samples, validated under GLP to evaluate recovery and PCR inhibition effect
2. Designing and validating sensitive and target-specific qPCR assay according to ICH guidelines
3. Running a qualification assay, to determine test article interference with assay performance
4. Analyzing the preclinical study samples

As performing complex BD studies can be challenging and prone to cross-contamination, we ensure that in each of our qPCR studies we include multiple assay controls to confirm the optimal performance of the assay and the absence of contamination and PCR inhibitors.
In this study, we used an endogenous control murine Polr2a genomic sequence to normalize the concentration of vaccinia virus isolated from different tissues, mean efficiency of isolation to normalize urine and serum samples, an exogenous spike test by Lambda DNA to assess sample quality, and an absolute standard in the form of target sequence on plasmid to analyze the samples.

Customer Benefit

- Design of the custom-made method capitalized the expertise of in-house R&D department
- Optimization of isolation process from different matrices achieved superior yields
- Use of in-house oligonucleotides and reagents for DNA isolation and qPCR assay enabled quick results and fast turn-around
- GENERI BIOTECH worked closely with the research investigator who designed and completed the animal studies at their own facilities

More info on website: https://www.generi-biotech.com/categories/gmp-glp-testing-en

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