Biodistribution and Expression Analysis

The GLP-compliant biodistribution and expression analysis program offered by WuXi AppTec is designed to assess the dispersal and activity of any nucleic acid sequence in a biological setting. Using real-time PCR technology, our program provides a powerful tool for evaluating the efficacy and safety of nucleic acid protocols by quantifying the copy number of a DNA or RNA target in a defined set of organs and tissues.

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

WX LISTED NYSE

APPLICATIONS

WuXi AppTec's biodistribution technology is applicable to any study requiring quantification of a nucleic acid in a biological setting. Broad capabilities of this technology include:

- Gene therapies
  (viral and non-viral compounds)
- DNA vaccines
- Transgenic plants and animals
- Expression profiling
- Preclinical drug efficacy studies
  (antivirals and anticancer agents)

Direct consultation with our clients allows for the design of custom protocols and the development of specific assays tailored to particular applications.

TECHNOLOGY

For its biodistribution and expression analysis studies, WuXi AppTec employs quantitative real-time PCR (qPCR). qPCR can quantify precise concentration, which is extremely useful for gene expression studies. Exceeding the limitations of classic end point PCR, qPCR offers a unique combination of sensitivity and quantification allowing rapid, accurate determination of DNA or RNA content by kinetic quantification.

Using kinetic quantification, the real-time PCR technologies offered by WuXi AppTec allow accurate measurements to be taken during the log-linear phase of PCR.

EXPERTISE

WuXi AppTec's knowledgeable scientists maintain an ongoing interactive collaboration with clients during every phase of the testing program. Toxicology, veterinary, and molecular biology staff members have many years of experience and are fully trained in GLP and GMP procedures. In addition, our advanced expertise allows WuXi AppTec to specialize in the development of custom assays.

PROGRAM PHASES

➤ Project Planning
- Initial discussions with Account Manager
- Both animal and molecular study components designed with AppTec study directors
- Initial proposal prepared, specific probes made
- Protocol validated

➤ Sample Receipt
- Sample submitted using custom submission form
- Sample received and assigned unique assession number(s) by validated database
- All test samples stored in continously temperature-monitored freezers

➤ Animal Studies
- Animals inoculated
- Tissues isolated individually to minimize cross contamination

➤ Sample Preparation
- Tissues processed using industry-accepted practices to prevent cross contamination
- Nucleic acids isolated in designated room
- Nucleic acid concentration determined

➤ Quantitative Real Time PCR
- Separate clean rooms used to prepare master mixes and negative controls
- Separate positive room used to prepare and store positive controls, and perform amplification
- PCR reactions performed and analyzed; data is acquired in real time

➤ Quantification
- Spike controls used to measure potential assay interference
- Linear regression analysis performed to determine copy number
- All assays run in accordance with FDA guidelines

➤ Final Report
- Final report completed
- Report reviewed by QA unit and signed by QA representative and study director
- Final report issued including: description of assay, results of the quantification, and tabulation of data

For more information on WuXi AppTec's services please contact:

U.S.
+1 (651) 675 2000 • +1 (888) 794 0077
info@wuxiapptec.com

www.wuxiapptec.com

LT250-06-05.01.12