AURIGENE
PHARMACEUTICAL SERVICES

Case Study

Developing a methodology for *In situ* perfusion based **combined** tissue distribution and toxicity evaluation study

Challenges:

- Several repeated in house validation studies were performed to optimize the suitable perfusate (liquid medium intended to pass through the heart), perfusate volume and perfusion rate to ensure complete perfusion of animal subjects (parameters weren't adjustable)
- Challenges were encountered in adjusting the perfusion volume and rate vis-à-vis ensuring tissue integrity for histopathology tissue sampling

Validation design:

- Typically, the validation process was planned to incorporate different volumes of perfusate at different flow rate.
- The perfusate liquid was filled in calibrated batch of disposal syringes and delivered into the right ventricle of the heart by means of a disposal needle fitted onto the disposable syringe.
- After adequately anesthetizing the animal, the perfusion process was performed using Harvard infusion pump.
- The vital organs (liver, lungs, spleen, brain, heart) were examined and graded for the perfusion efficiency

Aurigene solution:

- An efficient method with optimal perfusion volume and rate was established.
- This accommodated estimation of analyte concentration and evaluation of microscopic changes using special staining techniques.

Outcome:

- Assay was successfully established and launched for client offering under GLP compliance; we also received global regulatory acceptance for this assay.
- This assay replaces standalone assays which are time and resource consuming.

Highlights:

- Combining two study objectives in one experimental design is challenging, but we achieved it.
- On-site validation was accomplished successfully, as was GLP compliance.
- We received recurring business as a result of this study because trust was developed with consistent efforts.

Thank You

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