

Team Approach Scientific Expertise Customer Focus



Mass Balance Study

NEED

- The client needed to rerun a mass balance study due to poor radioactivity recovery
- Root cause for poor recovery was undetermined

APPROACH

- Specialized adhesion testing for all collection materials performed prior to study start to ensure no loss of study drug on the containers; this led to using additive for all urine collections
- Dosing solution analysis completed immediately prior to dosing to ensure proper dose administered
- Dosing solution residual analysis completed after dosing to determine any remaining radioactivity that was then subtracted from administered dose
- Real time scintillation counting performed on site to allow for daily recovery results to be sent to the client for review to prevent premature release of participants

BENEFITS

 Radioactivity recovery was >95% and study was successfully submitted to the FDA

See Other Case Studies

Bioanalytical Support of **Oncology Studies**

Standardizing Database Structure for Programs

IND Support for Asian Biotech

