
Bioanalytical validation

Margrét Thorsteinsdóttir*†¹

¹Faculty of Pharmaceutical Sciences University of Iceland – Iceland

Abstract

Bioanalysis is an essential part in drug discovery and development, where drug substances, metabolites and biomarkers are identified and quantified in a biological matrix. Bioanalytical method validation is the most important part of regulated bioanalysis. Validated bioanalytical methods are used for the evaluation and interpretation of pharmacokinetic, toxicokinetic and bioequivalence study data. It is therefore of great importance that the bioanalytical methods provide reliable and reproducible data. This presentation will mainly focus on validation procedure of small molecules according to good laboratory practice (GLP). The procedure recommended for the key validation parameters will be discussed, including calibration curve, range, accuracy, precision, limit of detection, lower limit of quantification, selectivity, sensitivity, recovery, matrix effect and stability. Additionally, harmonization of bioanalytical method validation guidelines will be presented as well as discussion about guidelines for the clinical analysis of herbal medicine.

Keywords: Validation, Bioanalysis, Research and Development

*Speaker

†Corresponding author: margreth@hi.is