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**QUANTITATION OF BIOTECH DRUG PRODUCTS IN PLASMA BY LC/MS/MS
FOR REGULATORY SUBMISSION**

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Quantitative analysis of drugs and/or metabolites from plasma using LC/MS/MS is ideal in the pharmaceutical industry due to its compound specific detection, sensitivity and reliability.

This poster will describe a method utilising LC/MS/MS, developed to quantify the peptide Melanotan-1 (α -melanocyte stimulating hormone) in plasma at an LOQ of 0.25 ng/mL for an Australian biotechnology company (Epitan Limited). This hormone is potentially a chemopreventative agent for sunlight-induced skin cancers and has never been quantified using LC or LC/MS/MS before (previous methods used radio-immunoassay and frogskin bioassay).

This method was applied to a Phase I clinical trial at CMAX Pty Ltd and conducted to FDA regulatory standards (CFR 21 Part 58 GLP, CFR 21 Part 320 Bioavailability). These regulatory standards require validation of the LC/MS/MS instrumentation and software.