Fidelta
A Galápagos Company

We make the difference in efficacy and safety

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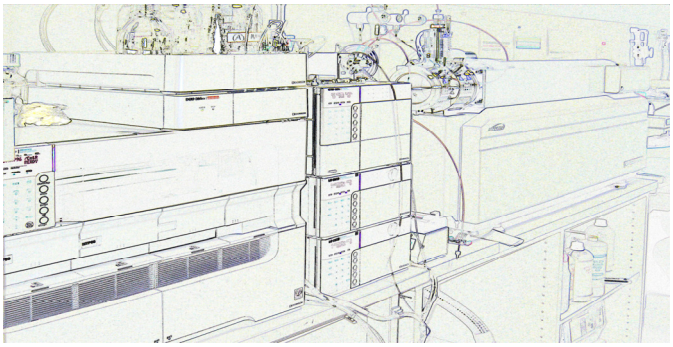
Quantitative bioanalysis

Bioanalysis usually refers to the quantitative measurement of a compound in a biological matrix from *in vivo* studies (e.g. blood, plasma, urine, tissues) and *in vitro* studies (e.g. cell lines, microsomes, hepatocytes). A bioanalytical method typically includes the extraction of the compound from a biological matrix (sample preparation) and the detection of the analyte via a combination of chromatography techniques (HPLC or UPLC) coupled to a mass spectrometer.

Selective and sensitive analytical methods are critical to sound quantitative evaluations of drugs and metabolites. Fidelta has extensive capability, expertise and experience in the field of bioanalysis and routinely provide quantitative analytical support for *in vitro* and *in vivo* ADME/PK, as well as *in vitro* and *in vivo* pharmacology and toxicology studies in discovery and early development.

Rapid turnaround quantitative analysis is ensured through efficient sample preparation, state-of-the art LC-MS/MS systems and a dedicated instrument maintenance team. All studies are performed according to SOPs and are in line with EMA and FDA bioanalytical guidelines and white papers. Protocols can be further customized in order to fit all requestor's need.

Fidelta has a well built logistical support for receiving material and biological samples world-wide.



Method development

The development of an LC-MS/MS method requires optimizing three separate methodologies:

- MS/MS method development
- Chromatographic separation
- Sample preparation method (e.g. protein precipitation, solid-phase extraction or liquid-liquid extraction)

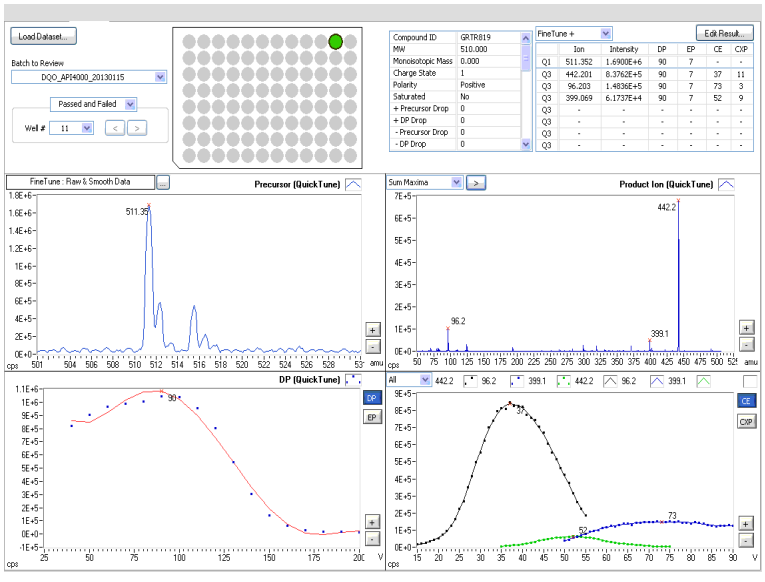
✓State-of-the art technologies

✓Rapid sample turnaround

✓High quality data

High-throughput bioanalysis

- supported through DiscoveryQuant, a state of the art plugin that enables batch based compound optimization and rapid method and batch creation, including results review and reporting



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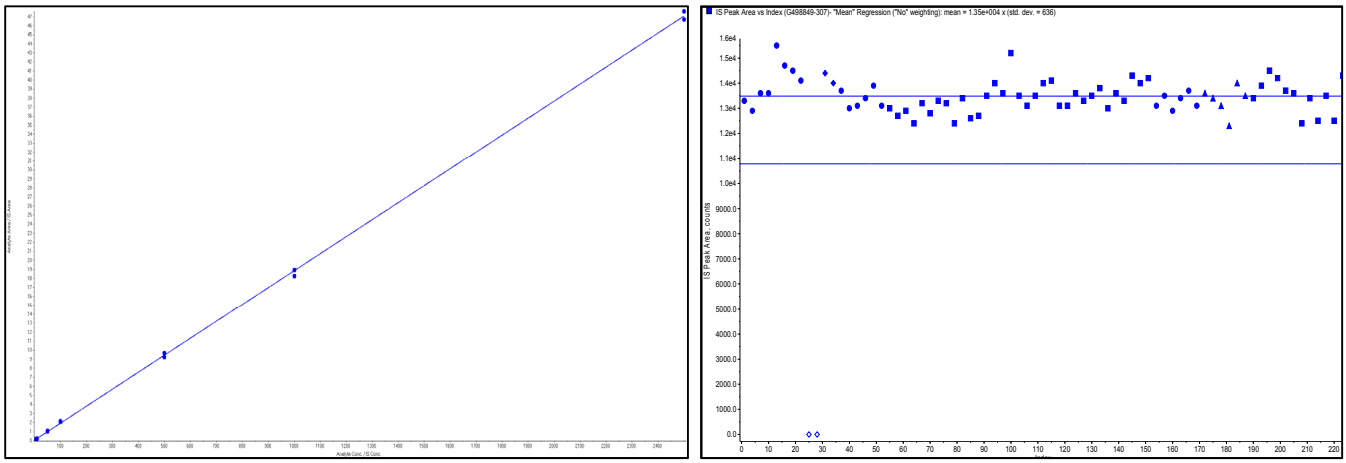
Quantitative bioanalysis

Analytical Method Evaluation	
Method Development	Optimize MS detection for suitable sensitivity Optimize LC detection for suitable sensitivity and separation
Pre-study validation and acceptance criteria	
Calibration curve	Eight calibration standards prepared in duplicate. ➢ Six of eight standards must follow acceptance criteria within ±15%, except at LLOQ (±20%)
QC samples	QCs are prepared by independent weighing at three QC levels (low, medium and high) and in triplicates.
Blank samples (Double blank)	Minimum two. ➢ Analyte peak area is no more than 20% of LLOQ Peak Area. ➢ Internal standard peak area max 5% of average IS Peak area
Number of zero samples (Blank)	Minimum two. ➢ Analyte peak area is no more than 20% of LLOQ Peak Area.
IS Area consistency	±20% overall precision throughout the complete analytical run
Intra-assay mean Precision and Accuracy	Determined from within-run replicate analysis of each QC. ➢ 2/3 of total QC samples must have accuracy within ±15% of nominal value and at least one QC per level must fulfil criterion ➢ Intra-assay coefficient of variation (CV) of replicates must be within ±15%
Specificity	Analysis of blank samples.



Figures 1 & 2. Typical 8 point calibration curve and IS overall Area plot (dashed line denotes acceptance criteria)

We are committed to provide high quality and timely data.

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