## Bioanalysis quantification applications eBook

Pushing the boundaries of your quantitative studies





# Bioanalysis studies are an integral part of the therapeutic development process. Scientists must quantify drug products to impeccable levels of sensitivity and selectivity to ensure proper dosage, efficacy and safety.

The therapeutic potential of biologic modalities has increased, driving an inevitable move toward exploring more complex biotherapeutic molecule classes. As biotherapeutics become more complex, there is still a demand for superior quantification while maintaining sensitivity, accuracy, reproducibility, throughput and robustness, regardless of the therapeutic class.

In 1981, SCIEX revolutionized small molecule bioanalysis by launching the first commercially successful triple-quadrupole MS instrument. This innovation started a long legacy of leading-edge solutions that give bioanalytical scientists a platform on which to master high throughput therapeutic quantification. SCIEX technology enables laboratories to achieve the required levels of compliance and data quality for both small and large molecules.

Today, SCIEX offers a comprehensive portfolio of instruments and software that simplifies analytical workflows. Data is easier to interpret, and analyses are easier to perform. SCIEX hardware and software are used worldwide to advance therapeutic development and to enable scientists to confidently submit their data to regulatory bodies.

Take time to explore the technical resources in this eBook. We invite you to learn how SCIEX continues to reimagine therapeutic quantification in innovative and productive ways that address the continuously evolving challenges facing the industry today.

## **Small molecule quantification**

### Accurate and robust quantification



Accurate and robust quantification of small molecule therapeutics can be complicated by matrix interferences, or by the need for achieving increasingly lower LOQs in complex sample matrices.

SCIEX continues to pioneer the quantification of molecules with mass spectrometry hardware that provides excellent sensitivity and linear dynamic range and helps to accelerate candidates from discovery to market.

However, the toughest analytical questions do not always get answered with sensitivity and dynamic range. Through our continuous innovation, we have introduced QTRAP® technology and SelexION® Differential Mobility Separation technology, tools that bring the next level of orthogonality when selectivity is required to answer the toughest analytical questions.

#### **Explore how with the following technical resources:**

Bioanalysis of ß-Lactamase inhibitors on the QTRAP® 6500+ system

Separation of diastereomeric flubatine metabolites using SelexION® technology

Quantitation of limaprost, an analogue of PGE1 in human plasma

Differential mobility separation: a novel technique for the bioanalysis of technology and the Triple Quad™ 5500 system

Differential mobility separation: a novel technique for the bioanalysis of poorly fragmenting molecules like valproic acid

Quantification of fluticasone propionate in human plasma, using the SCIEX QTRAP® 6500 system

Quantification of fluticasone propionate in human plasma, using the SCIEX QTRAP® 6500 system



Selexion DMS technology increasing the selectivity of LC-MS/MS analysis – Yves Le Blanc, senior research scientist and technical manager of the Applied Research Group, SCIEX



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## **Protein therapeutics**

### Streamlined sample prep through to data processing



Bioanalytical researchers need to develop and validate highly selective and sensitive assays to quantify peptides in complex matrices. Developing sample enrichment protocols, choosing signature peptides and optimizing LC-MS conditions are all critical to creating a robust and reliable quantitative assay.

SCIEX has designed solutions that tackle each challenging part of peptide quantification. From sample prep through to data processing, you can automate and streamline every aspect of your workflow throughout the therapeutic pipeline.

#### **Explore how with the following technical resources:**

AltaSciences - Algorithme Pharma

Differential mobility separation mass spectrometry for quantitation Quantification of the therapeutic peptide exenatide in human plasma of large peptides in biological matrices Quantitation analysis of human insulin-like growth factor I (IGF1) in serum by Sub-picogram level quantitation of desmopressin in small volumes of human -using SPE-LC-MS/MS workflow plasma using a trap-elute micro LC-MS System Universal solution for monoclonal antibody quantification in biological Improving sensitivity for an immunocapture LC-MS assay of infliximab in rat fluids using trap-elute micro LC-MS method plasma using trap-and-elute micro LC-MS An immunoaffinity coupled high resolution-MS workflow for Sensitive quantitation of glucagon in rat plasma with trapand-elute quantifying biotherapeutics in rat plasma micro LC-MS Quantitation of insulin glargine in human plasma using immunocapture-Signature peptide quantitation for follicle stimulation hormone (FSH) **→** based target enrichment and trap-and-elute microflow LC-MS/MS in human serum Sensitive and reproducible quantitation for pegylated interferon a-2b Multiple mass spectrometric strategies for high selectivity quantification of **→** protein and peptides A sub-picogram quantification method for desmopressin in plasma Hybrid LC-MS assays reaching standards for regulatory filings -• using the Triple Quad™ 6500 system Fabrizia Fusetti, director, biologics & mass spectrometry at QPS A new dimension in selectivity and sensitivity using differential mobility spectrometry - Mingluan Chen, senior scientist,

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## **Biomarker quantification**

## Easily verified and quantified



Couple with QTRAP and SelexION® technology to obtain an additional dimension of selectivity and these technologies can solve your most challenging quantification problems.

SCIEX has made huge strides in the advent of industrialized omics, where SWATH® Acquisition data has played a vital role.

SWATH Acquisition allows large sample cohort datasets to be transformed into more compelling and meaningful data. This data then can be transformed into valuable knowledge that allows you to make better, informed drug discovery and development decisions.

#### **Explore how with the following technical resources:**

Improving sensitivity for infliximab quantitation in rat plasma using trap-and-elute micro LC-MS/MS

Analysis of intact monoclonal antibodies using M3 microLC and TripleTOF® 6600

Sensitive and accurate quantitation of the ADC ado-trastuzumab emtansine in rat plasma

Dysregulated lipid profiles of non-alcoholic fatty liver disease (NAFLD)

Quantitative lipid analysis using MRM and differential ion mobility

New solutions for next-generation lipidomics –

### **Gene therapy**

spectrometry (DMS)

Gene therapy continues to be a highly attractive area of pharmaceutical research. Oligonucleotide therapeutics have played a significant role in clinical drug pipelines and in the past have encountered quantitative challenges. Now, through the utilization of the SCIEX OptiFlow quant solution and TripleTOF® systems, you can achieve qualitative and quantitative analysis for both low- and high-abundance species.



#### **Explore how with the following technical resources:**

Extending the lower limits of quantification of a therapeutic oligonucleotide through microflow LC-MS/MS



Quantification of large oligonucleotides using high resolution MS/MS on the TripleTOF® system

Steven Watkins, PhD. chief technology officer, Metabolon



Quantification of large oligonucleotides using high resolution MS/MS



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## Technology that powers the future of bioanalysis, today.

SCIEX innovative technology overcomes sensitivity and selectivity challenges that many bioanalytical laboratories face every day. Below, you can explore our featured bioanalytical products.

#### QTRAP® 4500 series

Intelligently re-engineered from the 4000 QTRAP platform, the SCIEX QTRAP® 4500 LC-MS/MS System offers vigorous and reliable high-throughput screening for a wide range of analytes.

Learn more >

#### QTRAP® 5500 series

The QTRAP® 5500 LC-MS/MS System is designed to deliver excellent sensitivity and robustness. It delivers reliable quantitative and qualitative results for all but the most demanding analyses. This system is ideal for the assays in your lab that may not need the ultimate in performance.

Learn more >

# **Mobility Separation Device**

SelexION® Differential

SelexION® DMS can help you address your biggest analytical challenges. DMS and ion mobility spectrometry are analytical techniques used to separate hard-to-resolve ions based on their gas phase mobility.

Learn more >

#### OptiFlow® Turbo V Ion Source

Now you can achieve high sensitivity quantification without sacrificing throughput and robustness with the all new OptiFlow quant solution from SCIEX. We open up new possibilities by combining the new easy to use OptiFlow® Turbo V Ion Source and the powerful M5 microLC system.

Learn more >

#### QTRAP® 6500+ series

The QTRAP® 6500+ LC-MS/MS System is for the most difficult, challenging analyses involving complex matrices, when you need the most sensitive instrument available. The QTRAP 6500+ System is the fastest and most sensitive QTRAP system available, delivering enhanced selectivity and improved levels of quantification.

SCIEX QTRAP\*6500

Learn more >

## **SCIEX** services and training

### Get the most from your lab instruments

#### Realize your lab's potential

SCIEX runs its business and its labs the same way it helps customers improve their workflows. Each member of our Lab Optimization Services team has over 15 years of experience in analytical labs and working with complex workflows. Our team of experts can help you increase your throughput, reduce your costs and improve quality by identifying and removing unproductive activity. Take your lab to the next level in as little as six weeks.

Learn more >

#### LC-MS training designed specifically for you

SCIEX University™ Success Programs provide LC-MS training customized to meet your specific needs. With a selection of training methods and certifications available, you can build a mass spectrometry program that is most suited to your lab and users.

Learn more >

#### **StatusScope® Remote Monitoring Service**

Your lab needs to be running at peak performance. StatusScope Remote Monitoring Service enables you to connect to your lab from anywhere securely, allowing you to stay ahead of potential instrument problems. With the StatusScope Remote Monitoring Service you can respond to issues quickly and efficiently, and reduce your work downtime.

Learn more >

### **SCIEX OS-MQ Software**

Streamlined mass spectrometry quantification

Turn the software you have into the SCIEX OS-MQ you want. MultiQuant™ Software has met your lab's needs for many years and has now evolved into an even more powerful software platform, SCIEX OS-MQ, for increased MS quantification productivity.

The single solution for quantifying large sample sets features superior data processing and visualization, powerful data integration, enhanced audit trail and helps users of different skill levels to perform their own automated analyses.





### Software capabilities:

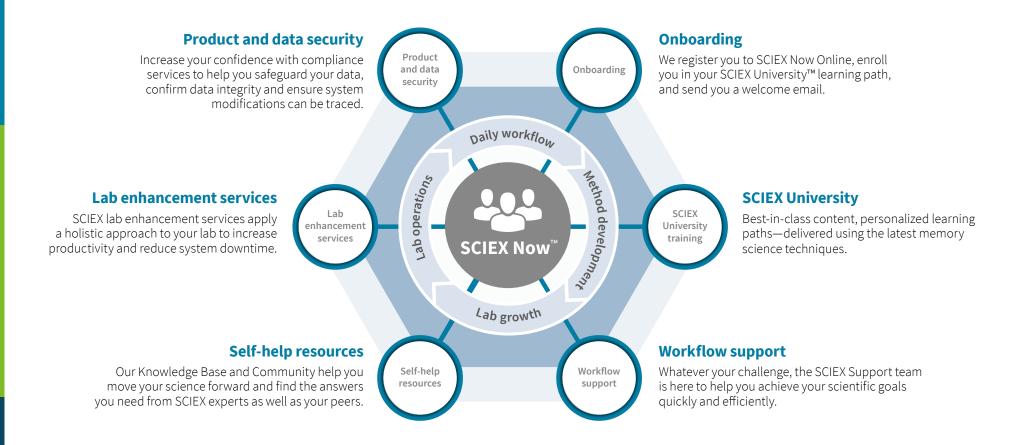


Data quantification

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