Pharmaceutical quantitation solution guide

From discovery to QA/QC, SCIEX is on your side

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Introduction

Explore our trusted LC-MS/MS solutions designed to simplify and accelerate the analysis of pharmaceuticals, their potential impurities and help understand biological processes.

All our systems are supported on a single software platform that is compliant-ready.

This guide takes you through the quantitative workflows and discusses challenges regularly faced by scientists, along with potential solutions for your lab.

Discovery

- Identify hits with accuracy and speed
- Easily report results with end-to-end workflows
- Measure molecular masses for small and large drug candidates

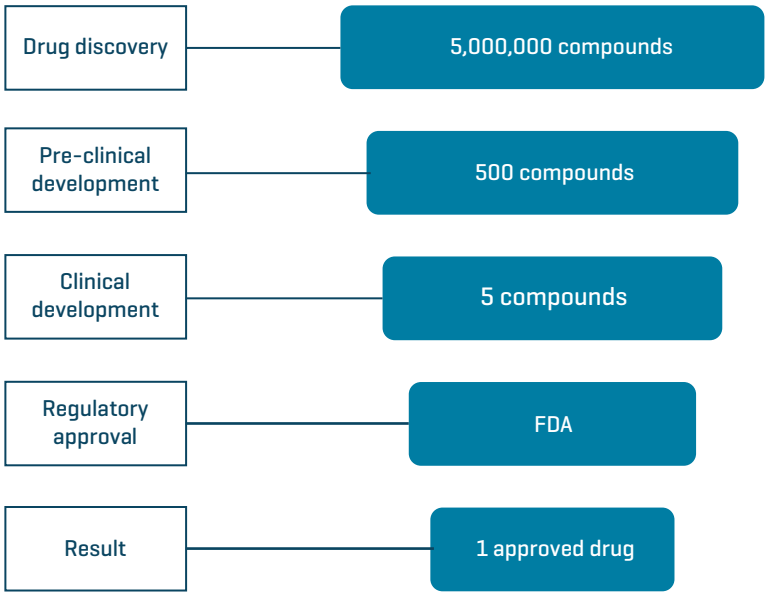
Introduction

Bring high-quality data to your drug discovery process quickly and simply. Regardless of scale, our integrated systems include software and services that come together as total solutions to deliver high-quality, rapid results for confident, data-driven decision making.

Get the information you need to make go/no-go decisions as quickly as possible in the drug discovery phase of your work.

Featured applications and assays

- Biomarker quantitation
- Compound quality assessment
- HTS for small molecules
- HTS for large molecules



Featured solutions

Complex samples

For complex samples requiring chromatographic separation before detection, our recommendation is the ExionLC AE system with SCIEX Triple Quad 6500+ system for excellent sensitivity.

High-throughput screening (HTS)

When you have analytes in simpler matrices, we recommend the Echo® MS+ system. The Echo® MS+ system offers contactless sample ejection at a rate of up to 1 sample per second. Samples are detected by our trusted MS instruments, using either the SCIEX Triple Quad 6500+ system or ZenoTOF 7600 system.

Biomarker quantitation

Bringing drug candidates through the development pipeline has multiple complicated steps. Improving the efficiency and accuracy of results can simplify and accelerate this process. Our systems provide in-depth coverage that enables you to characterize and confidently quantify biomarkers, including low-abundance analytes. With different technology options for specific needs, SCIEX can help you get the answers you need.

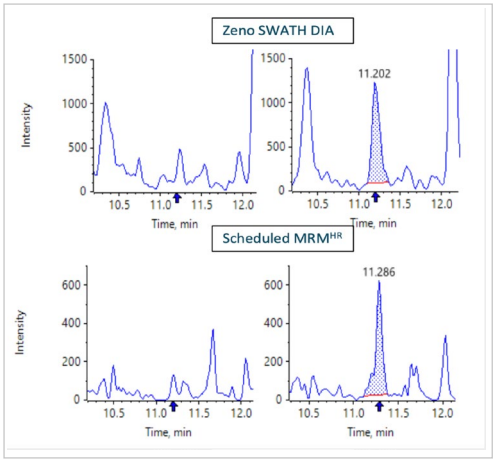
- Achieve confident answers in hours instead of days
- Confidently characterize and quantify small biomarkers with robust, sensitive analyses
- Improve workflows with support from our dependable team of experts

Small molecule

High-resolution mass spectrometry peptide quantitation for biomarker verification using the ZenoTOF 7600 system

Learn how MRM^{HR} can be used to achieve a lower limit of quantitation (LLOQ) of 0.02 fmol/µL for peptides spiked into a background of 400 ng cell lysate digest.

Read more >



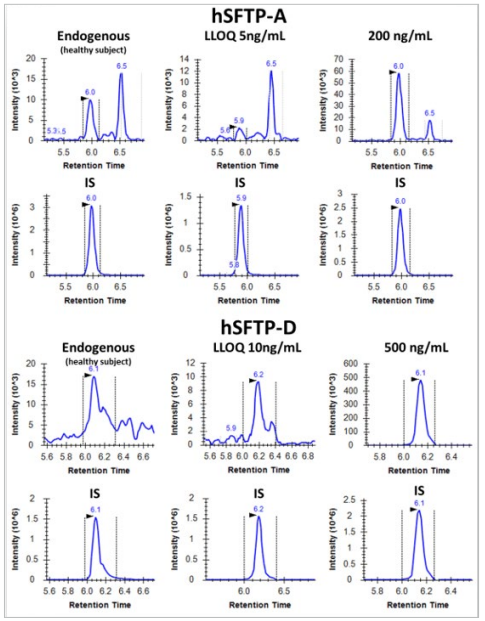
Extracted ion chromatograms (XICs) for the summed +2y6 and +2y5 fragments of the ANELLINVK tryptic peptide of ADH1.

Large molecule

Sensitive multiplexed quantification of protein biomarkers for early drug discovery and development

Reach outstanding accuracy, precision and linearity for the quantitation of multiple protein targets in plasma at low-ng/mL levels.

Read more >



XICs were used for the quantitation of hSFTP-A and hSFTP-D.

Compound quality assessment

Fully understand the identity of the target compounds within your compound library with high-throughput mass spectrometry-based testing. Reduce the risk of sending degraded or incorrect drug candidates for further development within your organization, saving time and money.

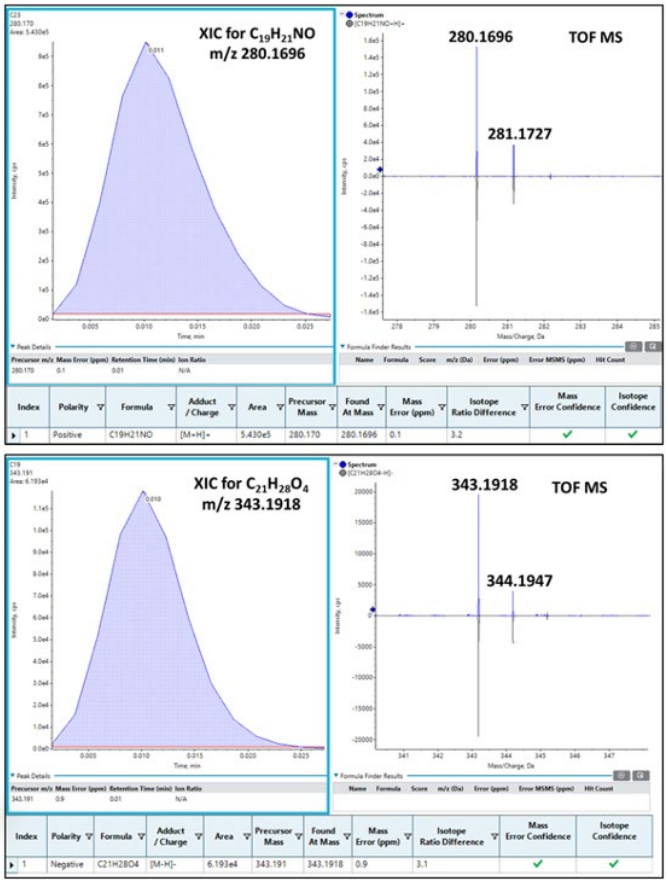
- Identify and confirm the presence of target compounds in libraries using acoustic ejection mass spectrometry (AEMS) for accurate and reproducible results
- AEMS allows for sample throughput of up to 1 sample per second and data reliability provided by mass spectrometry detection
- Easily report results with an end-to-end workflow

Compound quality assessment

High-speed compound quality assessment using acoustic ejection mass spectrometry

Read about how the Echo® MS+ system can be used to screen 45 compounds within 4 minutes using positive and negative polarity. All analyses are completed in SCIEX OS software for simplified system control, data acquisition and processing.

Read more >



Representative XICs and TOF MS spectra for compounds detected using positive and negative ionization modes.

HTS for small molecules

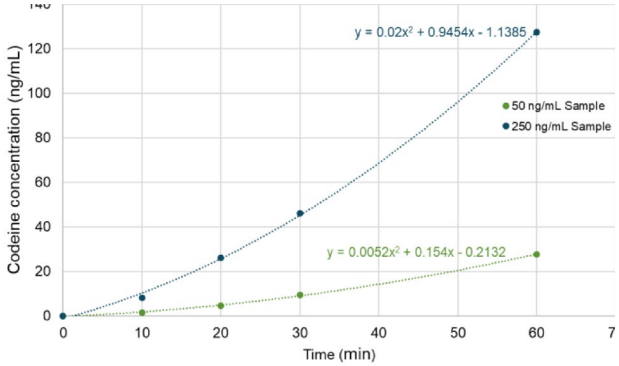
Gather high-quality data while reducing reagent and sample costs with high sample throughput for critical go/no-go decisions during drug discovery. The Echo® MS+ system enables you to run thousands of samples and report results on the same day.

- Reduce analytical bottlenecks with a sampling rate of up to 1 sample per second
- Minimize sample consumption, using as little as 2.5 nL of sample
- Screen millions of compounds with AEMS to identify bioactive compounds that inhibit enzyme activity during drug discovery

Automated HTS

An automated, real-time measurement of kinetic hydrolysis of glucuronide

Discover how real-time measurements of glucuronide hydrolysis are possible using the Beckman Coulter® Life Sciences Biomek i7 automated liquid handler to prepare and perform a kinetic study before transferring the samples to the Echo® MS+ system to quantify the analytes of interest.



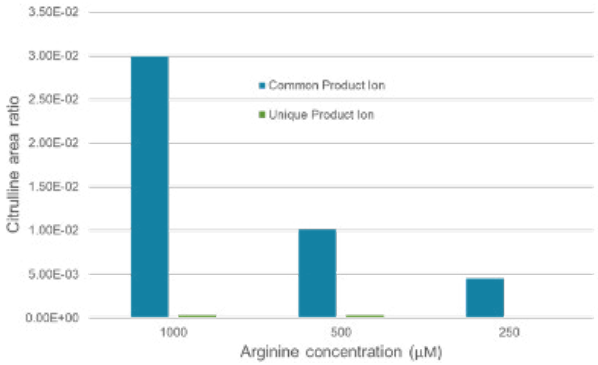
Rate of codeine production from the 50 ng/mL (green) and the 250 ng/mL (dark blue) codeine-6-glucuronide samples.

Read more >

Reduce complexity of assays

High-resolution, specific analysis of arginine and citrulline

Read abut how the Echo® MS+ system can rapidly quantify both arginine and citrulline in a single analysis with minimal sample preparation.



Observed arginine peak area ratios determined by the citrulline common and unique product ions. The peak area ratios were determined at concentrations of 1000µM, 500µM and 250µM.

Read more >

HTS for large molecules

Protein analysis is inherently challenging due to the complexity of the sample. The selection of a buffer that maintains the activity and folding pattern of the protein is important to allow accurate data to be collected. Additionally, when mass spectrometry is the analytical technique of choice, high salt concentrations in the buffers can cause ionization suppression.
The Echo® MS+ system alleviates some of these challenges:

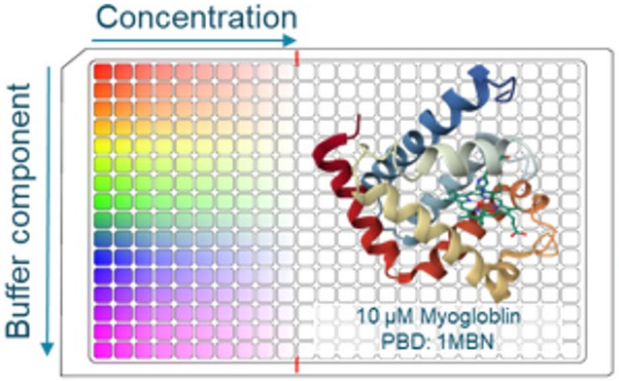
- With a sampling rate of 4 seconds per sample
- Sample dilution and low sampling volumes reduce the impact of salts

Automated HTS

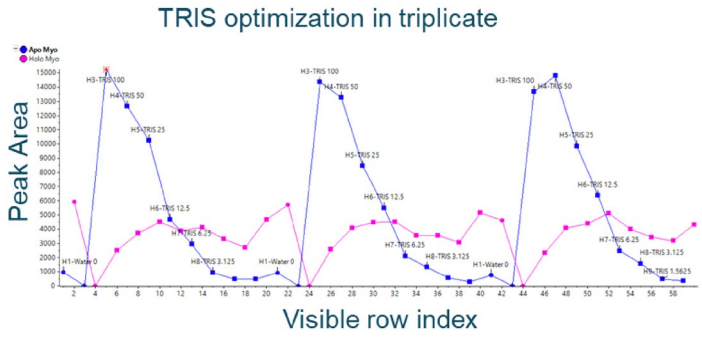
Determine optimal buffer concentration and compatibility for high-throughput intact protein analysis

Read about how the Echo® MS+ system can be used to screen 16 buffers at 10 concentrations in approximately 11 minutes.

Read more >



16 biologically relevant buffers



Introducing the Echo® MS+ system

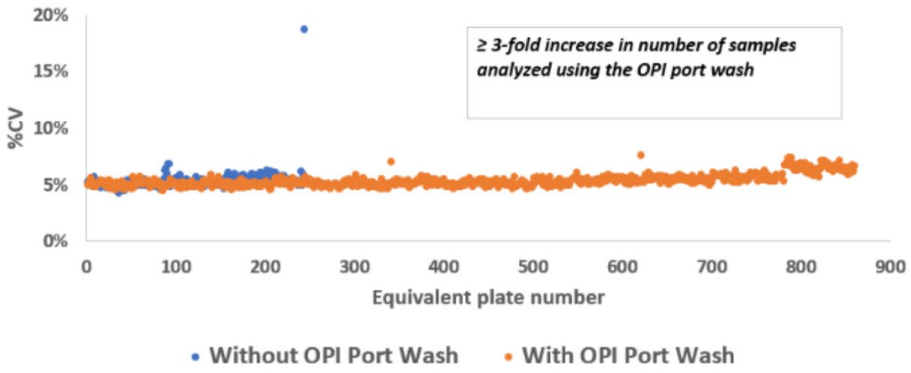
When the quantity of samples is your challenge, break through with the Echo® MS+ system. It gives you high-quality data, analytical flexibility and high sample throughput so you can make informed decisions today. These benefits are made possible with recent innovations to the hardware and software.

Technology innovations

Optimizing robustness for high-throughput screening

The introduction of the Echo® MS+ system brought new features to the technology. The introduction of the Open Port Interface (OPI) port wash increased the number of samples the system can run before cleaning is required.

Read more >

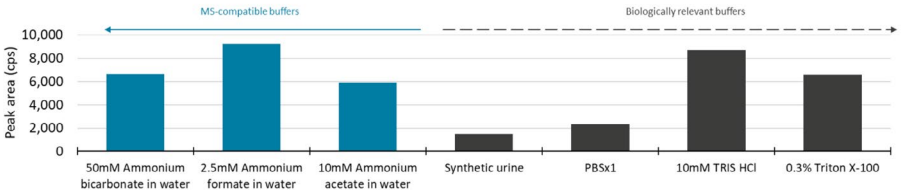


Method development

Automated, rapid method optimization and buffer screening

See how method development time can be reduced to minutes based on instrument settings to buffer selection. In minimal time, you can be sure you have the best settings for your analysis.

Read more >



Conclusion

Easily collect the data you need from compound screening to lead optimization to make informed go/no-go decisions for your drug candidates.

We can ensure a smooth and efficient transition to state-of-the-art mass spectrometry solutions with access to an expert-level support team.

Additional links for discovery assays

Selecting the right system for bioanalytical quantitation

Investing in a new LC-MS system is not an easy decision, especially if you have a range of analytical requirements in your laboratory. This blog is intended to help you choose the right system for your pharmaceutical drug development needs.
Read blog >

Want to accelerate your drug discovery workflow?

Bringing a new drug to market is a costly and complex process. With potentially hundreds of thousands of new compounds to screen during drug discovery, sample throughput is a common bottleneck for pharmaceutical companies. So how do you overcome this barrier?
Read blog >

5 Reasons to choose the Echo® MS system for high-throughput drug discovery

Have you thought about introducing new technology into your high-throughput drug discovery lab? Here are 5 reasons the Echo® MS system could make a difference for you.
Read blog >

Driving more sensitive bioanalysis using accurate mass spectrometry

Quadrupole-based liquid chromatography coupled with mass spectrometry (LC-MS) has been routinely adopted for the quantitation of therapeutics in bioanalytical laboratories. Advances in accurate mass spectrometry have enabled it to become a complementary option for quantitative bioanalysis. These advances include greater selectivity, improved mass resolution and the flexibility of time-of-flight (TOF) MS/MS for data analysis.
Watch webinar >

Development
(Small molecule)

- Reliable and sensitive bioanalytical data
- Perform studies with confidence using compliance-ready software
- Support by a team of dependable experts

Introduction

Enhance your pharmaceutical development assays, while simplifying method development and reducing training needs. Our liquid chromatography-mass spectrometry (LC-MS) solutions are intuitive, robust and sensitive. All of our solutions are supported by compliance-ready software and trusted service professionals.

Accurately identify and monitor biomarkers, active pharmaceutical ingredients (APIs) and metabolites on a single software platform.

Featured applications and assays

Featuring: Introduction to quantitation by high-resolution mass spectrometry

- ADME-Tox
- Biomarker quantitation

Bioanalysis of:

- Glucagon-like peptide (GLP-1) analogs
- Nucleic acids and oligonucleotides
- Peptides and cyclic peptides
- Targeted protein degraders

Featured solutions

Routine bioanalysis

Triple quadrupoles have been the gold standard for bioanalysis for many years. The SCIEX Triple Quad 6500+ system offers trusted long-term performance. For ultimate sensitivity and extended robustness, the SCIEX 7500+ system is the solution of choice.

Complex samples

If you are challenged with coeluting compounds with similar masses, analytes with complex structure, a complex background with low abundant analytes or analytes with a high molecular weigh, a high-resolution mass spectrometer is a great choice. The SCIEX X500R QTOF system is the go-to system for most assays. Alternatively, the ZenoTOF 7600 system can be used for additional sensitivity and analytical horsepower.

Introduction to quantitation by high-resolution mass spectrometry

- Easily quantify high-mass and complex analytes
- Quantify coeluting compounds with similar masses
- Filter out complex background noise to see more in your sample

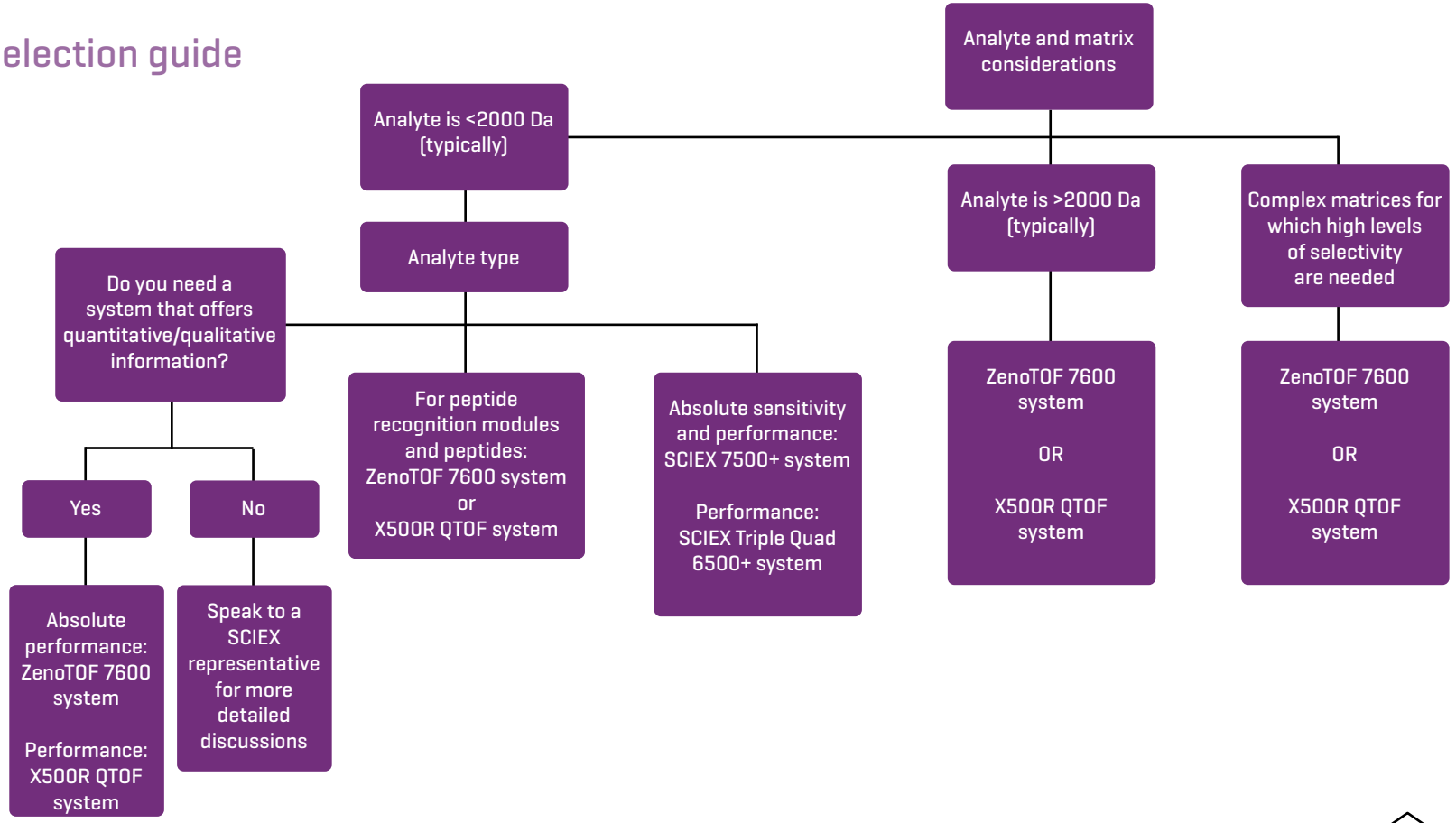
Benefits of high-resolution mass spectrometry for quantitation

Triple quadrupole mass spectrometers have been trusted for decades in pharmaceutical research and development for their quantitative performance.

In recent years, there has been a move to high-resolution mass spectrometry due to technology advancements, which has provided more sensitive and accurate quantitative performance. The appeal of high-resolution mass spectrometers is their ability to overcome the following challenges:

- Coeluting compounds with similar masses
- Separation of high background from low abundant analytes
- Quantitation of compounds with a high molecular weight

Quick system selection guide



Summary

We have worked with scientists across the drug development pipeline for decades, leading the way in quantitative mass spectrometry using quadrupoles. Our high-resolution systems are easy-to-operate, with integrated analytical solutions that can provide rapid and reliable quantitative data with the added benefits of high resolution.

When you need support, SCIEX is here for you.

Fit-for-purpose solutions combining LC and high-resolution MS enable quantitation in complex matrices with excellent sensitivity and robustness, even at low levels.

ADME-Tox

Complex samples, and possibly low-level analytes, are common challenges that are faced every day by analysts working on ADME-Tox studies. Our fit-for-purpose LC-MS solutions enable pharmacokinetic parameters to be monitored in complex matrices with excellent sensitivity and robustness, even for low-dose, highly potent drugs. Simplify the monitoring of ADME-Tox parameters with compliance-ready SCIEX OS software.

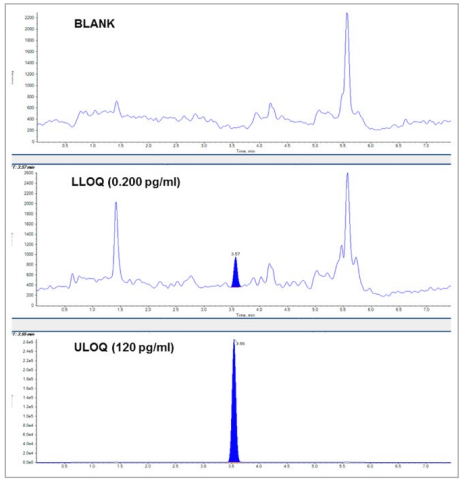
- Perform ADME-Tox studies with confidence using compliant-ready software
- Acquire reliable and sensitive bioanalytical data using fit-for-purpose LC-MS solutions

Regulated and non-regulated ADME-Tox solutions for all stages of the pipeline

Highly sensitive LC-MS/MS method for the quantification of fluticasone propionate in human plasma using the SCIEX QTRAP 6500 system

Learn more about a highly sensitive and reproducible method for quantifying fluticasone propionate suitable for use in regulated bioanalytical labs using a simple solid-phase extraction technique.

Read more >



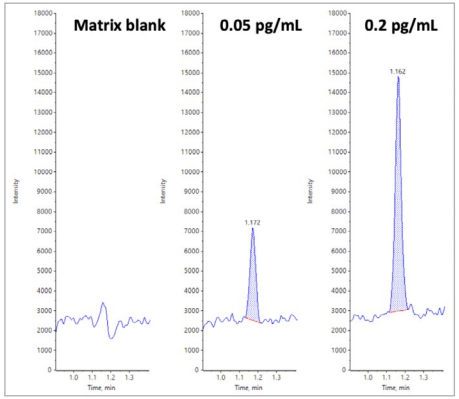
Sub-picogram detection of fluticasone propionate in plasma.

Low-level ADME-Tox analytes

A sensitive method for the quantification of formoterol in human plasma

Discover a quantitation method for low-dose, high-potency drug modalities combined with data acquisition and processing options that are simplified with SCIEX OS software, a 21 CFR Part 11-compliant platform.

Read more >



Representative extracted ion chromatograms (XICs) for formoterol in human plasma.

Biomarker quantitation

Our systems provide in-depth coverage that enables you to characterize and confidently quantify biomarkers, including low abundant species. With different technology options for specific needs, we can help you get the answers you need.

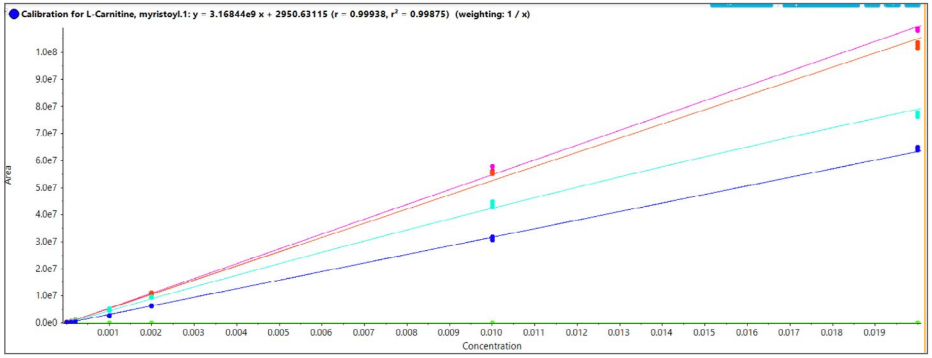
- Achieve confident answers in hours instead of days
- Confidently identify and quantify small biomarkers with robust, sensitive analyses
- Improve workflows with support from our dependable team of experts

Targeted panel assays

High sensitivity quantification of acylcarnitines using the SCIEX 7500 system

Discover how you can quantify low-level acylcarnitine species with high throughput, robustness and reproducibility without requiring derivatization.

Read more >



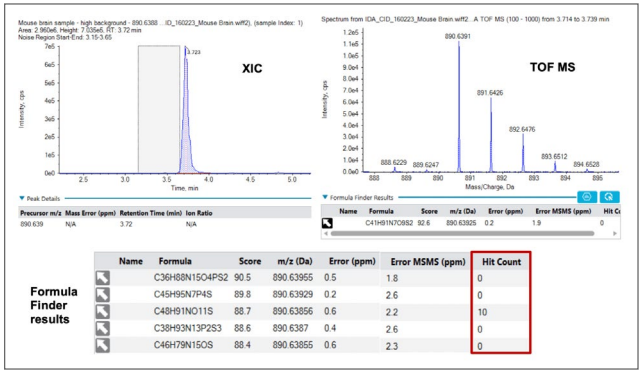
Linear dynamic range for several acylcarnitine compounds.

Identify and quantify unknowns

Identification and quantitation of lipid biomarkers using accurate mass spectrometry

Balance accurate quantitative performance with accuracy values between 80–120% at all concentration levels, with streamlined data management for acquisition and processing. Identification of lipid biomarkers becomes a simple task using the ChemSpider tool that is fully integrated into SCIEX OS software.

Read more >



Using Zeno DDA to determine the interference observed at ~3.7 minutes

Glucagon-like peptides (GLP-1)

Highly sensitive analytical methods are required to understand the pharmacokinetic and pharmacodynamic profiles of GLP-1 analogs. Developing and running these methods is challenging due to their low oral bioavailability and their structure that yields poor ionization and fragmentation.

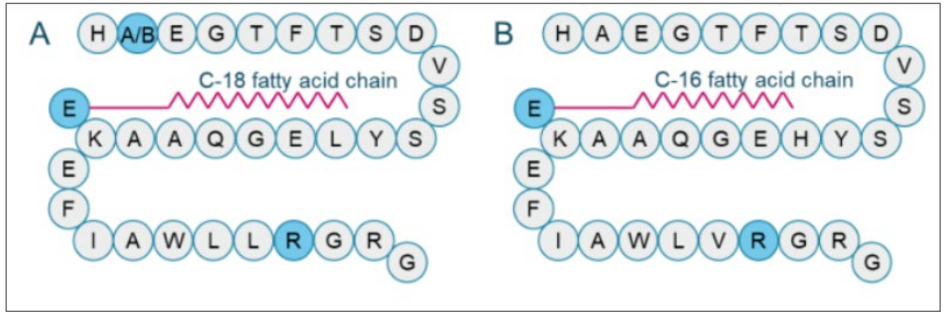
- Quantify GLP-1 analogs in complex biological matrices with outstanding reproducibility, precision, accuracy and linearity
- Employ a single platform for streamlined data acquisition, processing and management using SCIEX OS software

LC-MS/MS

Low-ng/mL quantitation of glucagon-like peptide-1 (GLP-1) analog in rat plasma

Discover options for a sensitive method to quantify a GLP-1 analog, semaglutide, in rat plasma with a lower limit of quantitation (LLOQ) of 0.2 ng/mL.

Read more >



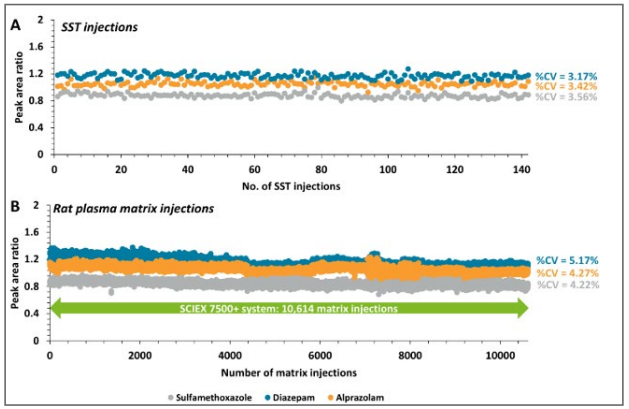
Structures of GLP-1 analogs. The left panel shows the structure of the target analyte, semaglutide (A) and the right panel shows the structure of the internal standard, liraglutide (B).

Enhanced robustness

Redefine bioanalysis with enhanced robustness on the SCIEX 7500+ system

This technical note demonstrates the measurement of alprazolam, sulfamethoxazole and diazepam in rat plasma matrix over 10,000 injections, with no divert valve. The SCIEX 7500+ system showed a >2x improvement in robustness for this analysis compared to the SCIEX 7500 system.

Read more >



Peak area ratio (raw peak area normalized to IS) from analysis of alprazolam (orange), diazepam (blue) and sulfamethoxazole (grey) SST (A) and rat plasma matrix (B) injections on the SCIEX 7500+ system.

Peptides and cyclic peptides

Peptide and cyclic peptide analysis presents unique challenges compared to the analysis of a typical small molecule. Peptides are large, complex molecules that often contain multiple amino acids and post-translational modifications. This complexity results in a higher degree of structural variability, a wider dynamic range of concentrations and multiple charging when analyzed by mass spectrometry. Additionally, peptides are more prone to sample loss, degradation and modifications during sample preparation and analysis than typical small molecules.

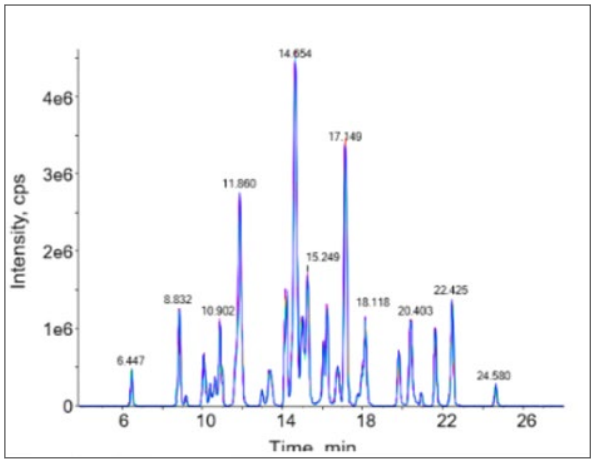
- Our software allows you to automatically schedule multiple reaction monitoring (MRM) functions, retention times and MRM transitions for simple method optimization
- Easily develop and optimize quantitative workflows using the M5 MicroLC system with seamless integration into SCIEX OS software to enhance the sensitivity of a method

Peptide: Targeted panel

Reproducible targeted peptide profiling using highly multiplexed MRM assays

Read about a simplified method development approach for large-scale targeted peptide analysis. By using our Scheduled MRM function, retention times and MRM transitions are automatically optimized to create an acquisition method based on a few key parameters provided by the user.

Read more >



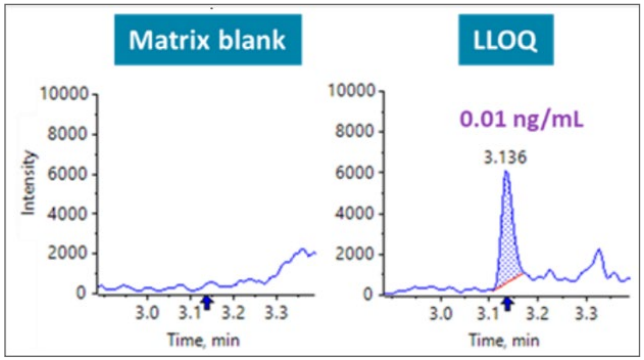
Chromatographic reproducibility for 30 min gradient runs.

Low-level cyclic peptides

Low-pg/mL quantification of cyclic peptides in rat plasma using microflow LC

Read about how to achieve low-level quantitation for human ANP at an LLOQ of 0.01 ng/mL in rat plasma with %CV values <12.3% at all concentration levels across inear dynamic range spanning 4.3 orders of magnitude.

Read more >



Extracted ion chromatograms (XICs) of a matrix blank and LLOQ sample of human ANP.

Nucleic acids and oligonucleotides

Synthetic nucleotide analysis is a complex pursuit because these drugs combine the learnings from nature's mechanisms with sophisticated technology. The diverse landscape of structural adaptations for bases and backbones has the potential to treat diseases with unprecedented specificity but also increases the challenges for analyzing synthetic oligonucleotides.

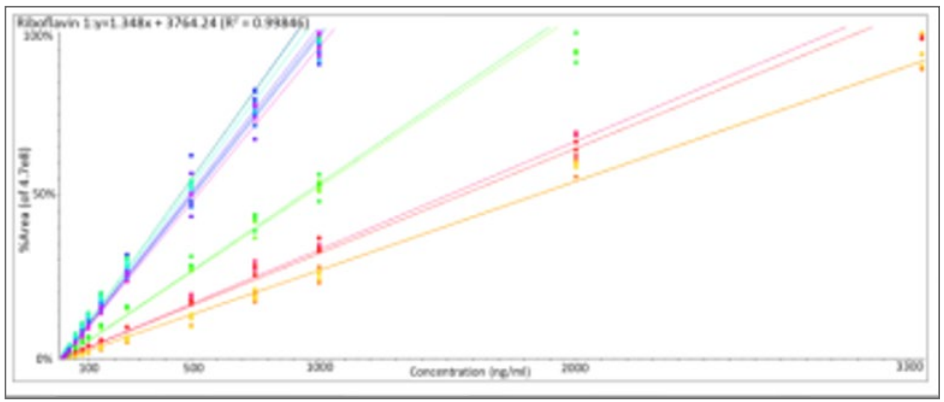
- Complete sequence confirmation, impurity identification, sizing and purity analysis with cutting-edge analytical solutions
- High-quality results for therapeutic oligonucleotides (antisense oligonucleotides, siRNA, aptamers) help you advance medicine

Quantitation of nucleic acids

Quantitative LC-MS solution for targeted analysis of cell culture media

Discover options for the measurement of polar and nonpolar analytes, in addition to positive and negative polarity components within a single method.

Read more >



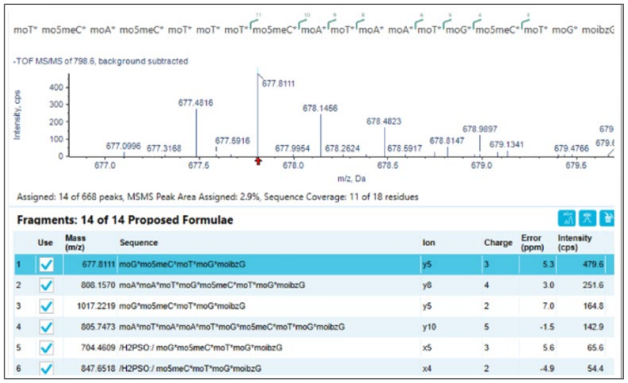
Linear calibration curves of representative cell culture component per group measured in positive and negative modes.

Identify and quantify unknowns

Characterization and relative quantification of oligonucleotide impurities

See how robust data quality and high mass accuracies provide confident assignment of oligonucleotide FLP and impurities using the Molecule Profiler software. The use of this software allowed straightforward relative quantitation based on the TOF MS peak.

Read more >



Confirmation of the sequence of the potential ASO-18PS2MOE impurity with 1 isobutyryl protecting group on G.

Targeted protein degraders

Lead the development of novel targeted protein degradation (TPD) therapeutics, such as proteolysis-targeting chimeras (PROTACs). Bring novel drugs based on this new class of compounds to market with analytical systems that enable precise and accurate identification and quantitation of low-level targeted protein degraders, even in complex matrices. Get to the important information quickly with fast, intuitive and integrated data acquisition and processing software.

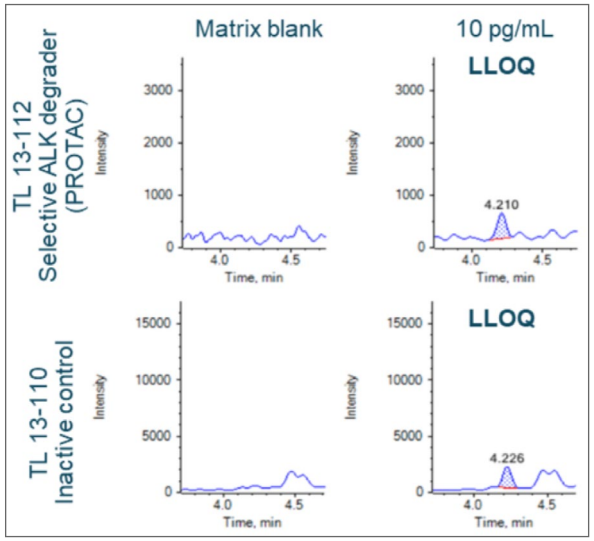
- Achieve sensitive quantitation of targeted protein degraders with excellent accuracy and precision
- Comfortably work with complex matrices

Quantitation

Low-pg/mL quantification of TL 13-112, a protein-targeting chimera (PROTAC) in rat plasma

See how it is possible to achieve low-pg/mL level LLOQs for the quantitation of PROTACs in rat plasma with robust analytical performance. These results were achieved in combination with streamlined, compliance-ready data management.

Read more >

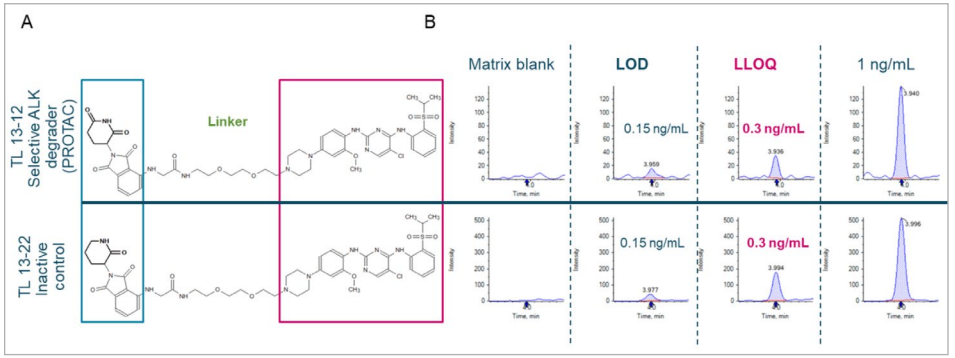


Representative XICs of the selective ALK degrader (PROTAC) and its inactive control in matrix and at the LLOQ level.

A sensitive method for the quantification of the protein targeting chimera (PROTAC), TL 13-12, in rat plasma using accurate mass spectrometry

Achieve an LLOQ of 0.3 ng/mL for the quantitation of TL 13-12 and TL 13-22 in rat plasma using MS/MS data acquisition. This approach allows you to minimize sample volume and sample preparation time.

Read more >



Sub-ng/mL level quantitation was achieved for the PROTAC and its inactive control.

Conclusion

Simplify your pharmaceutical development assays to save time and reduce the training needs of the scientists working in your team. Our LC-MS solutions, including our software and trusted services and support, are intuitive, robust and sensitive.

Additional links for development assays

Selecting the right system for bioanalytical quantitation

Investing in a new LC-MS system is not an easy decision, especially if you have a range of analytical requirements in your laboratory. This blog is intended to help you choose the right system for your pharmaceutical drug development needs.

Read blog >

Easing the demands of a compliant pharmaceutical laboratory

At SCIEX, we are proud to provide analytical systems to the pharmaceutical industry. We work hard to understand the demands of analytical work and the processes required to develop and manufacture drugs. This blog provides an overview of some of the ways we are here to help.

Read blog >

Sensitive LC-MS/MS approach for the quantification of proteolysis-targeting chimeras in a biological matrix

In this webinar, we explore a sensitive LC-MS/MS workflow for quantifying PROTACs in a biological matrix using the SCIEX 7500 system.

Watch webinar >

Driving more sensitive bioanalysis using accurate mass spectrometry

Quadrupole-based LC-MS has been routinely adopted for the quantitation of therapeutics in bioanalytical laboratories. Advances in accurate mass spectrometry have enabled it to become a complementary option for quantitative bioanalysis. These advances include greater selectivity, improved mass resolution and the flexibility of time-of-flight (TOF) MS/MS for data analysis.

Watch webinar >

Enhancing quantitative sensitivity in cerebrospinal fluid

This webinar discusses the sensitive quantitation of LRRK2 at 10 pg/mL in human cerebrospinal fluid. Dylan Bennett, a scientist at Neuron23, shares the details of this LC-MS/MS methodology for the sensitive analysis of this promising target.

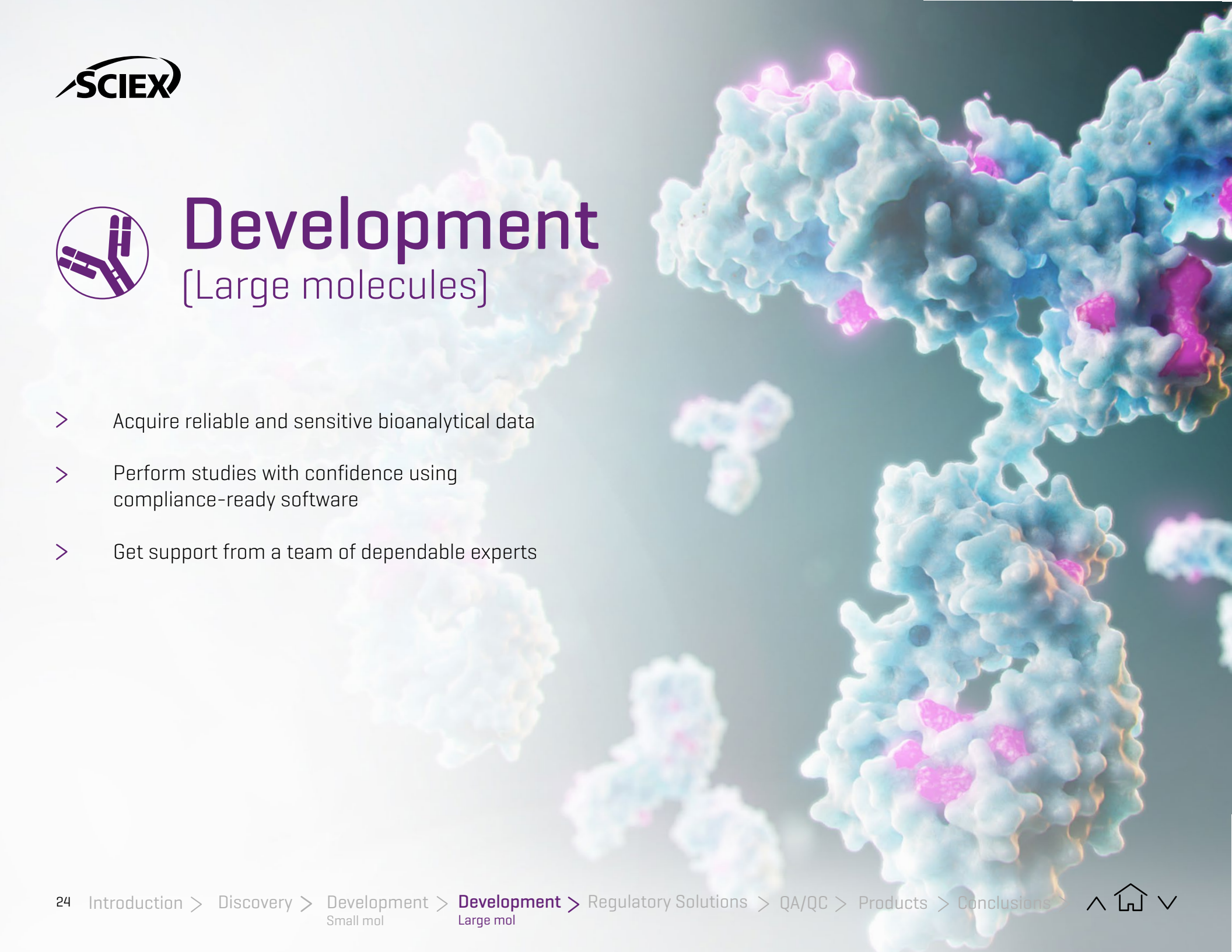
Watch webinar >

Identification and quantitation of lipid biomarkers using high-resolution MS

In this webinar, our speaker discusses the role of glucosyl and galactosyl ceramides as biomarkers and how their misregulation can be an identifier for various disease states including, but not limited to, Parkinson's, Krabbe and Gaucher diseases.

Watch webinar >

Development
(Large molecules)



- Acquire reliable and sensitive bioanalytical data
- Perform studies with confidence using compliance-ready software
- Get support from a team of dependable experts

Introduction

Enhance your large molecule quantitative assays while simplifying method development and reducing training needs. Our liquid chromatography and mass spectrometry (LC-MS) solutions are intuitive, robust and sensitive, and our trusted services and support help you get the most out of your investment.

Accurately identify and monitor molecules—such as biomarkers, proteins and antibodies—on a single software platform.

Featured applications and assays

- Antibody drug conjugates (ADCs)
- Antibodies and peptide surrogates
- Biomarker quantitation of large molecules
- Cell culture analysis
- Proteins

Featured solutions

LC-MS

The ZenoTOF 7600 system offers excellent sensitivity and mass resolution for large molecule quantitation. When additional sensitivity is required, combine the ZenoTOF 7600 system with either the ExionLC AE system or the M5 MicroLC system.

Software

SCIEX OS software offers an easy-to-use, compliance-ready software platform. Biologics Explorer software delivers highly accurate and informative data for full characterization of protein biotherapeutics.

Antibody drug conjugates (ADCs)

Understand ADC drug loading profiles regardless of the inherent heterogeneity and high molecular weight of these molecules. Assess the quality of ADCs using drug antibody ratio (DAR) information, so you are clear on what you have, how much you have and whether it will be effective. SCIEX software and solutions enable:

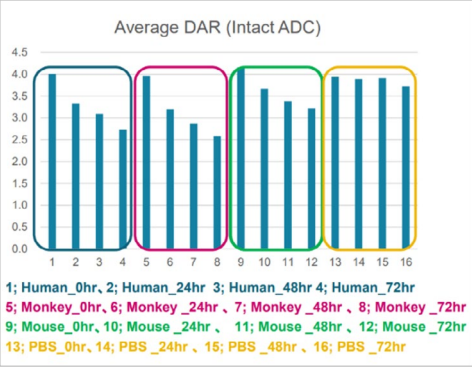
- Acquisition and tracking of DAR changes
- High-throughput DAR monitoring for large sample sets
- DAR quantitation and monitoring with compliance-ready software

Low-level quantitation

Simple and fast-tracking of DAR distribution using intact multiple attribute methodology (intact MAM)

Learn about a solution for high-throughput DAR monitoring of a large sample set. See how intuitive data analysis software enables product attribute definition, tracking and quantification with flexible custom calculations for critical quality attributes (CQAs) based on specific user needs.

Read more >

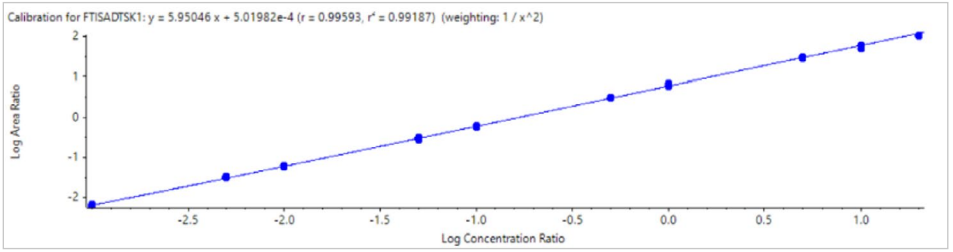


Average DAR of intact ADC and DAR of each payload results. (A) Average DAR monitoring from each sample. (B) DAR monitoring of each payload result.

Low-level sensitivity

Ultra-sensitive LC-MRM analysis for trastuzumab-emtansine quantification in rat plasma

Discover how an immunoaffinity-LC-MRM workflow enabled the quantitation of trastuzumab-emtansine in rat plasma at 1 ng/mL with high precision, accuracy and linearity. Learn how the data was processed with SCIEX OS software—an easy-to-use, compliance-ready software platform for acquisition, processing and data management.



Calibration curve for trastuzumab-emtansine in rat plasma displayed with log-log format. Concentrations range from 1 ng/mL to 20,000 ng/mL.

Read more >

Antibodies and peptide surrogates

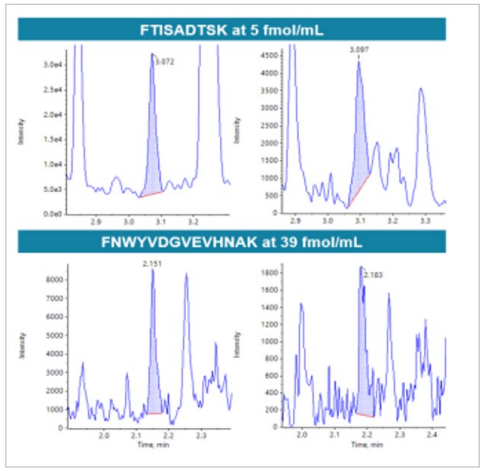
Simplify the quantitation of antibodies and peptide surrogates. Confidently understand and quantify these compounds, including low-abundance ions, faster than ever before with easy-to-use, integrated software software from SCIEX that enables you to:

- Obtain high-quality, reliable data
- Confidently characterize and quantify antibodies and peptide surrogates with robust, sensitive analyses
- Benefit from the support of experts eager to help you improve your workflows and move promising candidates forward

Surrogate peptide quantitation

High sensitivity MRM workflow for signature peptide quantification

Read about an LC-MS option to quantify peptides as surrogates (bottom-up proteomic workflows) using targeted LC-MRM. This approach offers not only high sensitivity but also a wide linear dynamic range (LDR) combined with high reproducibility to provide reliable quantitative measurements.



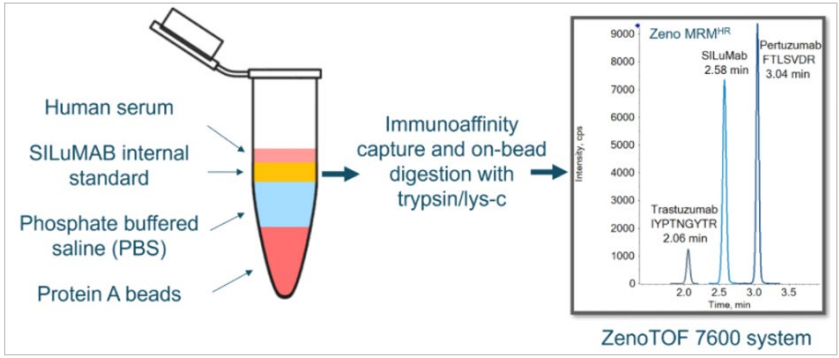
Sensitivity gains for peptide quantification.

Read more >

Quantitation/qualification workflows

Simultaneous quantification of trastuzumab and pertuzumab in human serum using accurate mass spectrometry

iscover a method for the sensitive quantitation of co-administered mAbs (trastuzumab and pertuzumab) in human serum that allows for reduced sample volume requirements.



Summarized workflow for the simultaneous quantification of pertuzumab and trastuzumab in human serum.

Read more >

Biomarker quantitation of large molecules

Discover better analytical solutions that meet your needs for in-depth coverage with robust and sensitive performance. Quickly and confidently characterize and quantify large-molecule biomarkers with intuitive SCIEX software that allows you to:

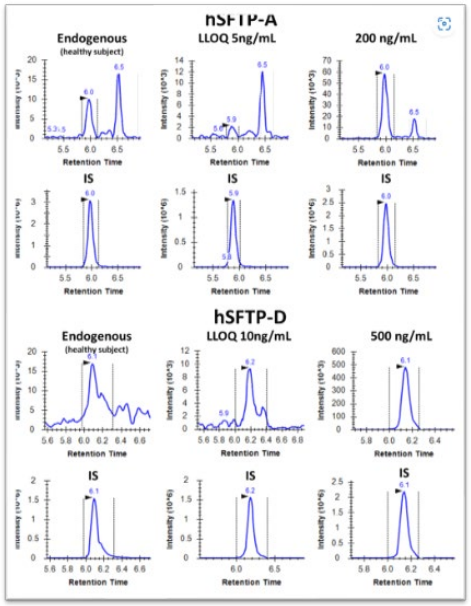
- Get confident answers in hours instead of days
- Confidently characterize and quantify large biomarkers with robust, sensitive analyses
- Take advantage of dependable service support

Low-level quantitation

Sensitive multiplexed quantification of protein biomarkers for early drug discovery and development

Read about the sensitive quantification of surfactant proteins in plasma at low-ng/mL levels. This technical note demonstrates how to reach outstanding accuracy, precision and linearity for the quantification of multiple protein targets in complex matrices.

Read more >

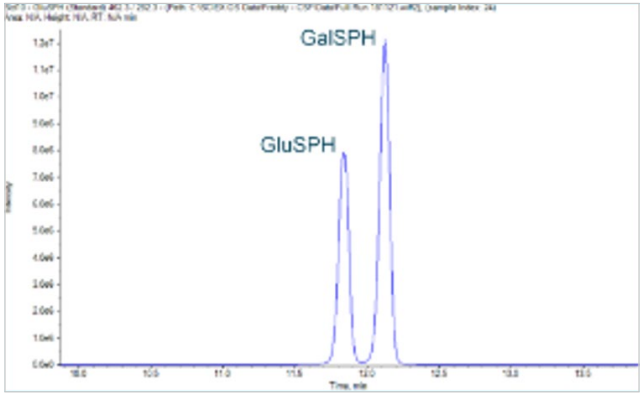


Extracted ion chromatograms were used for the quantification of hSFTP-A and hSFTP-D.

Quantitation/qualification workflows

Sensitive bioanalysis of galactosyl sphingosine (GalSPH) and glucosyl sphingosine (GluSPH) in cerebral spinal fluid

In this technical note, the method sensitivity for 2 glycosphingolipids (GluSPH and GalSPH) were evaluated in cerebral spinal fluid. The assay was developed using HILIC chromatography and using positive MRM analysis and electrospray ionization (ESI)



Extracted ion chromatograms of GluSPH and GalSPH.

Read more >

Cell culture

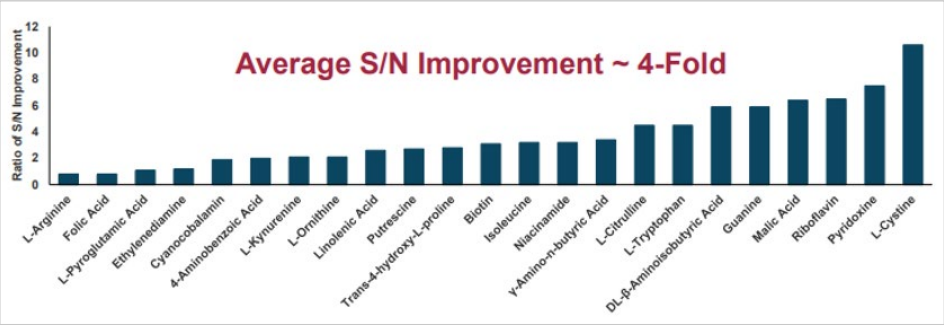
Comprehensive quantitation of the components in cell culture media (CCM) is an important factor during the development phases of biotherapeutic production. Often this analysis requires the quantitation of over 100 analytes from various compound classes, making it challenging to complete in a single analysis. Our solutions can help by allowing you to:

- Acquire highly sensitive, selective and robust data over a wide range of analytes
- Easily acquire, process and manage data with a streamlined interface using SCIEX OS software
- Utilize expert service and support to improve your workflows

Quantitative and qualitative workflows

Enhanced sensitivity for cell culture media analysis (CCMA)

The CCMA method demonstrated in this technical note offers high sensitivity, selectivity and robustness for the identification and quantitation of over 110 compounds in a single analytical method. The analysis was completed in under 20 minutes with a 4x signal-to-noise (S/N) improvement on average.

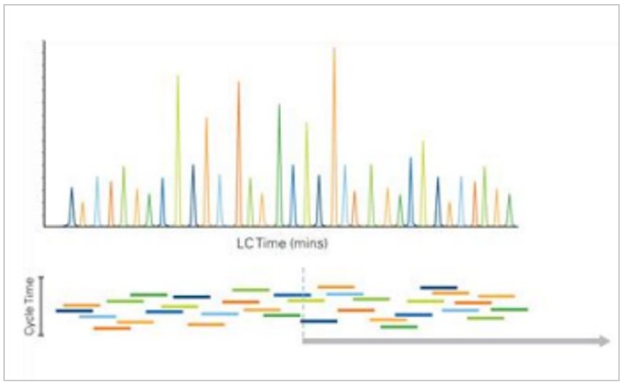


Demonstration of a 4-fold average S/N improvement, resulting in greater sensitivity.

Read more >

A comprehensive method for in-depth profiling of secreted metabolites in cell culture media from human adipose stem cells

This technical note demonstrates a sensitive profiling method for the analysis of secreted metabolites in cell culture media. Over 110 cell culture metabolites were monitored in under 20 minutes using a single method featuring fast polarity switching. Overlapping MRM transitions were optimized to maintain the maximum dwell times and optimal cycle times for accurate quantitation.



The Scheduled MRM Pro algorithm was used to optimize cycle times and maximize dwell times for each MRM transition.

Read more >

Conclusion

Simplify your large molecule quantitative development assays to save time and reduce the training needs of the scientists working in your team. Our LC-MS solutions—including our software and trusted services and support team—are intuitive, robust and sensitive.

Additional links

A 2-fold revolution: MS approaches for the bioanalysis of oligonucleotide therapeutics
In 1998, the US Food and Drug Administration (FDA) approved fomivirsen as the first oligonucleotide therapeutic. This approval marked a revolution in drug development, which then led to another revolution related to analytical solutions: instruments that could keep up with the ever-decreasing concentrations of analytes in more potent drugs, which required pushing the boundaries of sensitivity.
Read blog >

Antibody drug conjugate content pack
Take a deep dive into the characterization of an antibody drug conjugate. Understand ADC profiles regardless of the inherent heterogeneity and high molecular weight of these molecules.
Get content >

Rewrite the rules
In this vodcast series, we aim to inspire not just you, but the entire biopharmaceutical community. With insights from leading scientists around the world, it's an invitation to reshape and rewrite the rules of your laboratory.
Watch now >

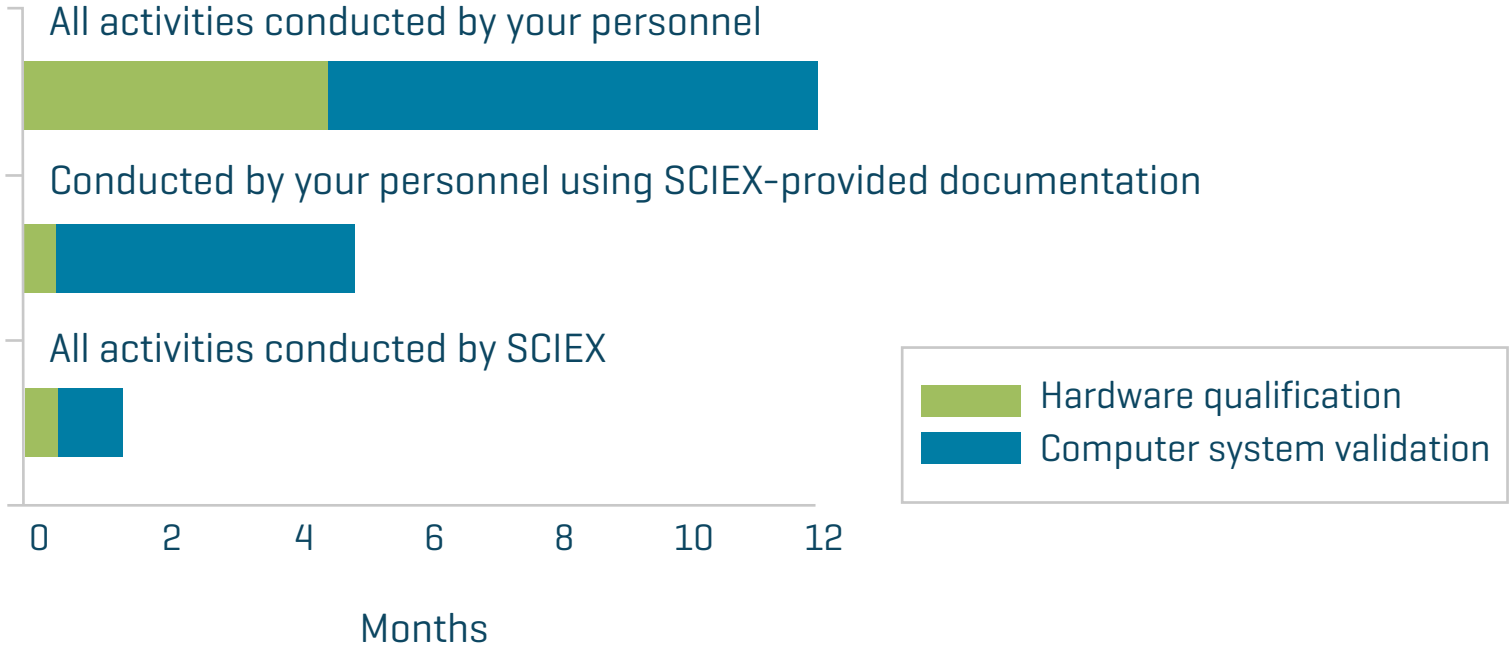
Regulated laboratory solutions

- Minimize regulatory risk with complete system solutions
- Ensure compliance for instruments through installation and maintenance qualifications
- Reduce human error with user access levels

Introduction

Achieving compliance in a regulated analytical laboratory is a complex, time-consuming and costly journey that takes you away from the day-to-day operations of your lab. We offer compliance-ready solutions that help ensure your lab produces compliant data without delaying your projects. From qualified instrument installation and system maintenance to compliant data reporting, our team of compliance experts can guide you through the complete process.

Compliance project timelines



Instrument qualification

Our compliance products provide a complete solution for instrument qualification—including LC, MS and LC-MS systems and software—all at a fixed, predictable cost. This can reduce the need for in-house expertise in regulatory compliance. We complete the installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) work using good documentation practices that are audit-ready, saving you both time and money.

Trained and certified SCIEX representatives:

- Work with you to manage the qualification process and simplify the experience
- Provide the knowledge and expertise you need to quickly get your instrument ready for regulated laboratory work
- Execute services that will help minimize compliance risk and provide you with peace of mind

Learn more >

Software validation

SCIEX provides software validation services that help ensure your SCIEX OS software is properly configured for data integrity and compliance with US FDA 21 CFR Part 11 regulations and similar global standards. These services feature a complete GAMP-5, V-model validation, including a validation plan, risk assessment, requirements specification, configuration specification, IQ/OQ/PQ protocols, traceability matrix, 21 CFR Part 11 assessment and validation summary report.

Software validation products include:

- Security and audit trail configuration
- Testing and confirmation of configurable settings
- Three tiers of service (essential, standard and advanced) to fit every need

SCIEX OS software features for compliance enable you to:

- Define and set appropriate permissions for your staff
- Set full traceability—including reasons, e-signatures and time-stamped event logs—using the audit configuration settings
- Generate printable reports

Did you know?

You can download and try any of our software products for free to test in your workflow

Learn more >

Audit preparations

SCIEX products and services give you peace of mind when preparing for an audit:

- We have a proven record of successfully delivering over 10,000 qualifications and 1,000 validations
- If auditors find any deficiency with our compliance services, we will address the issue at no cost to you
- Our integrated test and validation plans enable an efficient, streamlined audit process
- The consistent approach to style, content and purpose in our report documentation provides clarity for auditors

Webinar: Are you audit ready? >

Topics covered in this webinar include:

- The top 5 things you need to do to meet a typical audit requirement
- What auditors focus on (software/hardware/documentation)
- The most commonly identified instances of non-compliance

Watch webinar >

Conclusion

Partner with us to maintain your compliance status in a timely and cost-efficient manner.

Compliance solutions can help ensure your lab produces compliant data without delaying your projects. From qualified instrument installation and system maintenance to compliant data reporting, our team of compliance experts can guide you through the complete process.

Additional links for regulatory support

The costly consequences of unplanned downtime

Unplanned downtime is a formidable adversary that businesses across various industries strive to minimize. Defined as the unexpected interruption of regular operations, unplanned downtime can wreak havoc on productivity, profitability and customer satisfaction. In this blog, we delve into the causes of unplanned downtime, its far-reaching consequences and strategies to mitigate its impact

Read blog >

Easing the demands of a compliant pharmaceutical laboratory

While the performance of an analytical instrument is an obvious requirement, we also understand that developing a robust method is just the beginning. In one of the most highly regulated industries, it is no easy task to run a pharmaceutical laboratory and satisfy all the relevant regulatory bodies around the world. This blog shares how SCIEX can help make this easier.

Read blog >

Are you audit ready? Find out now!

Topics covered in this webinar include:

- The top 5 things you need to do to meet a typical audit requirement
- What auditors focus on (software/hardware/documentation)
- The most commonly identified instances of non-compliance

Watch webinar >

QA/QC and lot release

- Quickly identify deviations from product specifications
- Flexible system configurations that can be tailored to an ever-evolving regulatory landscape
- Expert application and service support

Introduction

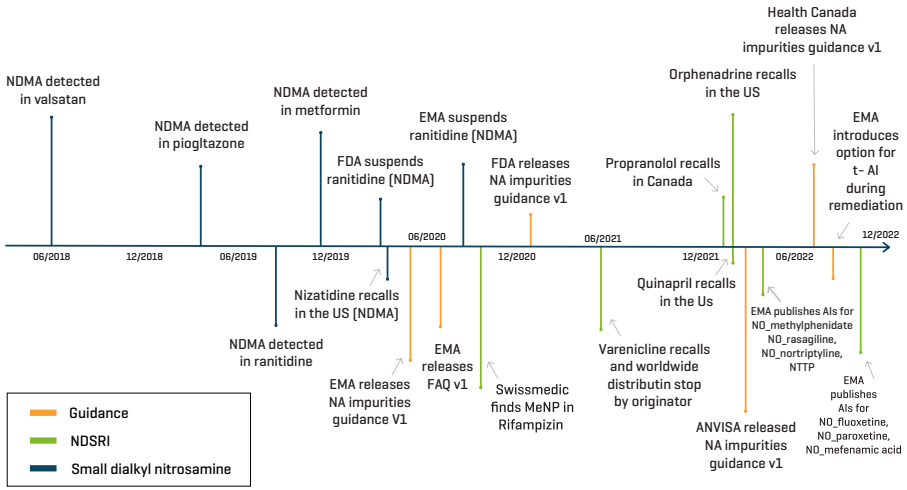
Completing risk assessment, confirmation and implementation of a control strategy for pharmaceutical impurities requires assays that are accurate, sensitive and highly reproducible.

We aim to provide systems that make this as simple as possible. We know that changes in the regulatory landscape can present additional challenges to implementing a robust quality management program.

Our solutions address these analytical challenges with fit-for-purpose hardware and compliant-ready software, all maintained with industry-leading service and support.

Featured applications and assays

- Pharmaceutical impurities
- Nitrosamines
- Extractables and leachables



Source: Org. Process Res. Dev. 2023, 27, 10, 1719–1735

Featured solutions

Our portfolio of systems offers you the flexibility to select the system that is right for your lab. The ExionLC AE system offers reliable chromatography with minimal carryover and is supported by our compliant-ready SCIEX OS software. The MS system of choice is dependent on the sensitivity of your assay, and potential requirements in the future.

Triple Quad 5500+ system offers robust quantitative performance that meets the detection requirements of most impurity analysis.
Triple Quad 6500+ system provides more sensitivity for challenging analytes and matrices.

Impurity analysis

Identify, quantify and control impurities as efficiently as possible using our systems for routine profiling and trace-level analysis. Our integrated hardware and compliant-ready software solutions provide accurate impurity detection with easy-to-use and learn workflows.

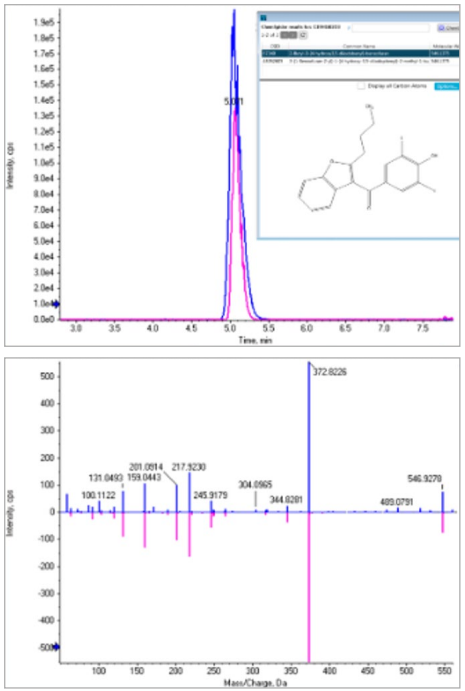
- Reliably identify, quantify and monitor non-intentionally added substances (NIAS)
- Understand the behavior of your packaged product during manufacturing and storage
- Support your team with compliant-ready SCIEX OS software

Identification by library matching

Impurity profiling of amiodarone stability samples using accurate mass analysis and automated data processing

Read about a routine, automated method for the identification of drug impurities under basic and oxidative conditions through library matching.

Read more >



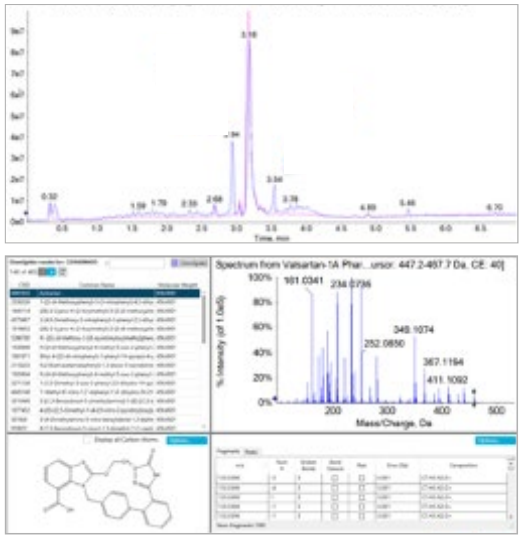
Identification of amiodarone impurity D.

Quality control

Next generation quality control in pharma applications

Detect and quantify trace amounts of critical impurities using the simple and easy-to-use general unknown comparative screening (GUCS) workflow based on SWATH acquisition for accurate impurity profiling and monitoring.

Read more >



Identification of unknown peak in valsartan product.

Nitrosamines

Complete nitrosamine impurity analysis with confidence, using fit-for-purpose triple quadrupole or high-resolution systems that provide robust and sensitive performance. Simplify this important analytical task using SCIEX OS software, a compliant-ready software for data acquisition, processing and reporting.

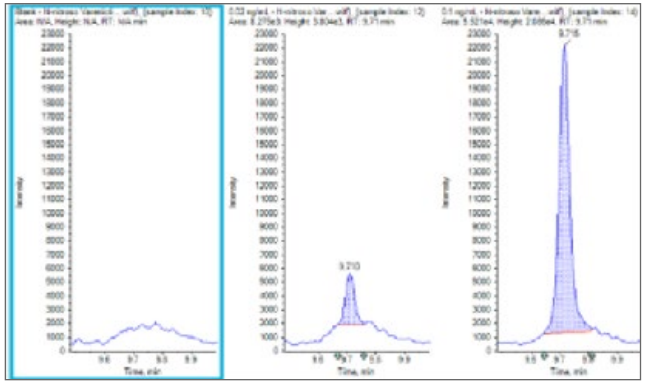
- Achieve robust and sensitive nitrosamine detection and identification
- Benefit from trusted and reliable instrument performance for nitrosamine analysis
- Simplify nitrosamine impurity analyses with intuitive, compliant-ready software

Routine quantitation

Varenicline nitrosamine drug substance-related impurity (NDSRI) quantification in a varenicline drug product

Using a simple sample preparation, a robust and routine method was developed for the quantitation of a nitroso-drug substance-related impurity (NDSRI) in a varenicline drug that provides a high level of sensitivity and specificity.

Read more >



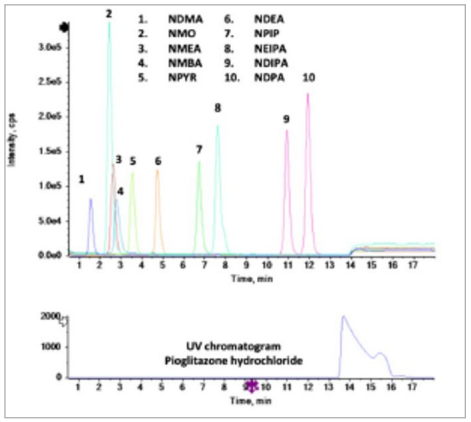
Quantification of varenicline NDSRI in a varenicline drug product.

Low-level quantitation

Low-level quantification of 10 mutagenic nitrosamine impurities in Pioglitazone hydrochloride using accurate mass spectrometry

Discover how fast scanning enables the simultaneous quantitation of multiple nitrosamine impurities with exceptional quantitative performance below the current recommended imit (30 ng/g) in a Pioglitazone hydrochloride drug product.

Read more >



Representative extracted ion chromatogram (XIC) for 10 nitrosamines and UV chromatogram for Pioglitazone hydrochloride.

Extractables and leachables

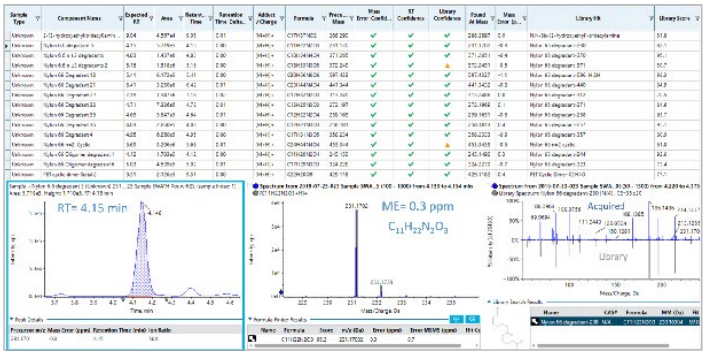
Find the perfect fit for your team with compliant-ready extractables and leachables (E&L) analysis solutions designed for your laboratory. We have developed E&L analysis solutions alongside our customers with ease-of-use in mind.

- Simpler method setup helps optimize lab investments
- Sensitive methods deliver analytical results your team can trust
- Compliant-ready software allows you to easily control and manage your processes

E&L identification

Confident identification in extractable and leachable screening

Discover how an open-access E&L high-resolution MS/MS spectral library can be used to search and identify compounds across a breadth of E&L compound classes for both targeted and non-targeted screening.



Obtain confident identification through the SCIEX open access extractables and leachables high resolution MS/MS spectral library.

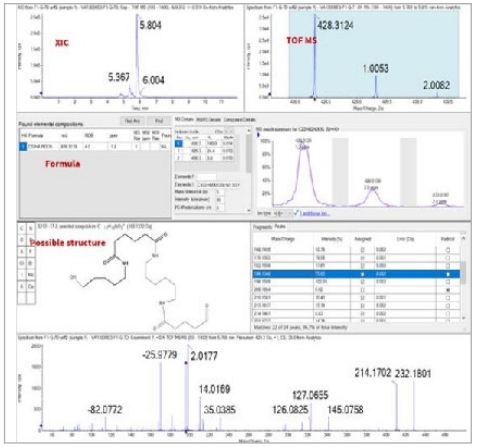
Read more >

Low-level detection

Comprehensive workflow for sensitive detection and confident identification of extractable and leachable (E&L) impurities

Read about a comprehensive and sensitive workflow for a high-resolution LC-MS/MS E&L method using library matching.

Read more >



Recommended molecular formula and identified structure for m/z 428.3124 using SCIEX OS software and ChemSpider.

Conclusion

We understand your quality needs.

- With fit-for-purpose solutions, SCIEX can help you better understand and ensure the safety of your products from early development to lot release. Our solutions enable reliable identification, quantitation and monitoring of NIAS.
- Our service team and suite of service tools can help you maintain the qualification status of your system and ensure your system is running at its best.

Additional resources

Overcoming N-nitrosamine analysis challenges with mass spectrometry and chromatography solutions - SCIEX Community
Three key analytical components must work together for the most sensitive and accurate nitrosamine impurity detection: mass spectrometry, chromatography and sample preparation.
Read blog >

What have we learned from the nitrosamine crisis? - SCIEX Community
The background and history driving the evolving regulatory landscape around genotoxic impurities are discussed.
Read blog >

Overcome N-nitrosamine analysis challenges with chromatographic and mass spectrometry techniques
Learn how the QTRAP 6500+ system equipped with a SelexION device were combined with a carefully selected chromatographic column to enable a simplified sample preparation workflow for the identification of nitrosamines.
Watch webinar >

Extractables and leachables analysis
SWATH Acquisition with a SCIEX X500R QTOF system enables fast detection and quantitation of E&L substances using SCIEX library searching and ChemSpider matching of MS/MS data.
Watch webinar >

Accurate mass extractables & leachables open access high resolution MS/MS spectral library
Download the open-access accurate mass library for E&L species that contains high quality accurate mass spectra for relevant chemical species and moieties allowing for automated simultaneous ID and quantification.
Access library >

Products

- Discover systems at the forefront of quantitative perfomance
- Benefit from compliant-ready software and trusted service partners
- Ensure your results are the best they can be

Triple quadrupole systems

The ExionLC AE system provides reproducibility, reliability and carryover performance to match your quantitative workflows. You can count on it's dependability, from injection to injection and batch after batch.

When combined with a SCIEX Triple Quad LC-MS/MS system there is no stopping you with their modern, robust and straightforward designs. These systems enable scientists to acquire multiple reaction monitoring (MRM), precursor, neutral loss and product ion scans to develop powerful methods for complex matrices, all while maintaining reproducibility and robustness. All are QTRAP-ready for enhanced scan functions offering method flexibility to provide the data you need.

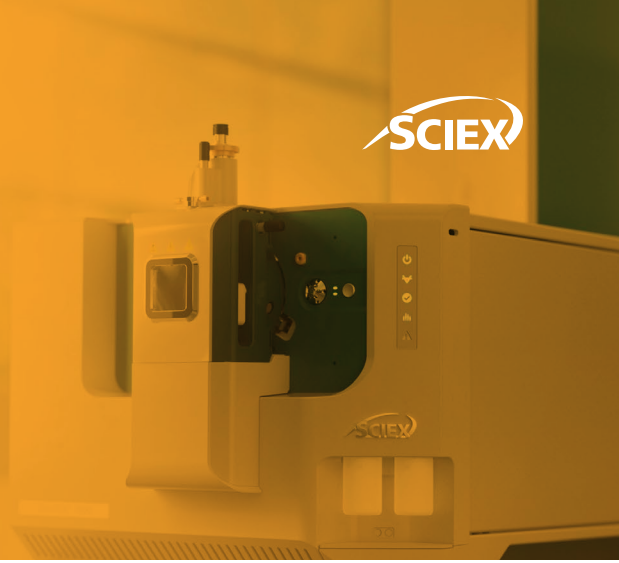
Performance, features and sensitivity

	SCIEX Triple Quad 4500 system	SCIEX 5500+ system	SCIEX Triple Quad 6500+ system	SCIEX 7500+ system
				
Ideal applications	· Nitrosamines · Extractables and leachables · Impurity and degradant analysis	· Nitrosamines · Extractables and leachables · Impurity and degradant analysis	· Small molecule bioanalysis · Biomarker quantitation · Lead identification	· Drug metabolism and pharmacokinetics (DMPK) · Small molecule biomarker quantitation · Targeted protein degraders (TPDs) · Trace-level lead identification
Example data	Analysis of nitrosamine compounds in multiple sartan APIs: a review and optimization of the Ph. Eur. monograph	Highly selective and sensitive method for quantification of nitrosamines in valsartan drug substances	High sensitivity quantification of triptorelin deca peptide using the QTRAP® 6500 system	Redefine bioanalysis with enhanced robustness on the SCIEX 7500+ system
MS specifications	· Sensitivity (MRM mode)*: S/N >300,000 · Scan speed: 12,000 Da/second · Mass range: 5–2,000 m/z	· Sensitivity (MRM mode)*: S/N >750,000 · Scan speed: 12,000 Da/second · Mass range: 5–1,250 m/z	· Sensitivity (MRM mode)*: S/N >1,500,000 · Scan speed: 12,000 Da/second · Mass range: 5–2,000 m/z	· Sensitivity (MRM mode)*: S/N > 5,000,000 · Scan speed: 12,000 Da/second · Mass range: 5–2,000 m/z

*Reserpine, 1 pg on column with electrospray ionization in positive ion mode (ESI+)

Quadrupole time-of-flight systems

Boost performance and productivity in your lab with quadrupole time-of-flight (QTOF) mass spectrometry systems for qualitative and quantitative analysis. Whether you need the most comprehensive coverage and workflow flexibility to take on new projects or a simplified and easy-to-use system for routine testing analyses, the SCIEX QTOF portfolio delivers unmatched speed, robustness and accuracy for the assays you need to run today and tomorrow.



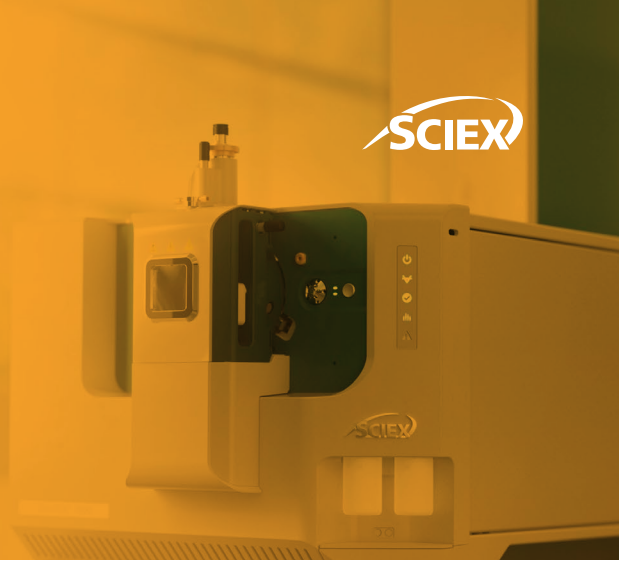
Performance, features and sensitivity

	X500R QTOF system	ZenoTOF 7600 system
		
Ideal applications	· Extractables and leachables · MetID (routine) · Nitrosamines (with LC separation challenges) · Pharmaceutical impurities	· Biomarker quantitation (complex matrices) · Biomarker quantitation (large molecules) · DMPK (quant/qual workflows) · MetID (with challenging analytes) · Oligo MetID/biotransformations · Targeted protein degraders (quant/qual workflows)
Example data	Analysis of nitrosamine impurities in a metformin drug substance and drug product	Confident identification of phase 1 metabolites using electron-activated dissociation (EAD)
MS specifications	· Sensitivity (MRM mode)*: S/N >750 · Scan speed: 42,000 FWHM at m/z 956 · Mass range: TOF up to 40 KDa	· Sensitivity (MRM mode)*: S/N >2,500 · Scan speed: 42,000 FWHM at m/z 956 · Mass range: TOF up to 40 KDa

*Reserpine, 1 pg on column in ESI+

Echo® MS+ system

When the quantity of samples is your challenge, break through with the Echo® MS+ system. Echo® MS+ system gives you high-quality data, analytical flexibility and high sample throughput to help you make the right decisions today. With ejection rates of up to 1 sample/second, you can get results on the same day they are submitted to your lab. The Echo® MS+ system is a complete solution that removes bottlenecks in high-throughput analytical workflows, from sample preparation to data reporting.



Performance, features and sensitivity

Echo® MS+ system with ZenoTOF 7600 system

Best suited for high-resolution targeted screening:
High-res targeted screening:
- HTS: small molecule
- HTS: intact proteins

Additional benefits:
- Reduce background interference with increased specificity and selectivity
- Ease of method development (MS method)

Echo® MS+ system with SCIEX Triple Quad 6500+ sysem

Best suited for absolute sensitivity for quantitative work:
Absolute sensitivity for quantitative work:
- HTS: biochemical assays

Additional benefits:
- Simplicity of general system operation
- Higher level of quantitative consistency

SCIEX OS software

Software to power your SCIEX ecosystem

Discover an integrated software platform solution for all SCIEX innovations. SCIEX OS software delivers data integrity, seamless usability and efficiency gains for your mass spectrometry workflows throughout your laboratory. Built on advanced and sophisticated algorithms, SCIEX OS software facilitates instrument control and automated data processing, simplifying your workflows and empowering swift, well-informed decision-making.

Web page
SCIEX OS software >

Manage your SCIEX ecosystem >

LC-MS service and support plans

Keep your workflows running and your instruments performing at peak levels with LC-MS service and support plans from SCIEX. Choose the plan option that best meets your response time, repair coverage and maintenance needs, and benefit from:

- Increased productivity
- Maximum uptime
- SCIEX technical expertise
- Total workflow support

LC-MS service and support plans >
SCIEX support >

Lab compliance services

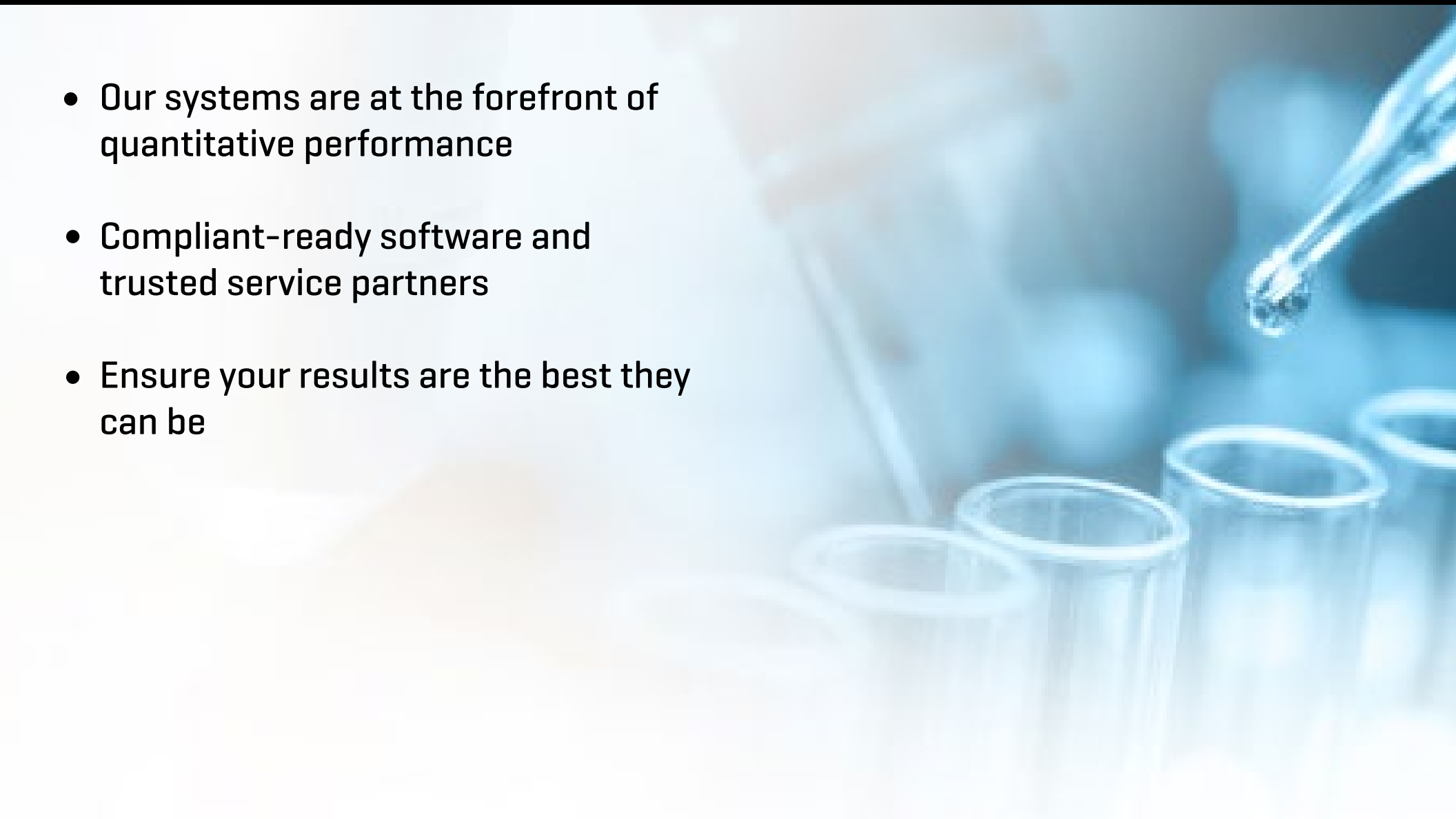
Achieving compliance in a regulated analytical laboratory is a complex, time-consuming and costly journey that takes you away from the day-to-day operations of your lab. SCIEX offers compliance solutions that help ensure your lab produces quality data without delaying your projects. From start to finish, our team of compliance experts can guide you through the complete process, enabling you to:

- Improve productivity
- Reduce costs
- Get expert advice
- Maintain best practices

Lab compliance services >

Conclusion

- Our systems are at the forefront of quantitative performance
- Compliant-ready software and trusted service partners
- Ensure your results are the best they can be



SCIEX Now support network

SCIEX Now

- Manage your instruments
- Submit and manage support cases, track status and view history
- Access online training courses and articles
- Manage software licenses linked to your registered instruments
- View and report critical instrument statistics when connected to the StatusScope remote monitoring service
- Be a part of the SCIEX community by submitting questions and comments
- Receive notifications from SCIEX with content based on your preferences

→ CONTACT SCIEX NOW

SCIEX Now Learning Hub

- SCIEX Now Learning Hub success programs provide LC-MS and CE training customized to meet your exact needs
- With a selection of training methods and certifications available, you can build a mass spectrometry learning program that is most suited to your lab and users
- By starting with a clear understanding of your desired learning outcomes, we help you improve lab productivity and consistency by designing and delivering a program that is focused on knowledge advancement and retention

→ FIND OUT MORE

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