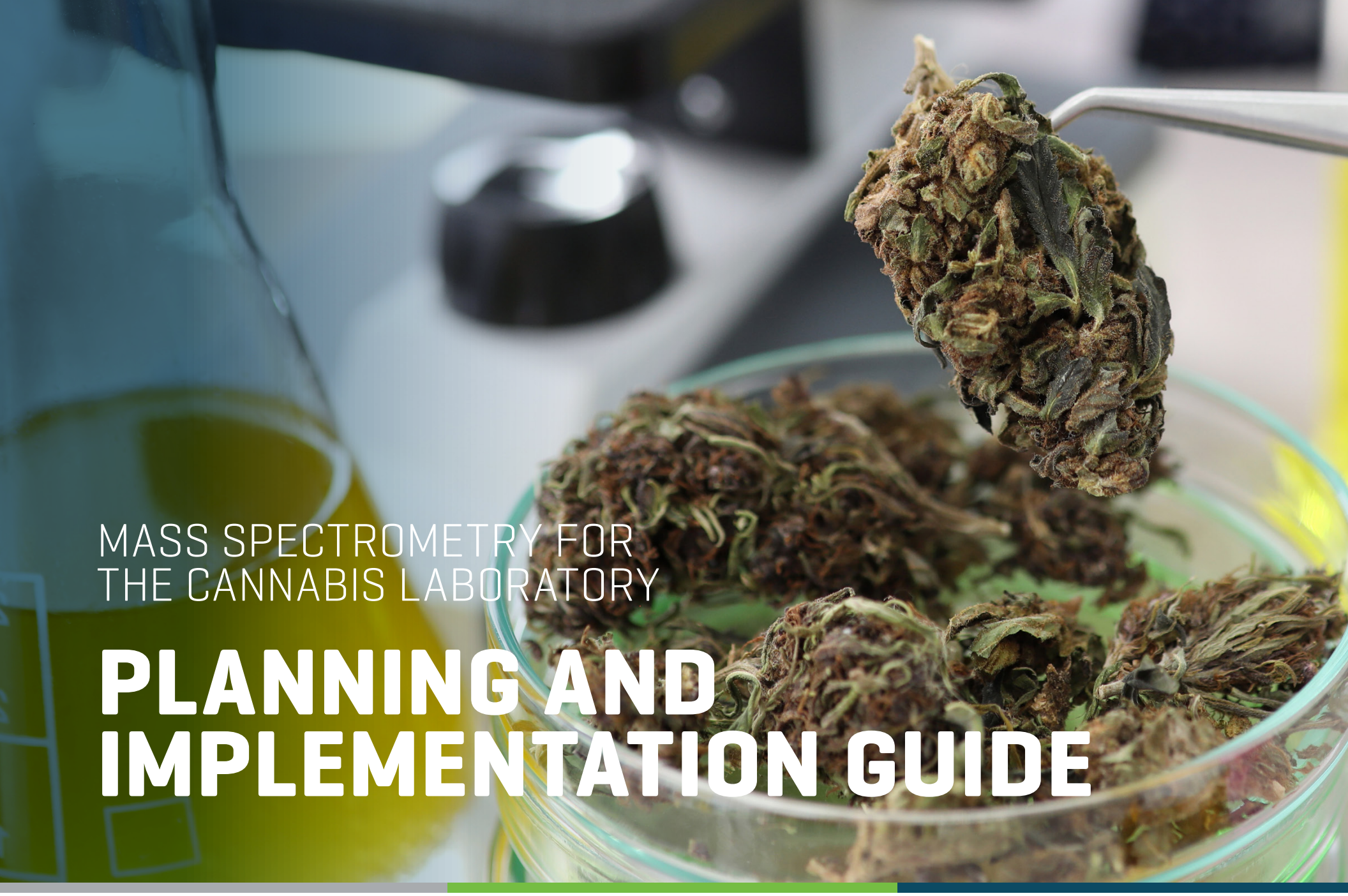

MASS SPECTROMETRY FOR
THE CANNABIS LABORATORY

PLANNING AND IMPLEMENTATION GUIDE

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SCIEX
The Power of Precision

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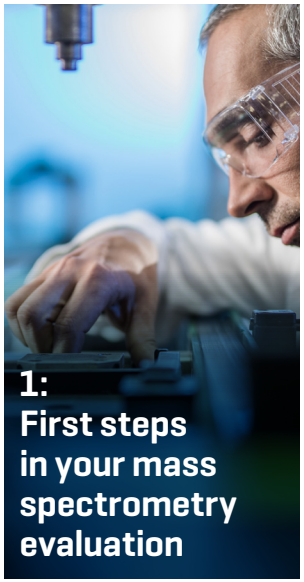

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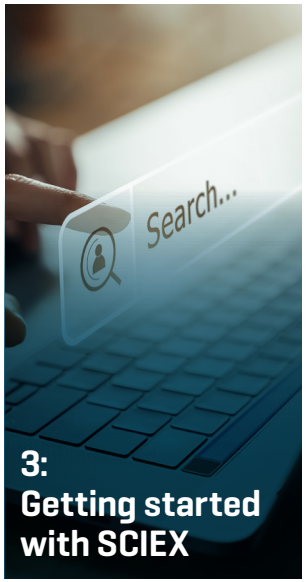

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SECTION 1:

First steps in your mass spectrometry evaluation

When purchasing a **mass spectrometer**, you need to make sure you are acquiring a system that best fits the needs of your laboratory. For those new to **mass spectrometry (MS)**, this guide will help you confidently prepare and plan for the purchase, implementation and operation of your **liquid chromatography with tandem mass spectrometry (LC-MS/MS)** system.

In these pages, you will find answers to the following questions:

- What is mass spectrometry?
- Which mass spectrometer is the right fit for my analytical needs?
- What do I need to consider when adding mass spectrometry to my laboratory?
- How do I prepare my organization for a successful implementation?
- How can SCIEX help ensure a smooth adoption and transition?

Getting started

What is mass spectrometry?

Mass spectrometers are at the forefront of quantitative and **qualitative scientific analysis**. They deliver accuracy and sensitivity to help ensure your results are the best they can be. Mass spectrometers use various techniques to measure the molecular mass of compounds, which is used to determine the identity of a chemical compound or obtain accurate quantification data for **analytes** of interest.

Mass spectrometers are composed of an **ion source**, a **mass analyzer**, a **detector** and associated computer equipment for data interpretation. The compounds present in a sample are ionized using the ion source. These ions are filtered by the mass analyzer through an electric or magnetic field to measure their **mass-to-charge ratio (m/z)** and are separated accordingly. Then, the separated ions enter the detector, which produces a signal that is sent to the computer workstation.

This guide focuses on triple **quadrupole** mass analyzers, which consist of three mass filters in a series. It also looks at their specificity, sensitivity, customizability and ability to handle high-throughput analyses. The information in the following sections will help you choose the instrument that is the best fit for your laboratory.

Getting started (cont.)

Mass spectrometry: accurate vs. nominal mass instruments

Both nominal and accurate mass MS instruments offer flexible and robust solutions to help address a variety of testing challenges you might face.

Nominal mass instruments, such as triple quadrupole and **QTRAP** systems, provide information about the mass of the analyte, where the *m/z* for each ion is measured to single-digit mass accuracy. These instruments offer the best-combined specifications for speed, sensitivity, specificity, dynamic range and the ability to analyze large numbers of analytes in a single injection for targeted quantitative **multiple reaction monitoring (MRM)** analyses.

Accurate mass instruments, such as quadrupole time-of-flight (QTOF) systems, provide information on the *m/z* for each ion measured out to four decimal places. These systems are useful for structural elucidation of novel or unknown analytes, screening for unknown compounds in complex samples and generating a comprehensive digital archive of a sample.

Getting started (cont.)

Triple quadrupole mass spectrometers: your quantitative solution

Triple quadrupole mass spectrometers are widely used as a mainstream analytical tool because of their data and quantification abilities. These systems enable scientists to acquire MRM, precursor, neutral loss and product ion scans to develop powerful methods for complex matrices while maintaining reproducibility and robustness.

If you are familiar with or using other scientific technologies—including, but not limited to **gas chromatography mass spectrometry (GC-MS)**, single quadrupole liquid chromatography mass spectrometry (LC-MS) systems or standalone **liquid chromatography (LC)** solutions—liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS) can improve your workflows by enabling:

- Faster, simpler sample preparation
- Less need for derivatization
- Shorter chromatographic run times
- Higher selectivity with less interference from co-eluting analytes and matrix
- Better **signal-to-noise (S/N)**, which allows for **lower limits of quantification (LLOQs)**
- Reliable identification of detected analytes using MRM compared to **selected ion monitoring (SIM)**
- A wide dynamic range of quantification
- Detection of a wider range of compounds in a single analysis

Nominal mass instruments can be taken a step further with the unique QTRAP system from SCIEX. In addition to providing triple quadrupole capabilities, QTRAP instruments provide unique MS and MS/MS scan functions to deliver both quantitative and qualitative information in a single platform. This enables structural elucidation and library-matched compound identification simultaneously with quantitative analysis. QTRAP instruments can also provide enhanced quantitative capabilities utilizing MRM^3, and they can assist in challenging cases where sample matrices require extensive extraction.

Scan the QR code or **click here** to learn about mass spectrometry technology from SCIEX.

Getting started (cont.)

Software: the gateway to usability

Software should be a key evaluation point in your decision-making process when considering a mass spectrometer. The right software is the gateway to usability for powerful, innovative hardware and can increase productivity.

The need for customizable and fit-for-purpose software applies to multiple steps of your workflow, including instrument control and data processing.

Consider the following when evaluating the software for a mass spectrometer:

- **Efficiency:** how will it make the job more efficient for analysts and quality assurance/quality control (QA/QC)?
- **User-friendliness:** how easily can you generate and access results with one or multiple end users?
- **Security:** can access be restricted based on job function and unique sign on?
- **Compliance and regulatory needs**
- **Integration:** is integration with a **laboratory information system** or **laboratory information management system (LIS/LIMS)** available?

Scan the QR code or **click here** to learn about software options from SCIEX.

Key questions to ask potential vendors

Getting the right information from vendors will help you evaluate your options when choosing solutions and partners. The questions outlined in this section can help prepare you for discussions with potential mass spectrometer vendors, so you can gather the information you need to make the right choice.

1. What instrument is best suited for my specific application/**assay** and why?

- **a.** Does it have enough sensitivity to meet my assay and regulatory requirements?
- **b.** Is it able to handle challenging matrices?
- **c.** How much sample prep is needed to meet detection limits?
- **d.** Is there an established upgrade path?

2. Can you help calculate a return on investment for my system purchase?

3. How will your service organization help maximize uptime for my LC-MS/MS system?

- **a.** How many service engineers in my area are trained in LC-MS/MS and readily available?
- **b.** What are the guaranteed call-back and on-site response times?
- **c.** What is the escalation process to address complicated or lengthy repairs?

4. Can your organization support my laboratory's LC-MS/MS training and method implementation needs?

- **a.** What options are available for virtual, classroom and on-site training?
- **b.** Do you have experienced application specialists?
- **c.** What are your strategies for getting a laboratory into production quickly?

5. How would you describe your market presence in the MS/MS space?

- **a.** What is your experience and history manufacturing LC-MS/MS instrumentation?
- **b.** What are the key differentiators between you and your competitors?

6. How does your data processing software help me save time and be more efficient?

7. How would you describe your software's ease of use for beginners?

Laboratory preparations and considerations

Establishing your laboratory with the right equipment, design and personnel requires planning. The information in this section will help you determine where to put your instrument, the supplies you need and the personnel you will want to employ in your laboratory.

Laboratory design: instrument placement

Deciding where to install your new instrument in your laboratory space should be part of your implementation plan. It will help to ensure the successful delivery, installation and implementation of your instrument.

If you need guidance on the best location for your instrument, the following information may help:

- Review the site preparation guidance provided by your vendor to verify you have the proper infrastructure in place, including a power source, space, ventilation and temperature control.
- Assess the workflow and ease of access by staff when evaluating laboratory design.
- Review the dimensions of the product and packaging to help ensure the space is accessible for the equipment.
- Confirm that the location is appropriate for the size and weight of the instrument configuration.
- Plan space for the auxiliary items that will be used in your workflow (for example, a workstation, waste bottles, trays, rough pumps, nitrogen generators, dewars and sample preparation supplies).
- Consider service accessibility.

Laboratory preparations and considerations (cont.)

General laboratory supply items

Your laboratory needs the right supplies and auxiliary equipment for the installation, your workflows and routine maintenance. Make sure your facility is ready to go by having the right tools in place for the job, such as:

- Appropriate gas regulators or connections if you are using dewars for nitrogen gas needs
- Equipment and consumables for sample preparation, including:
  - **Pipettes**
  - Pipette tips
  - **Microcentrifuge vials**
  - Sample vials/plates
  - **Vortex**
  - **Centrifuge**
  - Appropriate solvent and sample storage
  - Laboratory safety equipment
- LC-MS/MS-compatible **reagents**, including:
  - Water
  - **Acetonitrile**
  - **Methanol**
  - **Isopropanol**
  - **Formic acid**
  - **Ammonium formate**

Note: This list is for informational purposes only and may not include all items needed for your intended use. For a full list of the items required for your laboratory, please consult your standard operating procedure (SOP).

Laboratory preparations and considerations (cont.)

Laboratory personnel

Staffing your laboratory with a knowledgeable team is one of the most important things you can do to help your operations and applications run smoothly and successfully. The staffing process and the types of employees required will vary depending on the needs of your laboratory. For example, it may be necessary to have multiple team members to effectively utilize your new LC-MS/MS system, such as:

- A technician (or technicians) and/or an LC-MS/MS specialist for sample preparation, data acquisition and processing
- A QA/QC manager to oversee the implementation of your quality management system
- Consultants to accelerate the implementation of your quality management system and your methods

SECTION 2:

Acquiring a mass spectrometer and navigating your support and IT needs

This section will lead you through the next step of your journey toward acquiring a mass spectrometer. It reviews various financial considerations and other factors related to instrument acquisition that should be included in your implementation plan, such as information technology (IT) requirements and support plans.

Financial analysis

While investing in a new instrument can increase the efficiency of a laboratory and improve its competitive positioning, cost can be a key determining factor. Below are acquisition pathways to consider during your decision-making process.

Capital budget

Capital budgets can be used for significant one-time expenses, such as a major equipment purchase (the acquisition of a mass spectrometer, for example). When considering the use of capital budget to purchase a mass spectrometer, your laboratory may want to look at the instrument's present net value, return on investment and payback period as part of the financial analysis.

Leasing

Leasing can help your laboratory reduce up-front costs by allowing payments over a designated period of time. Two common types of leases are an operating lease and a capital lease.

Operating lease

Under an operating lease, payments are considered operational expenses and there is no transfer of ownership. At the end of the lease, the lessee generally has the option to return the instrument, renew the lease at a discounted rate or purchase the instrument.

Your laboratory may want to consider an operating lease for the following reasons:

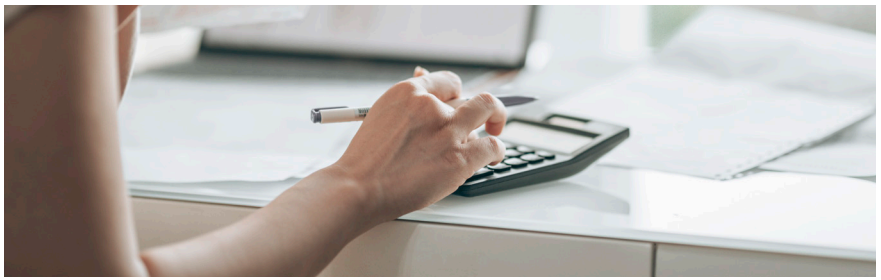
- To have the flexibility to obtain updated equipment
- To reduce the risk of the instrument becoming obsolete
- To simplify accounting

Capital lease

Unlike an operating lease, a capital lease is generally used to lease longer-term assets and give the lessee ownership rights. A capital lease (also known as a finance lease) is treated as an asset on a company's balance sheet and the respective value of the lease may be able to be depreciated over time.

Reasons to consider a capital lease include the following:

- Capital leases may recognize expenses sooner
- The lessee may be able to claim depreciation
- Interest costs may reduce taxable income



Financial analysis (cont.)

Grants

Grants can be instrumental in providing the necessary funds for your laboratory to pursue the resources it needs. They allow for exciting, groundbreaking research to happen where different fields, technologies and knowledge come together. SCIEX is committed to helping a laboratory achieve its research goals and make advancements in science.

Scan the QR code or **click here** for support and resources on grants

Understanding your return on investment

Return on investment (ROI) is used to determine the profitability associated with capital expenditure for your organization.

SCIEX offers an ROI calculator to help you explore the financial value a mass spectrometer can bring to your laboratory.

Scan the QR code or **click here** to utilize this helpful tool.

Understanding and implementing IT requirements for your system

Before purchasing an LC-MS/MS instrument, be sure to understand your IT requirements. This will help you determine if your network can accommodate the data you gather.

Here are some key terms to know when looking at IT requirements (please refer to the **appendix** for definitions of these terms):

- Licenses
  - **Perpetual license/node-locked**
  - **Subscription license**
  - **Concurrent license**
- PCs
  - **Acquisition PC**
  - **Processing PC**

Key considerations include:

- The number of acquisition and/or processing workstations and licenses needed
- If a network connection is required or desired
- The plan for any potential use of auxiliary software, such as Microsoft Office, a web browser and antivirus software
- The plan for data storage

Service and support: finding the right plan to fit your needs

When you invest in new equipment, you are creating a partnership with the manufacturer for your service and support needs. The right service provider will contribute to the success of your laboratory by helping to ensure your instruments are running at peak performance and by supporting your laboratory as it evolves and adapts to changing research needs.

Here are four key evaluation points to consider when selecting a service provider:

1. Engineer availability and expertise:

No one knows their instruments better than the company that made them. By choosing a service contract provided by the instrument manufacturer, you'll have access to factory-certified engineers who will deliver superior service to maintain instrument uptime. The number and location of engineers can give you confidence that issues will be addressed quickly.

2. Preventative maintenance:

One way to avoid downtime is to catch a problem before it happens. Manufacturers can support preventative maintenance requirements to help ensure that instruments are operational and meeting specifications.

3. Remote monitoring and diagnostic services:

To provide laboratories with help at a moment's notice, manufacturers can offer real-time alerts and remote troubleshooting. Continuous monitoring can immediately alert your laboratory if there is an issue so you can take action. Remote troubleshooting can allow the manufacturer to identify and potentially resolve any concerns, order parts in advance and decrease downtime.

4. Full inventory of quality parts:

If your instrument needs parts, you want to know that your manufacturer can help. The right service provider will have new, authentic parts that can help ensure the long-term quality and functionality of your instrument and support its full life cycle.

Scan the QR code or **click here** to learn about the service and support options available from SCIEX.

Training tailored to the needs of your laboratory

Personalized training and support from application scientists can help you save time on application development and implementation as well as give your users confidence in troubleshooting and maintenance. This benefits the laboratory by enabling you to obtain valid results faster and maximize instrument uptime, which together can lower the total cost of ownership of your instrument.

Scan the QR code or **click here** to view the training options available from SCIEX.

SECTION 3:

Getting started with SCIEX

Before you receive your new instrument, you need to know where to go to find resources and tools that can help you get the most out of it. This section explains how to access support from SCIEX that can help you meet your laboratory's needs.

SCIEX Now: one place for all your support needs

SCIEX Now is the single destination for answers to any questions related to LC and MS. It is designed to help you get the most out of your laboratory resources and assets. With SCIEX Now, you have access to personalized information and support whenever you need it.

The features available to you with SCIEX Now include the following:

- **Instrument management:** Create a custom profile to keep your instrument information organized and easily accessible.
- **Support cases:** Easily create and manage your support cases. Track the status of open cases and, with the click of a button, reply directly to the team with questions or comments. A history of past support tickets is available if you ever want to reference them.
- **Software management:** Effortlessly activate and manage software licenses linked to the registered instruments in your laboratory.
- **My learning hub:** Choose from a variety of courses, whether you are a beginner or an expert. Quickly find and access topics on instrumentation, software and workflows such as screening and quantification.
- **Resource section:** Quickly find answers to common questions. Save your favorite content for easy access and interact with other SCIEX users about applications and more. Browse the new and ever-growing library of SCIEX Now LC-MS/MS methods, which can be downloaded directly to your instrument for simple and rapid implementation in your system.
- **Marketplace:** Easily order parts and accessories.
- **Get help:** If you need to chat with a SCIEX specialist, help is just a click away with our chat feature.

To sign up for SCIEX Now and become a part of the SCIEX community, **click here** or scan the QR code.

Your account

- Manage your systems and software (registration required)

Support and training

- Submit a support request
- Live chat with experts
- Enroll in interactive courses
- Access SCIEX Now

Community

- Join our technical community for blogs and collaboration

Engaging with SCIEX

SCIEX offers a wide range of support to help laboratories get the most out of their instruments, including educational videos, blogs, application notes and training resources.

Access our LC-MS/MS 101 video series **here** or scan the QR code.

Scan the QR codes below to connect with SCIEX on social media and stay up to date on the latest events, activities and experiences happening in the industry.

LinkedIn

Twitter

FaceBook

Instagram

YouTube

Science is only a click away

SECTION 4:

Tools for building a site plan

Acquiring a new tool is an exciting time for a laboratory. Before your instrument arrives, your space must be set up correctly for a seamless installation. The information in this section will help you develop a site plan so that your laboratory is prepared to receive your new instrument.

Preparing your laboratory space

Site planning guides for your newly acquired instrument are available on the SCIEX website. These documents are comprehensive guides with detailed instructions for getting the facility ready, checklists to help ensure that you are prepared and details on the installation steps.

To access your site planning guide, **click here** or scan the QR code. Search for the specific instrument model to obtain the appropriate guide.

As you prepare your laboratory for your new instrument, keep in mind the following critical topics (note that these topics are also covered in the site planning guide):

- Proper electrical receptacles
- Correct gas requirements
- Working exhaust and ventilation
- A functioning workspace, including benches or tables for computers and LC-MS/MS systems
- An ample supply of required solvents and supplies
- A confirmed supply of properly stored standards

In addition to site planning, sharing site-specific information with your vendor will help enable a seamless installation and implementation of your instrument. Important topics to consider discussing with your vendor include:

- Restrictions or requirements for controlling visitor access to the laboratory
- Space availability to uncrate and unpackage your instrument
- Personnel availability to assist with uncrating and support installation needs
- A proper disposal process for packaging and solvents
- Access to a printer

SECTION 5:

Planning a strategy for a successful implementation

While choosing the right LC-MS/MS system for your laboratory is critical, a successful implementation plan is equally important. This section guides you through the development of a clear outline to help ensure a seamless implementation of your new instrument.

Developing your implementation plan

The following five initial steps will help you develop an implementation plan that is customized to the needs of your laboratory:

1. Understand and plan for accreditation and/or state licensure guidelines.

Laboratories that perform cannabis and hemp testing are generally required to obtain state and/or federal certification. Be sure to understand the regulations set in your region.

2. Finalize your testing needs.

The specific analytes may change, but in general, regulatory jurisdictions will require a full-service cannabis testing facility to have methods in place for potency, pesticides, mycotoxins, residual solvents and microbiology. Some regions (and many customers) also look for an analytical service provider that offers terpene quantification. Understanding your regulatory needs and the needs of your customer will allow you to proactively order all the assay consumables in advance to reduce method implementation delays and avoid wasting time.

3. Plan for staffing and training needs.

Employing a laboratory director and at least one technician can help get your laboratory up and running more quickly. If your laboratory purchased on-site support, work closely with your LC-MS/MS manufacturer to discuss your training needs and schedule the appropriate training. Your instrument vendor (or vendors) may also have other training materials available to help with onboarding new technical staff.

4. Establish a method validation plan.

Method validation should be performed on all test methods before offering a service to clients. Establishing a method development plan early, usually as part of your broader quality management system, can help expedite the validation process post-installation.

5. Plan for any computer-based information management system needs.

Often referred to as a laboratory information system (LIS) or a laboratory information management system (LIMS), this system is used to support workflows in the laboratory as well as act as a repository for storing laboratory results. To determine if this type of system is appropriate for your laboratory, evaluate your options and implement your choice of a software-based solution.

Post-installation service and support considerations

Once the installation of your new instrument is complete, you will want to think about how to keep your laboratory running at optimal performance. To maintain optimal performance of your LC-MS/MS system, evaluate the options that are available for employee training and hardware or software service and support..

Choosing the best service plan for your laboratory

No two service plans are alike. It is crucial to your laboratory's success to choose a plan that is best suited to your research needs. Here is what you will need to evaluate when looking at options for service offerings:

- Utilization of the instrument
- Number of instruments that need coverage
- Routine maintenance needs
- Length of service plan terms (single vs. multiyear)
- Yearly budget

Assessing support offerings

In addition, assess how the vendor will support your laboratory throughout your instrument's life cycle. Find out if they offer:

- Training and certification courses
- Remote troubleshooting
- A live call center
- Guaranteed response times

SECTION 6:

Appendix

A

Accurate mass: the measured mass of an ion of specified isotopic composition, which is calculated by summation of the exact masses of the constituent atoms

Acetonitrile (ACN): a chemical compound that is a clear liquid and is used as a polar aprotic solvent

Acquisition PC: a PC that is connected to the LC-MS/MS instrument; controls the instrument, enables it to run the selected tests and can conduct data processing

Ammonium formate: a colorless, crystalline solid with the formula NH_4HCO_2

Analyte: component of a sample being analyzed; typically, a specific chemical compound

Assay: an analysis performed to determine the presence of a substance or the amount of that substance

Appendix

C

Centrifuge: processing technique used to separate heterogenous mixtures into their components

Concurrent license: allows users to share a single software license with colleagues over their network

D

Detector: the final element of the mass spectrometer; records either the charge induced or the current produced when an ion passes by or hits a surface

F

Formic acid: an acid with the formula H_2CO_2; the simplest carboxylic acid

G

Gas chromatography mass spectrometry (GC-MS): a technique where a gas chromatograph is coupled with a mass spectrometer to separate, identify and quantify analytes in a sample

I

Ion ratio: determined when at least two multiple reaction monitoring (MRM) transitions from a single analyte have been collected into a group; calculated by taking the peak area or height of the qualifier ion transition and dividing it by the peak area or height of the quantifier ion transition

Ion source: region in the mass spectrometer where gas-phase ions are produced

Isopropanol (IPA): a colorless, flammable chemical compound

Appendix

L

Laboratory information system (LIS): a software-based solution with features that support a laboratory's operations, including workflow and data tracking and a data exchange interface; also referred to as a laboratory information management system (LIS)

Laboratory information management system (LIMS): a software-based solution with features that support a laboratory's operations, including workflow and data tracking and a data exchange interface; also referred to as a laboratory information system (LIMS)

Liquid chromatography (LC): an analytical technique used to separate ions or molecules dissolved in a solvent

Liquid chromatography tandem mass spectrometry (LC-MS/MS): a technique in which a mixture of analytes is separated into individual components by liquid chromatography followed by detection with tandem mass spectrometry capabilities; traditionally designates a triple quadrupole mass spectrometer

Lower limits of quantification (LLOQs): the lowest amount of an analyte in a sample that can be quantitatively determined with precision

M

Mass analyzer: the section of the mass spectrometer in which ions (formed in the source) are differentiated based on their mass-to-charge (m/z) ratios

Mass-to-charge ratio (m/z): a dimensionless quantity formed by dividing the ratio of the mass of an ion by its charge state

Mass spectrometer: an instrument capable of detecting molecular ions and ions formed by fragmentation of heterocycles, regardless of the amounts present

Mass spectrometry (MS): the study of matter through the formation of gas-phase ions that are characterized by their mass, charge, structure and/or chemical properties using mass spectrometers

Methanol: a chemical also known as methyl alcohol or methyl hydrate with the formula CH_3OH

Appendix

M (cont.)

Microcentrifuge vials: tubes made from polypropylene resin for easy viewing of contents

Multiple reaction monitoring (MRM): a technique that selectively quantifies compounds within complex mixtures, where data acquired from one or more specific product ions corresponding to selected precursor ions are recorded via two mass analyzer stages

N

Nominal mass: the mass of a molecule calculated using the isotope mass of the most abundant constituent element isotope of each element, rounded to the nearest integer value and multiplied by the number of atoms of each element

P

Perpetual license/ node-locked: a license that gives the customer the right to use the software permanently and perpetually at the version that was purchased

Pipette: a laboratory supply used to transfer and/or measure specific amounts of liquid

Processing PC: a PC that is designed to process the data collected from the LC-MS/MS instrument; can be a computer that is not connected to the instrument

Appendix

Q

QTRAP system: a hybrid triple quadrupole linear ion trap spectrometer that combines multiple reaction monitoring (MRM) scan mode with ion trap scanning to offer unique scan functions beyond traditional MRM mode

Quadrupole: mass analyzers made up of four parallel rods configured with an electric charge or current

Qualitative analysis: analysis used to identify a target or unknown compound

Quantitative analysis: analysis used to determine the concentration of a specific substance in a sample

R

Reagent: a compound or substance added to a system to facilitate a chemical reaction

S

Selected ion monitoring (SIM): operation of a mass spectrometer in which the abundances of ions of one or more specific *m/z* values are recorded rather than the entire mass spectrum

Signal to noise (S/N): a measurement used to compare levels of a signal to a level of background noise

Standards: materials containing a known substance for use in analysis; provides a reference to help determine identification and/or unknown concentrations

Subscription license: a license that gives the customer the right to use the software for the duration of the subscription; the software automatically expires at the end of the subscription period

V

Vortex: mixer used in a laboratory to mix small vials of liquid

Contents

SCIEX