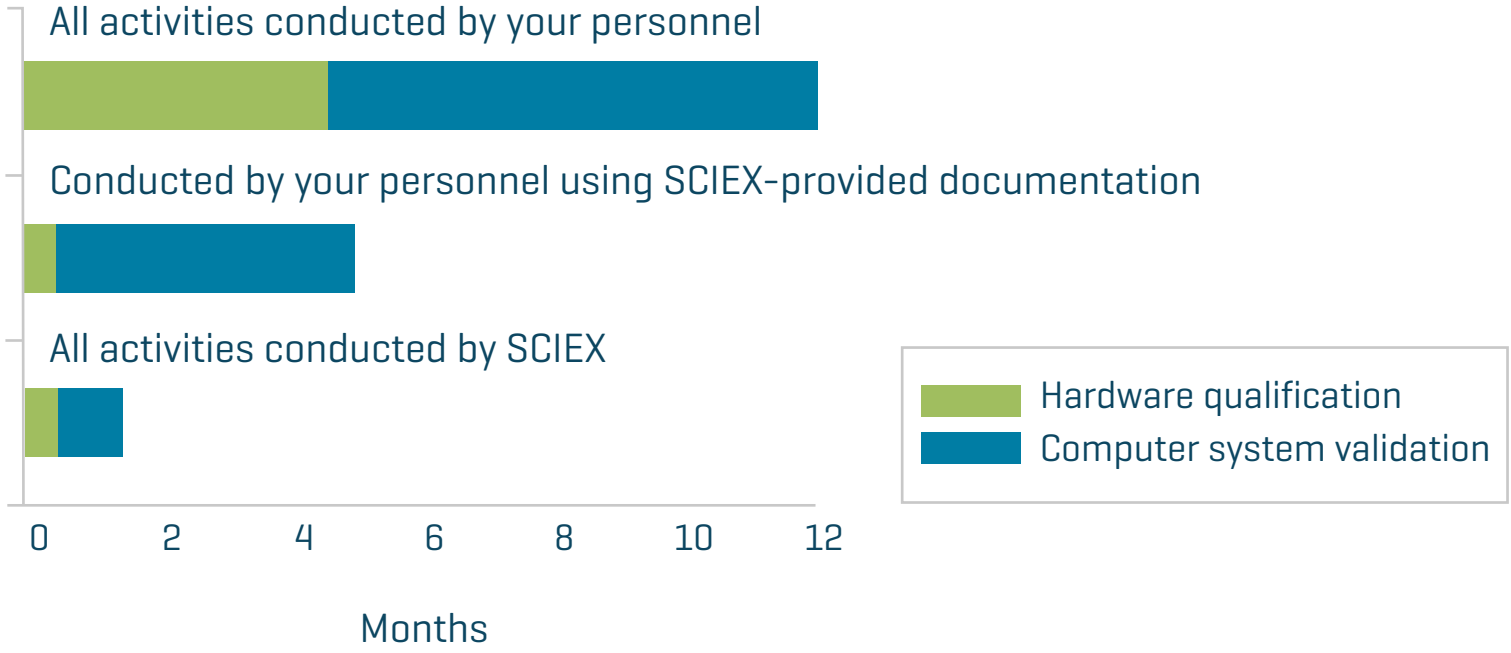
Regulated laboratory solutions

- 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:

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- 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:
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- What auditors focus on (software/hardware/documentation)
- The most commonly identified instances of non-compliance

Watch webinar >

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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