

# Re-Qualification-OQ/IPV Services for AB SCIEX Triple Quadrupole Mass Spectrometers

No one understands your AB SCIEX instruments better than the people who design, develop, and support them. When you use AB SCIEX Qualification Services, AB SCIEX trained and certified engineers will help you through your Operational Qualification/Instrument Performance Verification (OQ/IPV) as part of your overall system validation.



## HELP ENSURE INSTRUMENT ACCURACY AND REDUCE YOUR RISK

In regulated industries, compliance with government and international standards requires documented verification that your instruments are installed and functioning according to their operational specifications. The process can be complex, time-consuming, and costly.

The AB SCIEX Operational Qualification/Instrument Performance Verification (OQ/IPV) Service verifies and records the instrument's ability to meet specified performance criteria after installation, repetitive use, or major service events. The Re-Qualification-OQ/IPV service involves comprehensive testing of the complete system using established conditions and known sample characteristics.

We help confirm that the instrument hardware, firmware, and software revisions meet AB SCIEX tested and approved compatibility requirements.

A key benefit to the Re-Qualification-OQ/IPV service is to ensure the accuracy and precision of the instrument and to uncover potential problems. It is important to have your instruments checked and formally tested regularly to confirm continued high-quality performance and identify possible impact due to normal wear or inadequate user maintenance.

## OQ/IPV RECOMMENDATIONS

To help maximize the effectiveness of your Re-Qualification-OQ/IPV service, we recommend you do the following prior to the service:

- Review and approve the procedures in accordance with your organizational requirements
- Verify that the site requirements as outlined in the system site preparation guide are met or continue to be met
- Check that the AB SCIEX software that will be used to calculate results for the OQ/IPV test procedures is qualified according to your documented standard of operation
- For instruments that require a routine planned maintenance (PM) procedure, it is advisable to complete the PM immediately before a periodic OQ/IPV to ensure instrument maintenance is up to date

## SUPPORTED AB SCIEX TRIPLE QUADRUPOLE MASS SPECTROMETERS

We offer OQ/IPV services for the following triple quadrupole mass spectrometers:

- AB SCIEX TripleTOF™ 5600 System
- AB SCIEX Triple Quad™ 5500 System
- API 5000™ LC/MS/MS System
- API 4000™ LC/MS/MS System
- API 3200™ LC/MS/MS System
- API 3000™ LC/MS/MS System
- API 2000™ LC/MS/MS System
- API 300™ LC/MS/MS System
- API 365™ LC/MS/MS System
- API 150™ EX LC/MS System

## OQ/IPV TESTS

AB SCIEX engineers have unmatched experience and knowledge of our instruments and systems. To ensure linearity, sensitivity, and accurate performance, our comprehensive OQ/IPV service tests include the following:

- Quadrupole-mode operation for sensitivity, resolution, and extended mass range resolution in both positive and negative ion modes. Note that the masses tested for each API instrument are based on the mass range specification for the instrument.
- Tandem MS mode (MS/MS) for sensitivity
- Ion source purchased with the system (plus optional specified sources)

## RECOMMENDED TIMES FOR OQ/IPV

To help ensure optimal performance of your systems and to support compliance, we recommend that you have a Re-Qualification-OQ/IPV service performed at the following times:

- At instrument installation
- On a periodic basis in accordance with your standard operating procedures (SOPs)
- After a major repair such as: replacement of a quadrupole or other hardware/electrical component critical to the performance of the system, or performance of any service procedure that the AB SCIEX certified field service engineer deems is critical to the performance of the system
- After relocating an instrument to another laboratory
- After functionality is added to the system, such as a hardware or software upgrade
- After any software change that affects system security, data integrity or administrative controls

- Before a previously installed system will be used in a regulated test environment for the first time (e.g. an instrument used for basic research transitions for use in clinical trials research)

The OQ/IPV service is performed by an AB SCIEX certified field service engineer and includes recorded evidence that the system meets specified performance criteria using certified service tools, traceable and revision controlled test procedures, and certified chemical test kits. Travel and labor of the AB SCIEX field service engineer is also included.

## CONTACT US

To help you manage your compliance risk and your annual budget, we offer the AB SCIEX Re-Qualification-OQ/IPV Service as part of our comprehensive AB SCIEX Complete Service Plan. Our OQ/IPV services are also available on an à la carte basis to allow you to supplement in-house capabilities based on your laboratory needs and budget.

For more information on AB SCIEX Compliance Services, contact your local AB SCIEX Sales representative or email: [complianceservices@absciex.com](mailto:complianceservices@absciex.com)

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### Headquarters

110 Marsh Drive | Foster City CA 94404 USA  
Phone 650-627-2600  
[www.absciex.com](http://www.absciex.com)

### International Sales

For our office locations please call the division headquarters or refer to our website at [www.absciex.com/offices](http://www.absciex.com/offices)