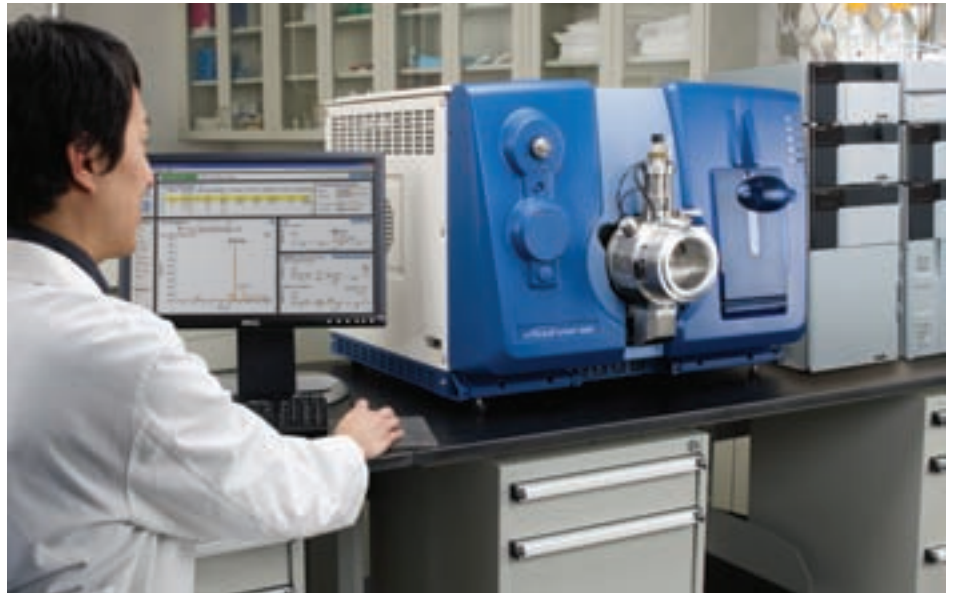


Re-Qualification-OQ/IPV Service for Shimadzu Series HPLC Systems

When you face the challenges of regulatory compliance, you need experienced support at your side. When you use our Qualification Service, 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.

Our 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.

This service ensures the accuracy and precision of the HPLC and uncovers potential problems. It is important to have both your HPLC and mass

spectrometer qualified (IQ/OQ) and requalified (OQ/IPV) regularly to confirm continued high-quality performance and identify possible impact due to normal wear or inadequate user maintenance.

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

HPLC/MS SYSTEM PERFORMANCE VERIFICATION

A key benefit of this AB SCIEX Re-Qualification-OQ/IPV service is the testing of both the HPLC and mass spectrometer system after all HPLC and the mass spectrometer has been qualified. Using established conditions and known sample characteristics, this serves as a generic performance qualification. Unlike competitive Re-Qualification-OQ/IPV services,

our procedures are executed using Analyst® Software.

OQ/IPV RECOMMENDATIONS

To help maximize the effectiveness of your Re-Qualification-OQ/IPV, 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 mass spectrometer attached to the HPLC is recently re-qualified
- Check that the AB SCIEX software that will be used to calculate results for the OQ/IPV test procedures is qualified according to your SOP
- Check that the Shimadzu software is qualified according to your SOP
- For instruments that require a planned maintenance (PM), it is advisable to complete the PM immediately before a periodic OQ/IPV to ensure instrument functionality is up to date

SUPPORTED HARDWARE

We offer Re-Qualification-OQ/IPV services for the following components:

- Pump (LC-20 AB/AD/AT/ xr)
- Degasser (DGA-A₃/A₃)
- UV-VIS Detectors (SPD-20A/AC/AV)
- Autosampler (SIL - 20A/AC/AHT/AHCT/A xr)
- Column oven (CTO-20A/AC)
- Photo diode array detector (SPD-M20A)
- CTC Analytics sample system

OQ/IPV Tests

Depending on your configuration, our comprehensive Re-Qualification-OQ/IPV service tests include the following:

- Pump flow reproducibility/accuracy test
- Autosampler linearity test
- Autosampler carryover test
- Autosampler temperature accuracy test
- UV detector wavelength accuracy test
- UV detector noise and drift test
- UV detector linearity test
- Pump gradient composition test
- Rack Changer temperature accuracy test
- Thermostatted column compartment temperature accuracy test
- LC/MS/MS system performance verification linearity and precision test

RECOMMENDED TIMES FOR OQ/IPV

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

- At instrument installation
- On a periodic basis in accordance with your SOPs
- After a major repair on one of the following device sub-systems:
 - > Pump head assembly
 - > Autosampler assembly
 - > Gradient proportion valve
 - > UV detector optical assembly
 - > Device main board replacement
 - > Resident or specific firmware upgrades

- When a device fails a test and calibration does not resolve the issue
- After Preventative Maintenance
- After relocating an instrument to another laboratory
- After functionality is added to the system, such as a hardware or software upgrade
- Before a previously-installed system is used in a regulated environment for the first time (e.g. instrument used for basic research transitions to clinical trials research)

The Re-Qualification-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

We offer our AB SCIEX OQ/IPV services as part of our comprehensive AB SCIEX Complete Service Plan on an à la carte basis to allow in you to supplement in-house abilities 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

AB SCIEX makes no representation whatsoever that the IQOQ or IPV Services satisfy or will satisfy any requirements of any governmental body or other organization, including, but not limited to, any requirement of the United States Food and Drug Administration or the International Organization for Standardization. The instrument owner agrees that it is the instrument owner's responsibility to ensure that the IQOQ and IPV services are adequate to meet its regulation/certification requirements. All requirements of any governmental body or other organization, including, but not limited to, any requirement of the United States Food and Drug Administration or the International Organization for Standardization are the responsibility of the instrument's owner.

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0705510-01 01/2011



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