



Ensure ongoing compliance for your Molecular Devices microplate readers

Be audit-ready with our comprehensive digital IQ/OQ/PM services

Qualifying your Molecular Devices® microplate readers in GLP or GMP environments can now be done with greater reliability, security, and convenience. Presenting Compliance Assurance Digital IQ/OQ/PM Services, a unique qualification solution that preserves the documentation of legacy services in a digital and compliant format that can be accessed remotely.

NEW UV OQ SERVICE

Ask about our enhanced qualification capabilities that now cover UV wavelengths from 220 nm to 350 nm. The service validates and confirms:

- Photometric accuracy, precision and linearity
- Wavelength accuracy
- Stray light

| | | | |
|---|---|---|---|
| Validation HO Cuvette Certification Date: | | 11-Apr-2014 | |
| Certificate of Calibration Number: | | XXXX | |
| UV Test Results | | | |
| Test Description | Test Specification | Test Results - Plate Passes/Fails/NA | Test Results - Cuvette Passes/Fails/NA |
| Photometric Accuracy | Average OD = Certificate Value +/- (.01*Certificate Value)+.003 | PASSES | PASSES |
| Photometric Precision | Average OD = Certificate Value +/- (.01*Certificate Value)+.003 | PASSES | PASSES |
| Photometric Linearity | Average OD = Certificate Value +/- (.01*Certificate Value)+.003 in the standard range of PD20 to PD 100 | PASSES | PASSES |
| Wavelength Accuracy | Measured Peak = Certificate Peak +/- 1 nm | PASSES | PASSES |
| Stray Light at 220nm | Minimum OD >= 2.5 | PASSES | PASSES |

Compliance Assurance Instrument Qualification

During each onsite Qualification, a trained Molecular Devices Service Engineer verifies and digitally documents instrument operation in accordance with IQ/OQ specifications. All qualification and preventive maintenance protocols are automated to expedite each service, while maintaining the integrity of your data and analysis results.

The service includes:

Installation Qualification (IQ) verifies and documents that all necessary components required for operation are received and properly installed in accordance with Molecular Devices' ISO 17025 certification requirements.

Operational Qualification (OQ) tests the mechanical, electrical, and optical components of each instrument to verify proper operating functions in accordance with manufacturer specifications.

Preventive Maintenance (PM) verifies each instrument meets operational specifications through comprehensive, multipoint inspection. Potential issues are proactively addressed, ensuring each instrument is maintained at optimal operational performance.

Certified Molecular Devices Service Engineers perform all onsite instrument services for superior quality assurance and optimized operational performance.

Assured audit readiness

Upon service completion, a comprehensive digital or printed report is generated onsite to ensure you are audit-ready. Each report can be customized to your company's workflow and contains:

- Qualification results
- Instrument service report
- Validation plate calibration certificate
- Validation certificate
- Training certificate for your specific Service Engineer

All qualification and preventive maintenance protocols performed under our Compliance Assurance Digital Services adhere to USP<1058> Analytical Instrument Qualification (AIQ) guidelines. The final, all-inclusive report contains all the necessary validation certificates to robustly support audits, and features:

- eSignature that meets SAFE-BioPharma standards
- Date and time stamp
- Pre-validated calculations to comply with US Pharmacopeia guidelines

Digital reports are securely stored in a central location and can be accessed remotely to ensure you have the necessary documentation at your fingertips to support auditors.



KEY FEATURES

- Conforms to US and EU Pharmacopeia guidelines
- Secure archiving of IQ/OQ report in digital format for on-demand access
- Electronic signature with date/time stamp for compliance assurance
- Automated validated calculations for accurate and faster results

Partnering with you for your success

For more information about our Service Plans, Value-Added Services and Support, visit www.moleculardevices.com/Support. Or contact Molecular Devices to get started on adding a whole new level of confidence and security to your laboratory.

| | USA/CANADA | EUROPE |
|---------------------------------------|--|--|
| COMPLIANCE ASSURANCE INQUIRIES | | |
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delivering technology

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