



# Ensure ongoing compliance for your CloneSelect™ Imager

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

Qualifying your Molecular Devices® CloneSelect Imager 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.



## Compliance Assurance Instrument Qualification

During each on-site 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' 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.

5. Computer (Select NA if no test s required).			Yes
Test #	Test Description	Test Specifier	Observed Results
1	Check desktop has either MolDev logo or standard Windows background.	Desktop has either logo or standard Windows background.	PASSES
2	Check the Windows start up and shutdown is functional.	Windows start up and shutdown is functional.	PASSES
3	Deactivate all screensavers – set to none.	All screensavers are deactivated.	PASSES
4	Turn off Power management.	Power management is turned off.	PASSES
5	Install if required, all relevant PDF manuals for the installed version of software.	All relevant PDF manuals for the installed version of software.	PASSES
6	Check Adobe reader is installed.	Adobe reader is installed.	PASSES
7	Backup .fcb file : Start> All Programs> MolDev> CloneSelect Imager> Configuration Manager	Backup .fcb file can be accessed.	PASSES
8	Backup .fcb file to computer.	.fcb file backed up to computer.	PASSES
9	Empty the Recycle bin.	Recycle bin emptied.	PASSES

## 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

## Assured audit readiness

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

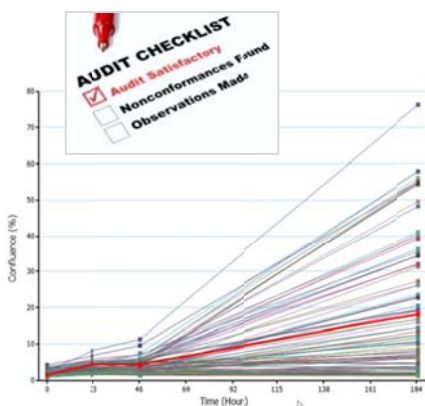
- Qualification results
- Instrument service report
- CSI Reference Plate certificate of compliance
- Validation certificate
- Training certificate for your specific Service Engineer



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.



## Partnering with you for your success

For more information about our Service Plans, Value-Added Services and Support, and our Exclusive Service Plan discounts, visit [www.moleculardevices.com/Support](http://www.moleculardevices.com/Support). Or contact your Molecular Devices sales representative to get started on adding a whole new level of confidence and security to your laboratory.

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