SoftMax Pro Validation for Life Sciences Organizations

CASE STUDY

PROJECT AT A GLANCE

Business Sector:
- Pharmaceutical
- R&D
- Biotechnology
- Clinical

Informatics Systems:
- Molecular Devices SoftMax Pro

Service Offering:
- Validation

Elements:
- 100+ Projects

CSols Inc. has partnered with Molecular Devices to validate their SoftMax Pro microplate reader software. SoftMax Pro is the primary software for microplate reader control and data analysis. Microplate readers measure multiple biological and chemical reactions simultaneously.

The software can import raw data in microplate format that has been acquired from any scientific instrument, not just microplate readers. In this way, SoftMax Pro becomes an informatics system, much like a chromatography data system. Additionally, SoftMax Pro can be integrated with Laboratory Information Management Systems (LIMS) and other scientific data platforms to streamline data management and workflows.

SoftMax Pro is primarily used by laboratories in the pharmaceutical, biotechnology, academic research, and clinical diagnostic industries, and requires validation on first installation and then periodic revalidation, specifically for:

- integration with other laboratory informatics systems
- software updates, reconfiguration, or upgrades
- changes to associated hardware or standard operating procedures (SOPs)
- regulatory changes
- scheduled maintenance and calibration as part of a quality assurance program

This document summarizes many examples of the work CSols has done for Molecular Devices, covering the value that CSols can bring to this validation process.

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Objectives & Challenges

TValidated software is critical to data integrity and to compliant operations in life sciences businesses. Molecular Devices experiences a high volume of validation and software upgrade requests for their SoftMax Pro software. Additional resources are required to provide their clients with timely service when executing the software validation requests. Molecular Devices knew the validation experts at CSols could fill gaps for them and their clients, and so they contracted CSols to provide this validation support. Client engagements can vary from one day to a couple of weeks, depending on the number of instruments and client workstations involved.

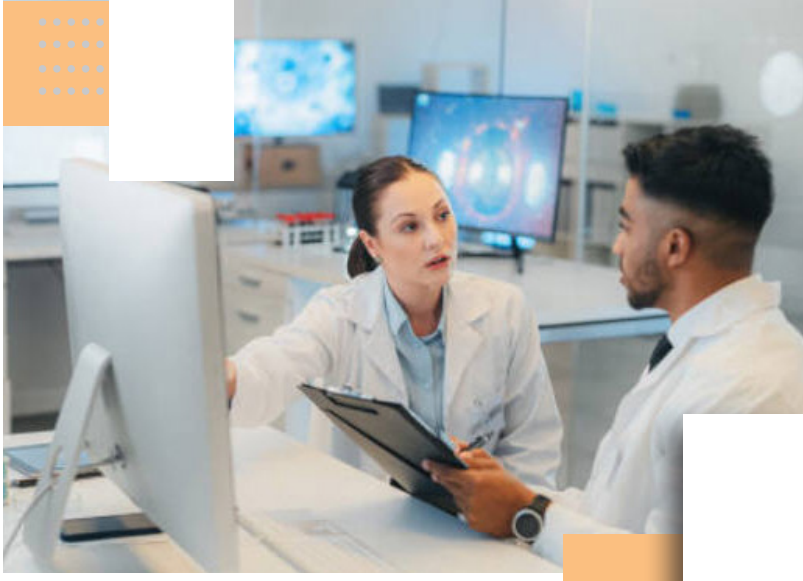
SoftMax Pro is configured to perform complex calculations and data analysis. The software allows various user-defined workflows and calculations. This flexibility, although beneficial to the users, can complicate its validation, as it necessitates testing each function thoroughly and documenting the results.

The assays that the microplate readers perform are also diverse, which can complicate the establishment of validation criteria. The validation test plans, test results, and any deviations or corrective actions taken must be meticulously documented and acted upon so that the validation work can stand up to a regulatory audit.

CSols' Role in the Solution

The validation experts at CSols provide installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) for the SoftMax Pro software. These qualification steps ensure that the software is validated under 21 CFR Part 11 and GAMP 5 and that it is fit for its intended use.

In addition, because the CSols validation experts have deep knowledge of all aspects of laboratory informatics, they are often able to suggest



enhancements to the client's broader systems while they are working with SoftMax Pro. For one client, CSols has integrated STARLIMS with SoftMax Pro using data parsing automation. This greatly reduced manual transcription errors and accelerated the result turnaround times.

Benefits

Users of SoftMax Pro benefit by having their software validated by outside experts from CSols.

- The gains in regulatory compliance, data reliability, efficiency, risk mitigation, and confidence in their results pay dividends for our clients.
- As a neutral third party, CSols can provide expert advice that benefits the client without the perception of bias.
- Because the CSols validation experts are so experienced and knowledgeable about laboratory informatics software, instrument integrations, and data integrity, they are quick to identify and act on deviations to eliminate risks that may be questioned in a regulatory audit.

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