

# Ensure data integrity, compliance, and audit readiness – in line with the latest FDA Guidance

SoftMax® Pro GxP Software is the latest, most secure software to help you achieve full FDA 21 CFR Part 11 compliance with streamlined workflows to ensure data integrity. Every step is optimized to simplify analysis and reporting.

Our expert team will partner with you to support your GMP/GLP regulated work.

## Benefits across your organization



### IT

- Compatible with Windows Active Directory (server)
- Single portal for user admin, including:
  - Creating project folders with custom permissions
  - Enterprise-level document sharing
- Data generated in a software validated for Windows 10/11



### **Quality assurance and compliance**

- System audit trail tracks and records all user actions in the database
- Document audit trail tracks and records all user actions in the SMP data document
- Enforces e-signature at each stage of the document workflow
- Features a new historical raw data feature that tracks overwritten data
- · Improved auto-save functionality
- Ensures that the most up-to-date protocols are always in use



### **Scientist**

- Easy to use, protocol-based software for reproducible results
- Powerful data analysis options to create or import validated protocols from collaborators
- Each user only sees the functions they are permitted
- Reassurance you are using the most published microplate reader control and data analysis software in a regulated, secure environment
- Technical Support

Failure to meet the 2016 update to FDA Guidance may impact your ability to pass External or Customer audits.

Are you or your QA Manager looking for improvements in your current microplate validation or data management system?

Contact us today to learn how we can help!

Contact Us

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