MOLECULAR DEVICES

PURCHASE GUIDE

Compliance that scales with your laboratory

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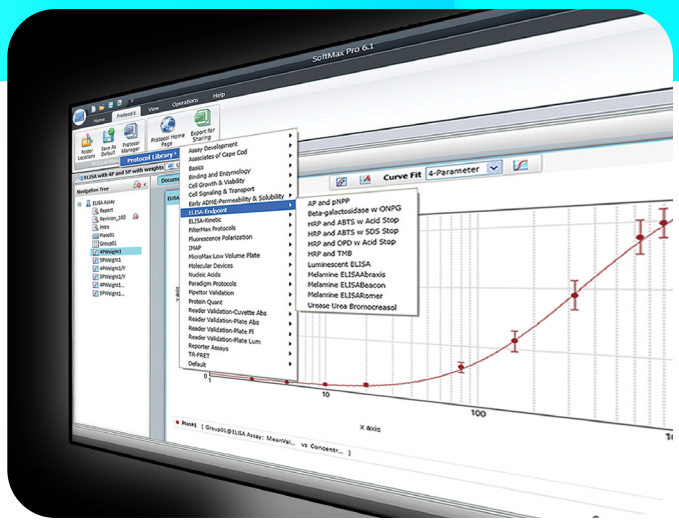
SoftMax Pro GxP Software Suite provides a right-sized compliance approach that allows laboratories to implement the controls they need today while maintaining a path to GMP-ready workflows tomorrow.

Most laboratories do not start with full GMP requirements. They typically begin in discovery or development, where scientific flexibility is critical, then gradually add controls as products move toward clinical development, QC release testing, and commercial manufacturing.



The GLP → GMP journey

A common misconception is that laboratories must replace their software as they transition into more highly regulated environments. In reality, growth from research and discovery through development, validation, and commercialization can be supported on a single, scalable platform.

SoftMax Pro GxP was designed to accompany laboratories throughout this journey, enabling organizations to progressively strengthen compliance controls as regulatory expectations increase. Rather than implementing a new software system at each stage of growth, laboratories can continue using the same trusted SoftMax Pro platform while adding the governance, data integrity, security, and audit capabilities required for GMP operations.

This approach minimizes disruption, preserves user familiarity, reduces validation effort, and provides a clear path from GLP and research workflows to GMP-compliant manufacturing and quality control environments.

Example transition

Year 1
Discovery

A startup biotech purchases:

- SoftMax Pro GLP Edition
- Single Computer deployment
- One SpectraMax reader
- Three users

Primary focus:

- Assay development
- Scientific productivity
- Data traceability

Year 3
Clinical development

The company now has:

- Multiple scientists
- Multiple instruments
- QA oversight
- Stability studies

The laboratory upgrades to:

- Multi-computer deployment
- Centralized SQL database
- Additional user licenses

Primary focus:

- Cross-team collaboration
- Centralized administration
- Inspection readiness

Year 5
Commercial GMP operations

The company now:

- Manufactures a commercial product
- Performs release testing
- Supports regulatory inspections

The laboratory transitions to:

- Controlled review workflows
- Electronic approvals
- Segregation of duties
- Expanded governance controls

Primary focus:

- Regulatory defensibility
- Data integrity
- Audit readiness
- Controlled record lifecycle

Which solution is right for you?

Discovery and early development

At this stage, scientists are still developing assays, optimizing methods, and generating proof-of-concept data. Workflows are exploratory and frequently change.

Typical laboratory examples:

Biotech startup

- Developing a new antibody therapeutic
- Running cell viability and potency assays
- Methods change as scientists optimize protocols
- Team consists of 2–10 researchers

Academic core laboratory

- Shared plate reader supporting multiple research groups
- Data integrity and reproducibility are important
- Formal GMP controls are unnecessary

Preclinical research group

- Performing PK, biomarker, or toxicology studies
- Requires traceability and secure records
- Does not require formal batch release workflows

Why SoftMax Pro GxP – GLP Mode fits:

- Supports electronic records, audit trails, and electronic signature/statements
- Enables scientific flexibility without introducing unnecessary workflow approvals
- Reduces reliance on spreadsheets and manual documentation
- Creates the foundation for future regulatory compliance
- Lower administrative burden and simpler deployment than full GMP workflows

What success looks like:

Scientists can:

- Develop and modify assays rapidly
- Maintain traceability of experiments
- Preserve data integrity
- Prepare for future regulatory needs without slowing innovation

Process development and QC readiness

As programs mature, laboratories begin generating data that supports regulatory submissions, process characterization, stability studies, and release testing.

Typical laboratory examples:

Late-stage biotech company

- Preparing for Phase III or BLA submission
- Assay methods are largely locked
- QA reviewers must independently review results

Cell & gene therapy manufacturer

- Using plate reader assays within manufacturing support workflows
- Requires formal review and approval processes
- Data may be used for product disposition decisions

CDMO quality control laboratory

- Performing release and stability testing
- Supporting multiple customer programs
- Must demonstrate inspection readiness

Why SoftMax Pro GXP – GxP Mode fits:

- Formal review and approval workflows
- Controlled document lifecycle management
- Expanded user permissions and segregation of duties
- Enhanced governance for regulated data
- Improved inspection readiness

What success looks like:

QA can easily answer:

- Who created the record?
- Who reviewed it?
- Who approved it?
- What changed?
- When did it change?
- Why was it changed?

Without reconstructing information from spreadsheets, paper records, and emails.

Imaging laboratories

Imaging laboratories often require compliance controls earlier because they generate much more than a final numeric result. In addition to assay results, regulated imaging workflows may include:

- Raw images
- Metadata
- Derived calculations
- Review records
- Analysis settings
- Acquisition parameters
- Audit trails
- Approval records

These records must remain linked throughout the record lifecycle.

Typical laboratory examples:

Cell therapy development lab

- Cell counting and viability assays
- Confluency measurements
- Longitudinal cell-growth studies

Biopharma QC laboratory

- Imaging-based potency testing
- Marker expression analysis
- Stability studies

GMP manufacturing support lab

- Regulated image-derived release testing
- Long-term retention requirements
- Data integrity inspections

Why SoftMax Pro GXP Imaging Edition fits:

- Imaging and analysis in a single controlled environment
- Traceability from image acquisition through approval
- Centralized management of image-derived records
- Audit trails that capture scientific context
- Scales from R&D imaging workflows to regulated GMP processes

What success looks like:

Scientists, QA reviewers, and IT administrators can confidently answer:

- Where did this image originate?
- Which acquisition settings were used?
- Which analysis method generated the reported result?
- Who reviewed the data?
- Who approved the record?
- What changes occurred during the experiment lifecycle?
- Can every reported result be traced back to the original image and associated metadata?

Without searching across multiple file shares, image repositories, spreadsheets, analysis applications, or paper records.

Regulatory compliance mapping to GxP Admin capability

The GxP Admin Portal and SoftMax Pro GxP Software Suite provide controls that support compliance with applicable requirements of 21 CFR Part 11 and related data integrity expectations.

Regulatory requirement	GxP Admin Portal capability
§11.10 (a) – Systems/ Software Qualification	• Installation Qualification – SoftMax Pro GxP Software Suite • Operational Qualification – Admin Portal functionality • Performance Qualification – SoftMax Pro functionality
§11.10 (b) – Accurate and Complete Copies of Records	• Proprietary File Formats: (*.sdax)(*.sprx) • Exportable to formats: (*.pdf)(*.txt)(*.xls)(*xml) • Convertible (from GxP to Standard) via export: (*.sda)(*.spr) • Auto export and auto save capabilities
§11.10 (c) – Protection of Electronic Records	• Controlled document and experiment storage model with managed save states • Prevents modification or overwrite of approved or signed records • Records remain human-readable and exportable throughout the retention period • Associated audit trails remain linked and retrievable with the electronic record

§11.10 (d) – System Access Controls
§11.10 (g) – Authority Checks
	• Enforces **unique user accounts** (Active Directory integration available in Multi Computer deployments).
	• **Role based permissions** controlled at the project level
	  • GxP & GLP Modes: Acquisition & Analysis; Statements & Signatures; Document/Folder Management
	  • GxP Mode only: Additional controls for Document Access/Workflow; Instrument permissions
	• Centralized management of users, groups, roles, and permissions
	  • Manage Users into Groups
	  • Manage Permissions into Roles
	  • Assign User/Groups with Roles
	  • Assign/User/Groups to Projects with Roles
	• Administrative actions are segregated via the **Admin Portal**, creating a clean separation of duties.
	• Generic or shared accounts are explicitly prevented.

§11.10 (e) – Audit Trails	• Admin Portal Audit Events: System; Instrument; Admin; User; Project • SoftMax Pro GxP Audit Events: Acquisition; Analysis; Experiment; Document
§11.10 (f) – Operational System Checks	• Supports structured, paperless workflows within controlled projects • GxP Mode provides controlled document release workflows with pre-release and post-release review, statement, and signature controls

Regulatory requirement	GxP Admin Portal capability
§11.50 (a) – Electronic Signature Manifestations	• Explicitly binds signer name, signing timestamp, and signature meaning to the executed record and ensures the information is present in both on screen and printed outputs. • GXP Mode only: Signature meaning is enforced via document state (pre release/ release) and role logic rather than free text
§11.70 – Signature/ Record Linking	• Electronic signatures are permanently bound to the regulated record • Changes to methods, parameters, calculations, or results invalidate existing signatures and require re-signing • Signatures cannot be exported or reused independently from their associated record
§11.200 – Electronic Signature Components and Controls	• Supports two-component authentication through username and password credentials • Requires credential re-entry at the time of signature execution • Credentials are role-controlled and non-transferable
§11.300 – Electronic Signature and Account Security Controls	• Enforces **unique credentials** (local or Active Directory). • Password complexity, aging, expiration, and reuse are centrally configurable. • Automatic account **lockout** after configurable failed attempts. • User provisioning and deprovisioning activities are fully auditable

Administrative Reporting	• Supports periodic review and reporting of system activity, including:
	  • Username and full name;
	  • Contact information;
	  • Account status and creation date;
	  • Application Access rights;
	  • Assigned Projects, Groups, Roles, and Permissions;
	  • Last login date and associated computer name

SoftMax Pro Imaging Edition Support	• Available for configured MiniMax imaging workflows. • Supports controlled image acquisition, image analysis, metadata, audit trail review, document workflow controls, and electronic signature functionality for regulated imaging records.

Quick decision guide

Choose GLP Mode
when scientific flexibility is your primary requirement.

Choose GXP Mode
when review, approval, and regulatory defensibility become business-critical.

Choose Imaging Edition
whenever image acquisition, image analysis, and image-derived records are part of your regulated workflow.

While both GxP Mode and GLP Mode provide controls for regulated laboratory environments, they are designed for different levels of regulatory oversight and workflow complexity.

Capability	GLP Mode + Imaging Edition	GMP Mode + Imaging Edition
Intended use	Non-clinical research, discovery, preclinical studies, academic and industrial R&D	GMP, QC, manufacturing, clinical, and highly regulated environments
Regulatory focus	Supports Good Laboratory Practice (GLP) principles including data integrity, traceability, and accountability	Supports electronic records and electronic signatures requirements of 21 CFR Part 11, Annex 11, and related GxP regulations
User authentication	Unique user accounts and role-based permissions	Unique user accounts, role-based permissions, and Part 11-compliant signature controls
Audit trails	Enabled	Enabled
Electronic signatures and statements	Optional	Fully supported
Controlled document workflow	Not applicable	Document lifecycle management with review, approval, release, and revision controls
Statements & signatures permissions	Limited to statements where applicable	Full signature authorization and workflow permissions
Signature meaning	Limited to statements where applicable	Captured and linked to the electronic record
Signature invalidation	Limited to statements where applicable	Changes to records invalidate signatures and require re-signing
Administration	Centralized user, role, and project management	Same centralized administration plus workflow and signature governance
Document workflow & status	Simplified document handling	Controlled states such as In Work, Review pending, Reviewed, Released, In progress, Approval pending, Approved, Canceled, Obsolete

If you are...	Recommended SoftMax Pro GxP solution
Discovery research group	GLP Mode
Early-stage biotech	
Preclinical laboratory	
Phase III/BLA preparation	GXP Mode
QC release laboratory	
GMP manufacturing support lab	
MiniMax Imaging Cytometer user	SoftMax Pro Imaging Edition
One instrument, ≤5 users	Single Computer installation
Multiple instruments or departments	Multi-Computer installation
Enterprise QA/IT governance environment	GXP Edition + Multi-Computer installation
High-volume imaging workflows	SoftMax Pro GxP Imaging Edition + Multi-Computer installation

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