

# Software Validation Manager

Proven tools to help you validate your AB SCIEX software

Software Validation Manager provides tools to navigate the validation process and help your organization reduce validation time, control costs, and minimize compliance risk.



## SUPPORT FOR COMPLIANCE IN DEMANDING REGULATORY ENVIRONMENTS

If your laboratory operates in a regulated environment, you may be required to validate your software. Meeting global standards (e.g., GLP, GCP, GMP) and country-specific regulations for electronic records and signatures (e.g., FDA 21 CFR Part 11) can be time-consuming, costly, and complex.

The AB SCIEX Software Validation Manager provides your validation team with the tools they need to test your AB SCIEX software and demonstrate compliance in even the most demanding regulatory environments.

## SUPPORT TO MEET YOUR SPECIFIC NEEDS

Software Validation Manager has two versions to meet the specific needs of your laboratory or manufacturing group:

- The standard version includes a complete set of electronic software documents and protocols to validate standard, pre-defined system definitions.

- The extended version includes additional documents and test procedures to support a comprehensive validation. In addition, the documents in the extended version can be modified, giving you the flexibility to customize the validation to meet your specific system definitions, validation requirements, existing workflow, and standard operating procedures (SOPs).

## SUPPORT THAT PROVIDES REAL VALUE

Software Validation Manager provides real value to your laboratory or manufacturing group by:

- **Reducing validation time** – At AB SCIEX, we have decades of experience in testing and validating systems for regulatory compliance. Using that knowledge, we have developed documentation and protocols to streamline the process.
- **Controlling validation cost** – Software Validation Manager helps you save money by eliminating costs associated with developing validation documents and test cases. Shorter validation times also help

you get up and running faster, reducing the opportunity cost of downtime for both initial installations and software upgrades.

- **Minimizing compliance risk** – With Software Validation Manager, you have all the documentation and protocols you need to validate your installation. By completing the package, your Validation Team can help ensure that all critical validation steps have been performed.

#### SUPPORTED SOFTWARE

Software Validation Manager is available for Analyst® Software.

#### SOFTWARE VALIDATION MANAGER EXTENDED

The extended version of Software Validation Manager features a comprehensive, customizable set of typical validation user requirements and test cases. Your Validation Team will modify the electronic documentation set as necessary to meet your specific needs and fit it within your established validation process. Completing the extended documentation set and protocols provides added assurance that your system complies with all appropriate global regulatory requirements.

#### SOFTWARE VALIDATION MANAGER

The standard version of Software Validation Manager includes a complete set of validation documents, user requirements, and test cases. Your Validation Team will execute the step-by-step test procedures to demonstrate compliance with the minimum global regulatory requirements.

#### ADDITIONAL REASONS TO CHOOSE SOFTWARE VALIDATION MANAGER

- **An externally reviewed and approved Computer System Validation approach.** Robert McDowell, PhD. C Chem. FSRC, an authority in validation of laboratory data systems, consulted with AB SCIEX to develop this validation approach to meet global regulatory requirements.
- **Volume pricing** – To help you control validation costs, we offer licenses for re-use at a minimal incremental expense.

#### THE RIGHT KNOWLEDGE AND EXPERIENCE

No one understands AB SCIEX instruments and software better than the company that

designed, built, and supports them. And no one has a longer history of integrating our systems into complex laboratory environments. We constantly update our body of industry best practices and keep abreast of regulations so we can help you comply with complex and changing regulatory requirements. Our software validation expertise and tools can help you reduce your software validation time and cost.

#### CONTACT US

To learn more about AB SCIEX Compliance Services, please visit [www.absciex.com/service](http://www.absciex.com/service), call your local service sales representative, or email [complianceservices@absciex.com](mailto:complianceservices@absciex.com)

	SOFTWARE VALIDATION MANAGER EXTENDED	SOFTWARE VALIDATION MANAGER
<b>FEATURES</b>		
Customizable Documentation	•	
Supports Regulatory Compliance (e.g., GLP and FDA 21 CFR Part 11)	•	•
Specifications	pre-defined; can be modified	pre-defined
Technical support	email and phone support	email and phone support
<b>DELIVERABLES</b>		
Software Validation Plan	•	•
User Requirements Specification (URS)	comprehensive	standard
System Design Specification	comprehensive	standard
Software Validation Test Plan	comprehensive	standard
Installation Qualification (IQ)	comprehensive	standard
Operational Qualification (OQ)	comprehensive	standard
Performance Qualification (PQ)	comprehensive	standard
Assessment for Compliance with Regulations Pertaining to Electronic Records and Signatures (e.g., FDA 21 CFR Part 11)	•	•
Test Cases	comprehensive	standard
Validation Traceability Matrix	comprehensive	standard
Vendor Assessment	customer requested	customer requested
Quality Assurance Review	•	•
Validation Summary Report	•	•

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