

SDMS VISION PUBLISHER

An Electronic Laboratory Notebook (ELN) to document scientific observations and results, document and control procedures, and easily find and collaborate on scientific results.

INTEGRATED FEATURES EXTEND THE CAPABILITIES OF NUGENESIS SDMS

Waters® SDMS Vision Publisher™ extends the capabilities of the NuGenesis® Scientific Data Management System (SDMS) by adding a new dimension to the processing, controlling, and reporting of scientific results. While you can collect and catalog all relevant scientific information generated within the laboratory in the SDMS repository, Vision Publisher optimizes your ability to interactively process, interpret, and report that information, adding significant value to your laboratory's output while increasing the usability of the SDMS platform for individual analysts. As an extended capability of SDMS, Vision Publisher can also facilitate the integration of information arising from other lab systems such as LIMS, instrument software, resource management systems, and data management systems to better streamline laboratory workflow.

With Vision Publisher, you get a complete and secure analytical chemistry ELN for your business processes in a single system.

The combined functionality of NuGenesis SDMS and Vision Publisher is ideally suited for organizations challenged with:

- Documenting the free flow of scientific observations and results while safeguarding intellectual property rights
- Documenting analytical test execution as with Standard Operating Procedure (SOP) worksheets
- Using spreadsheets while employing electronic document safeguards (GxP)
- Creating bioanalysis method validation reports
- Generating Bioequivalence reports
- Electronic Common Technical Documents (eCTDs)
- Abbreviated New Drug Applications (ANDAs)
- Reagent & Solution Inventories
- Scientific reports
- Instrument use logs
- Instrument calibration logs

SDMS VISION PUBLISHER SOLUTION

SDMS Vision Publisher can dramatically improve how you manage data, results, and routine procedures in both a compliant-ready and intellectual property secure scientific authoring environment, eliminating the need for traditional static laboratory recordkeeping - delivering a new level of dynamic content availability.

- Address the entire scientific content lifecycle: from documenting, and storing the initial thoughts of your key researchers, to managing data across discovery, development and production.
- Integrates with a majority of software programs, with advanced interoperability with Waters Empower™ 2, NuGenesis SDMS, and MassLynx™ Software.

With SDMS Vision Publisher, you can:

- Increase the utility of information collected by NuGenesis SDMS.
- Document the discoveries of your scientists in an electronic laboratory notebook.
- Access high-quality scientific information from NuGenesis SDMS.
- Automate routine calculations
- Drag-and-drop documents such as PDFs or Microsoft Word directly into Vision Publisher to streamline laboratory documentation.
- Work with Microsoft Excel in a compliant-ready environment
- Easily compare and contrast results from different analytical techniques and vendors.
- Tightly control experimental results to ensure intellectual property traceability.
- Make decisions faster in an operationally consistent and efficient environment.
- Help satisfy compliance requirements.

IMPROVE LABORATORY EFFICIENCY

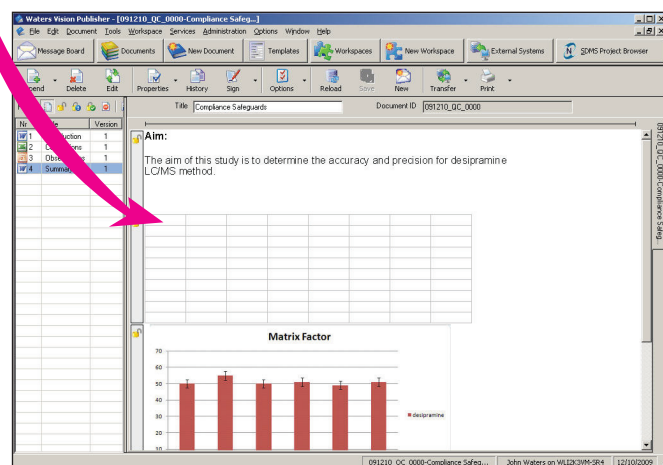
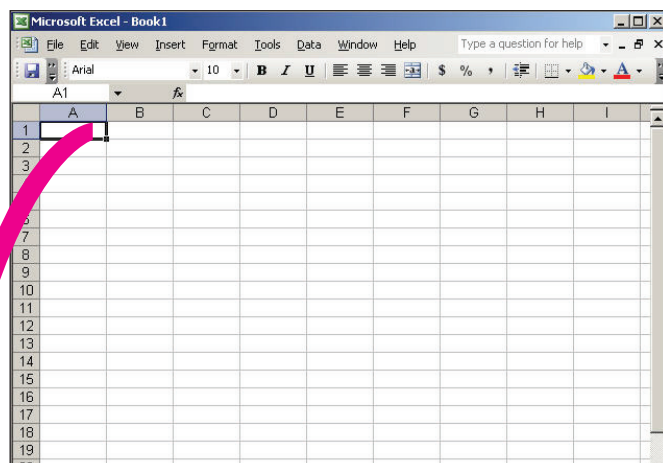
SDMS Vision Publisher allows structured scientific documents to be easily created from predefined templates, making it easy to adapt to the existing workflows in your lab – you can easily add selected content to these documents by interactively or automatically extracting information from NuGenesis SDMS, Empower, MassLynx, or other applications.

- Includes messaging, project and team organization, document review features, customizable reporting capabilities, and multiple search engines.
- Supports your workflow with optional document-integrated business logic functionality, including pre-formatted SOP worksheets for common pharmaceutical QC tests such as identity, assay, dissolution and content uniformity.
- Configurable to enforce prescribed workflows.
- Existing forms can easily be migrated into Vision Publisher.
- Built-in inventories for instruments and reagents integrate within SOP worksheets.
- With a web-based interface, Vision Publisher documents are accessible for review and approval through any device-desktop workstation, tablet PC, or other wireless devices.

ACCESS YOUR SCIENTIFIC RESULTS AND CONCLUSIONS

SDMS Vision Publisher enables scientists to capture, process, record, search, and share data of all types in a completely digital workspace. Manage text, authored reports, and comments; spreadsheets and tables; images, movies, chemical structures, and reactions, along with analytical data such as spectra and chromatograms.

Vision Publisher automatically imports information – you can integrate captured information from the SDMS repository into Vision Publisher documents or integrate content managed by other software, such as word processing software, spreadsheet programs, structure editors, image editors, statistics software, and others. File data, whether from the file system or from instrument servers, may be uploaded manually or automatically via the NuGenesis SDMS repository, which takes advantage of integrated agents for file capture, file parsing and metadata extraction.



Using Microsoft Excel spreadsheets while employing electronic document safeguards (GxP)

Personal Workspace Editor

SDMS Vision Publisher includes the Personal Workspace Editor, a personal or collaborative authoring environment that allows you to create scientific document content in secure, digital workspaces. With the Personal Workspace Editor, the author decides when to release content to the team for comment and collaborative work. It's a secure replacement for a local desktop file system and makes Vision Publisher your personal secure documentation portal.

DESIGNED FOR LONG-TERM INTEGRITY

Data storage and electronic recordkeeping in Vision Publisher are designed for long-term integrity. Contents are stored without modification in a one-to-one electronic record with all related information (metadata), thus retaining the rich experimentation environment in your labs. Information is saved independently from its originating software and is stored in stable, human-readable data formats — ready for you to retrieve when you need them.

SECURITY, EVIDENCE PROTECTION, AND COMPLIANCE

NuGenesis SDMS and SDMS Vision Publisher were designed to be compliant ready and have a Certificate of Structural Integrity to support users in a regulated environment. The Certificate of Structural Integrity is signed and approved by the Director of Worldwide Quality.

These products also enable you to be cGxPs, EU GMPs, and other regulatory requirements worldwide for users of this product. These products also enable you to be compliant ready for 21 CFR Part 11, the U.S. FDA's Electronic Records and Signature Rule:

- Time stamping, with role and status-based user access and inactivity log outs
- Configurable and flexible electronic signature and workflow for all documents and content
- Version control with full audit trails — including system and document audit trails



In addition to providing regulatory safeguards, SDMS Vision Publisher ensures the authenticity of electronic records and is certified to support the SAFE BioPharma™ digital identity and signature standard.

WATERS LABORATORY INFORMATICS

The Waters Laboratory Informatics suite is made up of powerful, integrated information management solutions that enable you to compile, manage, and share the vast quantity of data generated in your laboratory. Whether you're searching for application-specific software or looking to augment your data management strategy, Waters Laboratory Informatics solutions transform raw data into your competitive advantage.

For more information, visit: www.waters.com/informatics



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SDMS is covered under a formal Quality Management System certified by the TÜV Rheinland Group.

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