

NUGENESIS SDMS INTELLIGENT PROCEDURE MANAGER

AUTOMATING METHOD SOPS FOR GREATER EFFICIENCY AND FEWER ERRORS

The Waters® NuGenesis® SDMS Intelligent Procedure Manager is a workflow software package designed to guide the laboratory analyst through a routine, comprehensive method standard operating procedure (SOP) and integrate results with a chromatography data system, such as Waters Empower™ 2 Chromatography Data Software (CDS).

Manual or paper-driven guidelines still dominate certain laboratory functions, especially those focused on method or analytical SOPs. The Intelligent Procedure Manager addresses the predominately manual activities required to perform an analytical method or test, supporting a 'right the first time' philosophy – reducing cycle times up to 50-75% as compared to a traditional paper trail with fewer opportunities for human error.

Apply to any lab environment

From late-stage development to final product quality control and lot release, Intelligent Procedure Manager can be applied to any lab environment where rigorous adherence to approved test methods and SOPs must be followed, including compliance requirements for cGMP operations.

All primary laboratory data and metadata are quickly and easily acquired in electronic form and stored in a secure, 21 CFR Part 11, cGMP-, GLP-compliant database.

The application package

The NuGenesis SDMS Intelligent Procedure Manager is an application package for SDMS Vision Publisher™, a reporting and authoring module for NuGenesis SDMS, which consists of an automated form creator, intelligent forms, and electronic interfaces to external data sources such as electronic balances, pH meters, LIMS, CDS, chemical reagent, and instrument databases, among others.

Facilitate SOP form generation

The Intelligent Procedure Manager facilitates SOP/GxP form generation by including a form wizard to guide the author through the necessary steps to create a predefined template. For example, the form wizard allows the author to define input and output fields, define acceptance criteria for data input, and link external data sources to the form (e.g., linking a sample weight field with input from an electronic balance).

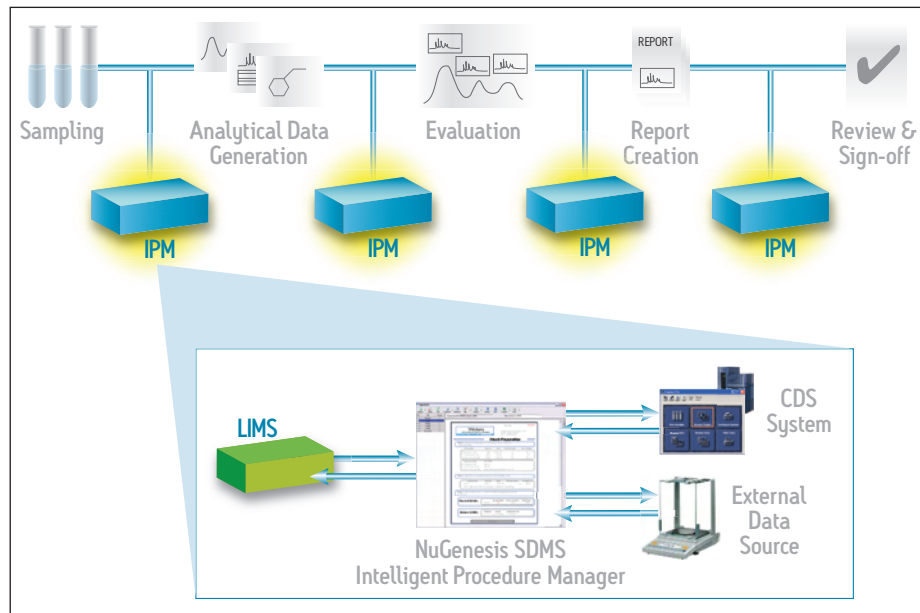
Reduce the time and errors associated with laboratory tasks that depend on paper guidelines, including:

- Instrument checks
- Standards and sample preparation
- Solvent and mobile phase preparation
- Analysis review
- Result approval
- Final product release



Streamline workflows

The resulting form not only guides the analyst through the prescribed workflow (without skipping required steps) but also verifies that input meets established criteria (e.g., by only allowing use of calibrated balances and fresh stock solutions), accepts data from external sources (CDS, LIMS, pH meters, balances, etc.), and readily incorporates results acquired on external data acquisition systems back to the completed form. The resulting document is electronically searchable thus facilitating comparisons between previous studies. Finally, the review and approval process is streamlined because it is accomplished electronically.



NuGenesis SDMS Intelligent Procedure Manager guides analysts through SOPs.

Improving laboratory productivity, strengthening business

With the Intelligent Procedure Manager, Waters continues to expand the open architecture operating platform anchored by SDMS that facilitates scientific collaboration. SDMS and SDMS Vision Publisher already give laboratories the ability to collect, catalog, author, and report critical scientific information, allowing them to improve decision making. The addition of Intelligent Procedure Manager's powerful capabilities to the SDMS platform allows laboratories to further improve the efficiency of laboratory workflow and ensure data quality – for the organization, this means developing and delivering products that are crucial to both short and long term success at an even faster pace.

Waters

THE SCIENCE OF WHAT'S POSSIBLE.™



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April 2008 720002562EN LB-PC

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