

## NuGenesis 9.3 – What's New

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### INTRODUCTION

Waters™ NuGenesis™ Lab Management System uniquely combines synergistic data, workflow, and sample management capabilities to support the entire product lifecycle from discovery through to manufacturing. This user-centric platform encompasses NuGenesis SDMS, a compliance-ready data repository, NuGenesis ELN, a flexible analytical electronic laboratory notebook, NuGenesis Sample Management, and Empower™ Software.

NuGenesis LMS seamlessly links data from the lab to the business operations of the enterprise with functionality such as sample submission and results review, stability testing, scientific search, multi-vendor software connection, laboratory inventories, data retention and legal hold, and laboratory execution methods.

NuGenesis LMS combines high impact functionality with a high degree of flexibility, readily adapting to your organizations' existing Informatics environments – facilitate software integration and standardization without the complex, costly, and time consuming deployments often encountered with traditional information management solutions.

Despite the increased pace of digitalization, many laboratories are still experiencing challenges caused by the need to keep and maintain paper records to fully document the workflow of a sample, challenges such as:

- Space required to store paper records
- Difficulty finding data
- Inefficient sample management
- Lack of visibility to the test statuses
- Poor inventory (instrument and consumables) management
- Time consuming reviewing and reporting of data
- Data integrity and compliance concerns

All these challenges significantly impact the productivity of the laboratory and can be costly, particularly when data integrity and compliance is at risk.

## NUGENESIS LMS OVERVIEW

NuGenesis Laboratory Management System (LMS) is a comprehensive, flexible, and scalable laboratory workflow and documentation solution. In this White Paper we will explore each element of NuGenesis LMS and highlight the latest features of NuGenesis 9.3.1.

## SCIENTIFIC DATA MANAGEMENT (SDMS)

In a typical lab environment, there may be many instruments which have computers attached where data is acquired from the instrument and processed. Managing the data on all of these stand-alone computers is difficult, time consuming, and error prone. Additionally, if users are printing reports from these instruments, that information also needs to be managed, either in folders, filing cabinets or lab notebooks. NuGenesis SDMS stores any file or printout generated in a lab in a secure database and can be set up to automatically sweep lab computers for instrument data files. The data swept by SDMS can be single data files, or an entire directory structure. During the sweeping process, the files are cataloged so they can be easily searched using a simple web interface. Any printable Windows™ application can also be printed directly to SDMS, where they are saved into the database in a searchable and reusable format. All data stored in SDMS can be searched, viewed, and reused, such as sending data to a LIMS system, creating reports, or sending data back to the original application for reprocessing.

## SAMPLE AND TEST MANAGEMENT

NuGenesis LMS provides the capability to manage specifications and test definitions, which in turn allow users to log samples based on those specifications or tests. Personnel who generate samples can enter details about their samples in the system, choosing the appropriate specifications or tests. The samples can then be received by the analytical lab and assigned to specific users or groups for analysis. The analysts can enter results into NuGenesis LMS, where the results will be checked against the test limits and flagged if they do not meet the acceptance criteria. At all points during the process, samples and tests are assigned a status, so anyone can see where in the testing process a sample is. Once the experiment has been run, the results can be reviewed and approved with a series of electronic signatures which will release the results back to the sample submitter.

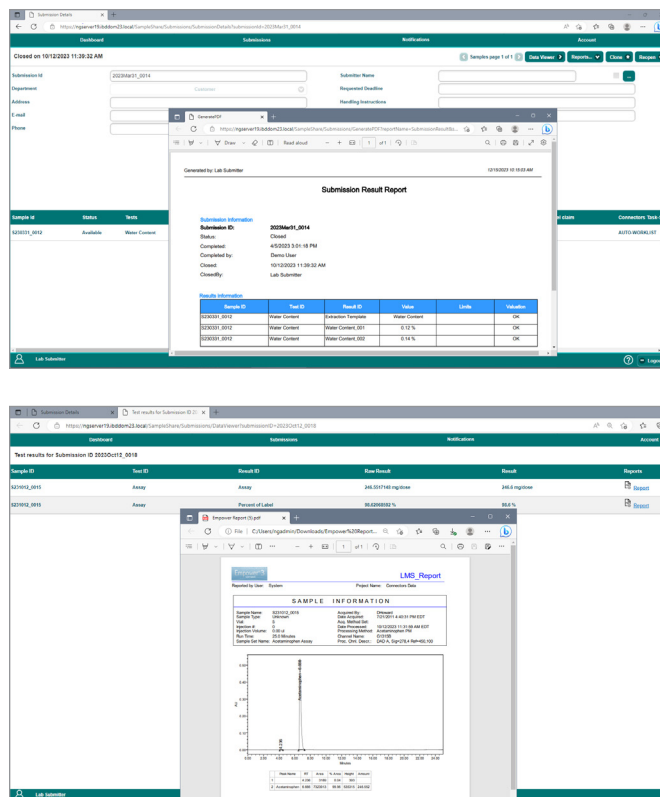


Figure 1. Sample Share Data Viewer allows users to view results for a submission in a configurable table grid and combine sample, result and raw data link in a single view

## ELECTRONIC LAB NOTEBOOK (ELN)

NuGenesis LMS contains a built-in electronic lab notebook which gives lab personnel the ability to document their activities electronically instead of on paper. The ELN is a flexible tool that can be used to document basic research activities in a freeform workflow or as part of strict quality control environment where specific protocols must be executed to perform testing (often called a test execution workflow). The research workflow and test execution workflow are the two extremes of lab documentation, and NuGenesis can cover both of these and everything in-between. Additionally, experiments in the ELN can be linked to samples and/or tests in sample management which can facilitate easier documentation for sample testing.

The ELN can also interface with both Empower and the Scientific Data Management System to allow chromatographic and other data generated in the lab to be entered into an experiment in electronic format.

## INVENTORY MANAGEMENT

NuGenesis contains inventories for instruments and consumables, including lab-prepared solutions and can replace traditional paper log books or electronic log books stored across multiple informatics systems. The consumable inventory allows users to keep track of all materials in the lab, such as chemicals, solvents, pipet tips, and gloves. The electronic lab notebook can be used to document the creation of lab solutions like buffers and mobile phases, with the resulting solution then entered into the inventory after preparation, or the information can be entered directly into the Inventory Management user interface. The electronic management of inventory enables easier and quicker auditing and searching.

The top screenshot displays the 'Instruments' management interface. It features a sidebar with 'Create' and 'Log' options. The main area shows a table of instrument details:

Instrument ID	Active	Type	System Status	Node Name	Node Location	System Fit For Use	Calibration Date	Calibration Due Date	Preventive Maintenance Due Date	Preventive Maintenance Due Date	Firmware	Software	Last Sync Date
<b>System: Acquly_KClass (3 Items)</b>													
ACQ-B5MACQSM1		ACQ-B5M	Idle	Emplice	Demotown	Critical	2/16/2023 5:11:04 PM	3/16/2023 6:11:04 PM			1.50.301 (Aug 21 2015)		12/15/2023 10:30:31
ACQ-S8MACQSM1		ACQ-S8M	Idle	Emplice	Demotown	Critical	2/16/2023 5:11:04 PM	3/16/2023 6:11:04 PM			1.65.301 (May 2 2016)	1.73.4159	12/15/2023 10:30:31
ACQ-TLWACQTVG		ACQ-TLW	Idle	Emplice	Demotown	Critical	2/16/2023 5:11:04 PM	3/16/2023 6:11:04 PM			1.70	1.76.2843	12/15/2023 10:30:31
<b>System: Acquly_HClass (4 Items)</b>													
ACQ-CM#ACQCM2		ACQ-CM	Idle	Emplice	Demotown	Critical	3/30/2023 5:30:31 PM	4/30/2023 5:30:31 PM			1.62	1.77.3169	12/15/2023 10:30:31
ACQ-FTN#ACQSMFT		ACQ-FTN	Idle	Emplice	Demotown	Critical	3/30/2023 5:30:31 PM	4/30/2023 5:30:31 PM			1.65.301 (Aug 21 2015)	1.76.2843	12/15/2023 10:30:31
ACQ-PDA#ACQSDA1		ACQ-PDA	Idle	Emplice	Demotown	Critical	3/30/2023 5:30:31 PM	4/30/2023 5:30:31 PM			1.70	1.70.2074	12/15/2023 10:30:31
ACQ-QSM#ACQQSM1		ACQ-QSM	Idle	Emplice	Demotown	Critical	3/30/2023 5:30:31 PM	4/30/2023 5:30:31 PM			1.60.60 (Jun 30 2015)	1.76.2843	12/15/2023 10:30:31
<b>System: ABC_HPIC (3 Items)</b>													
ACQ-FTN#ARC5MFT		ACQ-FTN	Idle	Emplice	Demotown	Acceptable	10/12/2023 11:19:5...	10/12/2024 11:19:5...	10/12/2023 11:16:30 AM	10/12/2024 11:16:30 AM	1.65.301 (Nov 23 2016)	1.73.3047	12/15/2023 10:30:31
ACQ-QSM#ARCQSM		ACQ-QSM	Idle	Emplice	Demotown	Acceptable	10/12/2023 11:19:5...	10/12/2024 11:19:5...	10/12/2023 11:16:30 AM	10/12/2024 11:16:30 AM	1.60.60 (Nov 23 2016)	1.76.2740	12/15/2023 10:30:31
W099#W099PDA		W099P	Idle	Emplice	Demotown	Acceptable	10/12/2023 11:19:5...	10/12/2024 11:19:5...	10/12/2023 11:16:30 AM	10/12/2024 11:16:30 AM	1.65	1.76.2843	12/15/2023 10:30:31
<b>System: (1 Item)</b>													
ACQ-FTN#ARC5MFTN		ACQ-FTN					2/16/2023 5:08:09 PM	3/16/2023 6:08:09 PM			1.65.301 (Nov 23 2016)	1.73.3047	5/3/2023 10:54:48

The bottom screenshot displays the 'Reagents & Solutions' management interface. It features a sidebar with 'Create' and 'Log' options. The main area shows a table of reagent details:

Substance ID	Name	Active	Batch Type	Manufacturer	Lot Number	Internal Lot Number	Department	Expiry Date	Expiry Period After Crack Date	Critical	Quantity	Critical	Center
Phosphate	Phosphate 20031		MOBILE PHASE	Phosphate 20031	231215_0001			12/15/2023 10:59:47 PM	1	0	0	0	
Mobile Phase...	Mobile Phase 20031		MOBILE PHASE	Mobile Phase 20031	231215_0000				1	0	0	0	
Mobile Phase...	Mobile Phase 20031		MOBILE PHASE	Mobile Phase 20031	230230_0000				1	0	0	0	

Figure 2. Easy-to-use, searchable inventory management for reagents, consumables, and instruments.

## STABILITY STUDY MANAGEMENT

Stability studies are extremely important in the pharmaceutical industry, as they determine how long drug material or finished products can be stored, and under what conditions. NuGenesis LMS has the capability to create and manage these stability studies, including generating testing matrices, which detail what conditions materials are stored under and how often material in each condition is tested. Samples are pulled from the storage conditions at intervals specified in the testing matrix, and NuGenesis can generate the pull schedule notifying stability coordinators when samples need to be pulled. NuGenesis can then manage all of the results generated in the study, once enough results have been generated in a study, they can be analyzed with the built-in statistics package purpose built for calculating shelf-life projections. NuGenesis is directly aligned with the guidelines published by regulatory agencies specifying how stability data should be analyzed.

## WATERS PROFESSIONAL SERVICES

Waters has a team of service personnel to perform installation and qualification of NuGenesis systems. In addition, the Waters Professional Services Team can provide consultation services including managing projects, development of templates for the ELN or reports, and providing validation services. They can also provide training to NuGenesis users, either on site, at regional facilities, or via e-learning.

## NEW FEATURES FOR NUGENESIS 9.3

### SINGLE LOGIN

All elements of NuGenesis LMS can be accessed via a single login, enabling much easier and faster access to all the features of the software. A single login account for the whole application also provides additional security as once logged in, access to specific features and functionality is defined by the assigned user privileges.

### COMMON LANDING PAGE

The introduction of a common landing page ensures all users can easily use and navigate the software, regardless of their experience. The welcome page can also be customized according to the users access level and their individual needs.

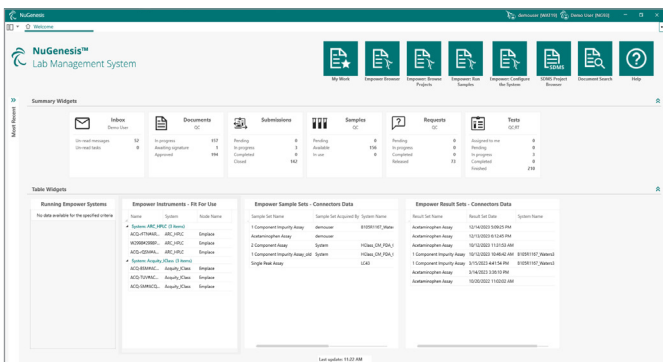
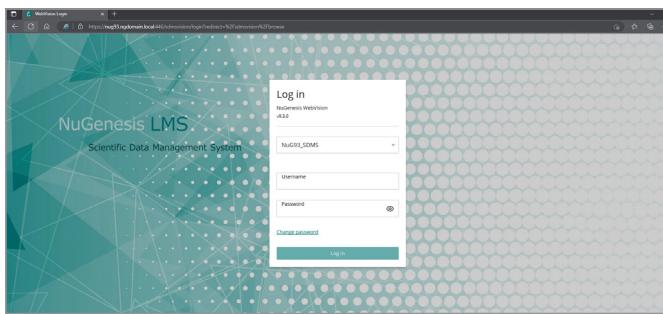


Figure 3. NuGenesis LMS single login (top) and login page for the new NuGenesis SDMS Web Vision (bottom).

## WEB VISION

The NuGenesis SDMS Web Vision no longer requires Internet Explorer™ but now runs on the latest Web Browsers such as Microsoft Edge™ or Google Chrome™. Users can make use of the easy shortcut to the Waters Knowledge Base where any topic can be searched including troubleshooting error messages.

Viewing captured data within SDMS is easy with Web Vision which shows the projects that contain the file or print data plus the associated project content. Improvements have been made to the filters allowing users to start typing into the filter for the column to see if it is indexed or not (if it is indexed then the searching performance is very quick). Users can also highlight the text in the row and right click and the text will automatically go to the filter tab, avoiding the need to re-type.

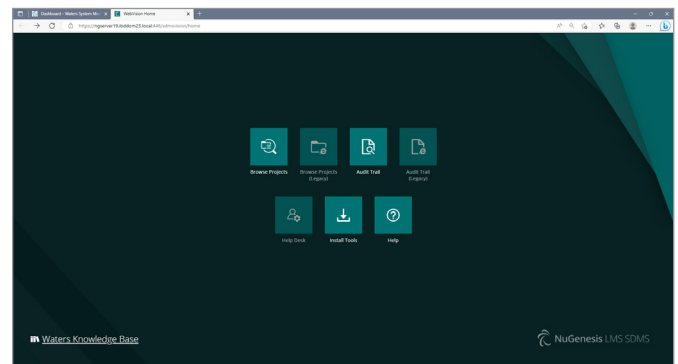


Figure 4. NuGenesis SDMS Web Vision now runs on the latest web browsers and provides a quick shortcut to the Waters Knowledge Base for easy topic searching and troubleshooting.

## AUDIT TRAIL VIEWER

The new SDMS Audit Trail Viewer now segments the audit trail into category groups which are further segmented into additional categories. This enables much simpler searching and filtering through the SDMS audit trail.

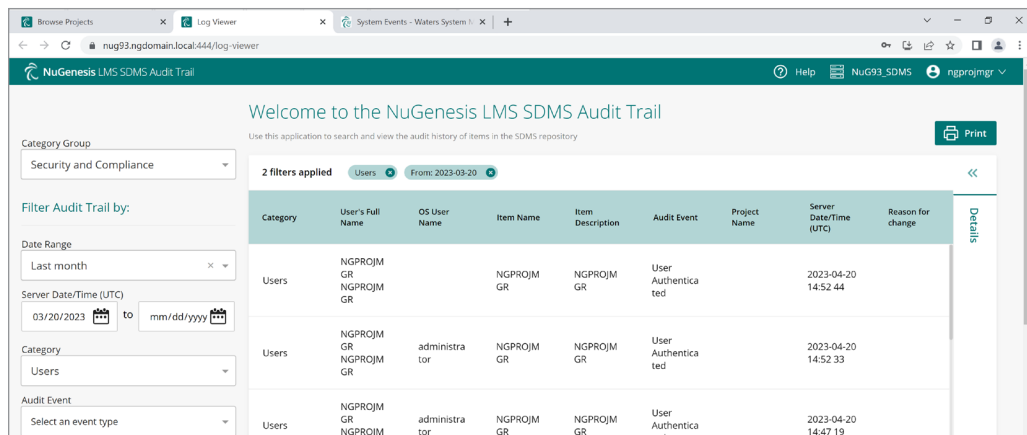


Figure 5. Simplified category groups and filtering to review the SDMS Audit Trail.

## WATERS SYSTEM MONITOR AND WATERS DATABASE MANAGER

The new Waters System Monitor and Waters Database Manager tools allow users to proactively address potential warnings or error messages from the NuGenesis system by detecting system failures earlier, ensuring the right infrastructure is in place for the lab workflow, and eliminating performance problems.

The dashboard of Waters System Monitor shows all the LAC/E™, LMS Agents, and Archive Agents connected to NuGenesis plus their statuses. What is deemed a warning, error, or failure, and the associated messages, are fully customizable and the relevant information can be easily forwarded to Waters Support teams if more support is required.

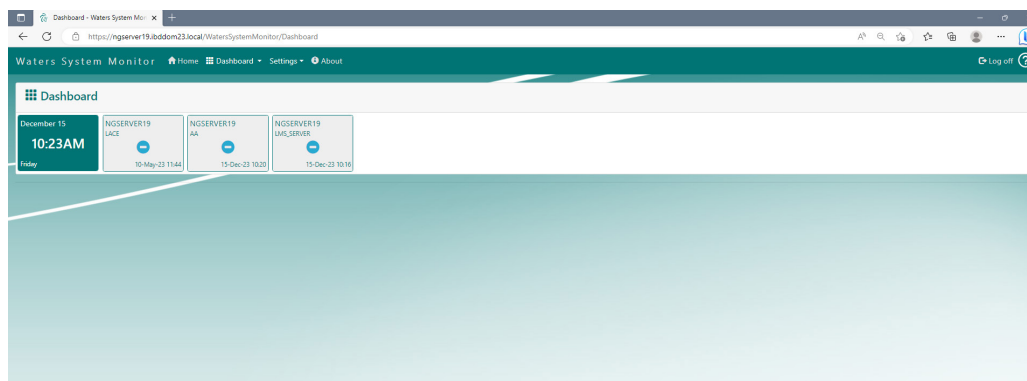


Figure 6. Waters System Monitor dashboard showing all LAC/E and Archive Agents connected to NuGenesis and their status.

The Waters Database Manager tool allows users to see the status of the database, define the backups, see if any table spaces are filling up, view the log files, and manage the Oracle Database users.

## SOFTWARE UPDATES

NuGenesis 9.3 is compatible with Empower 3.8, and runs on Windows Server 2016 and 2019.

For further information on any of the information in this White Paper, please contact your local deployment specialist.

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**Waters Corporation**  
34 Maple Street  
Milford, MA 01757 U.S.A.  
T: 1 508 478 2000  
F: 1 508 872 1990  
[waters.com](http://waters.com)