Waters
THE SCIENCE OF WHAT'S POSSIBLE.™

NuGenesis Laboratory Management System Solution for Stability Management

Preconfigured to ensure you never miss a pull

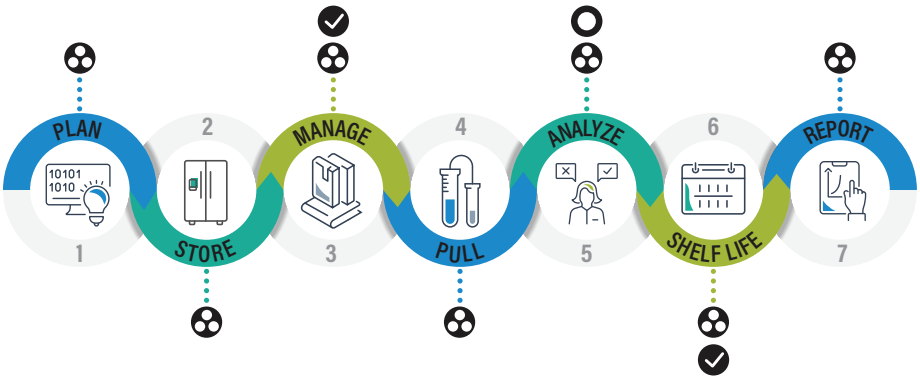
INTRODUCTION

Stability testing is a vital and required function in the pharmaceutical, cosmetic, and food industries to ensure the long-term safety and efficacy of products for patient and customer use.

Managing stability studies can be a complex and demanding process. Manual paper-based workflows or use of hybrid systems for study creation and approval are inefficient and can introduce errors. This can lead to missing a sample pull, which could result in repeating an entire study, or product recall. Errors in stability studies require companies to notify regulatory agencies, potentially resulting in a warning letter. Stability testing issues are common in FDA warning letters, in fact they are in the top 5 cited violations in 2016, 2018, 2019, and continue to be growing in 2020.[1,2]

IMPLEMENT A TURNKEY STABILITY MANAGEMENT SYSTEM WITH MINIMUM EFFORT

NuGenesis™ LMS Solution for Stability Management contains key features and benefits to ensure compliance and efficiency. NuGenesis LMS for Stability Management facilitates the entire stability workflow, enhancing productivity and data integrity improvements at every step of the process.



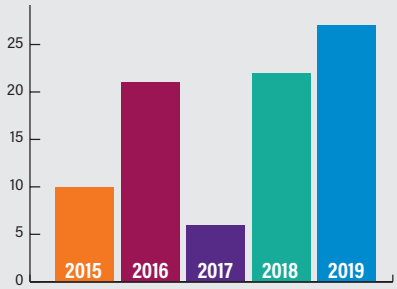
NuGenesis LMS for Stability Management facilitates the entire stability workflow, enhancing productivity and data integrity improvements at every step of the process.

KEY FEATURES AND BENEFITS

- Save time with tools for stability study and matrix creation
- Create stability study summary report for electronic review and approval
- Manage inventories for stability samples
- Automate scheduling of sample pulls
- Automated data transfer to/from Empower™ as a package add-on
- Statistical analysis reports for shelf life projection included
- Developed in accordance with current GAMP and ICH guidelines

STABILITY TESTING PROGRAM IS A COMMON PROBLEM IN RECENT FDA WARNING LETTERS[2]

~1 in 5 warning letters cite inadequate stability testing (2016, 2018, 2019, and growing in 2020)[1]



EVERYTHING YOU NEED TO ENSURE SUCCESS

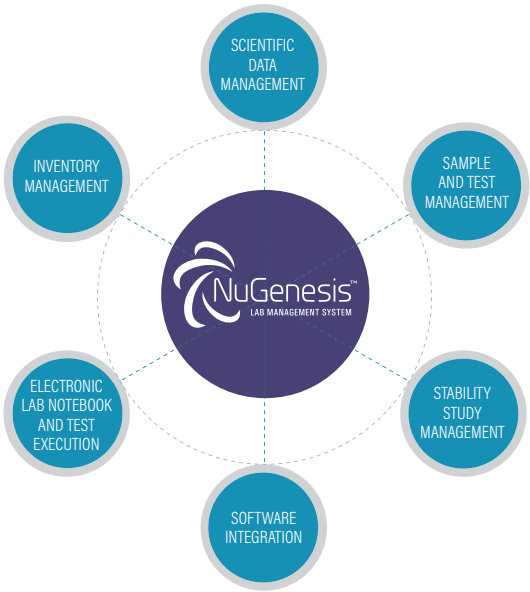
NuGenesis LMS for Stability Management contains the software, services, and training you need to get started quickly and with minimal effort.

✔	NuGenesis LMS Software
✔	Sample management named user license including maintenance
✔	Installation, configuration, and IOQ execution by Waters Professional Services*
✔	User training by Waters certified trainers
✔	Waters project manager

**Additional validation services not included, but are available through the Waters Validation Consultation team.*

TURN ON WHAT YOU NEED: AS YOUR LAB AND BUSINESS GROWS, THE SYSTEM CAN GROW TO MEET YOUR NEEDS

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



WATERS GLOBAL SERVICES

Delivering world renowned services and support

Waters Service and Support offerings are tailored to optimize your laboratory productivity while addressing your budget realities. Our offerings help maintain system peak performance, minimize down time, address scientific application challenges, and support stringent compliance requirements. As your services and support provider, we are committed to the success of your laboratory and business.

Waters quality support and consultative services ensure your success wherever your laboratory is located in the world.

Confirmit ACE AWARDS
Achievement in Customer Excellence

Waters has consecutively earned the ACE Award since 2001 for providing best-in-class technical knowledge, issue resolution, and process support.

References

1. Stability Testing Program as a Common Problem in recent FDA Warning Letters https://www.gmp-compliance.org/gmp-news/stability-testing-program-as-a-common-problem-in-recent-fda-warning-letters
2. https://www.gmp-compliance.org/gmp-news/batch-release-without-determination-of-identity-and-strength-and-other-gmp-violations-a-look-at-fdas-warning-letters-over-the-la

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