

## Equilab Improves the Data Integrity of its Operations with NuGenesis Laboratory Management System

Compliance with ISO 17025:2017 and GLP helps validate client confidence in Equilab's laboratory analysis and improves global reputation

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### BACKGROUND

Equilab International is a leader in the field of bioavailability (BA)/bioequivalence (BE) studies and clinical trial services in Indonesia and Southeast Asia. Established in 2003, Equilab is the first independent BE center in Indonesia, serving domestic and international pharmaceutical companies in Asia, Australia, North America, Africa, and Europe.

As a BA/BE laboratory and clinical research unit, they currently have a team of more than 50 who work in specialist competencies in the clinical and analytical aspects of research. Equilab has completed over 500 BA/BE studies with over 200 validated bioanalytical methods, while their study reports have been accepted as official accreditation by regulators from ASEAN nations and European countries, like the United Kingdom, the Netherlands, and Poland.

Equilab also carries out clinical tests with human subjects, especially to test for ICH-GCP standards. These tests include subject screening, drug administration management, blood sampling and collection, and tests on the adverse effects of drugs. In addition, the lab's analytical method development and validation procedures meet good laboratory practice and clinical laboratory requirements.

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### CHALLENGE

Equilab needed to be compliant with ISO 17025:2017<sup>1</sup> and GLP standards, to propel it further as a leader in the global BA/BE industry.

"To allow us to operate in international markets, and work with a more diverse set of clients, it was important for Equilab to obtain the ISO accreditation and GLP Standard. It would enable us to demonstrate that we operate with the highest standards of testing, generate valid results with sound data, providing added confidence for work both in Indonesia and around the world," said Yantirta Indra Kurniawan, Bioanalytical Manager at Equilab.

The ISO accreditation would also help to facilitate cooperation between Equilab's laboratory and other bodies through wider acceptance of Equilab's test results abroad. With the accreditation, test reports and certificates can be accepted between countries without the need for further testing.

With this goal in mind, Equilab kicked off its search for a solution that would allow it to comply with ISO 17025:2017 and GLP with a focus on data integrity, especially for Excel spreadsheets. The potential vendor also needed to offer a more efficient workflow to improve productivity and to reduce repetitive steps, such as data transcription.

## THE SOLUTION

Equilab has several Waters™ instruments already in use in their laboratories, such as a liquid chromatography-mass spectrometry system. Thus, it was a natural choice for them to choose the Waters NuGenesis™ Laboratory Management System (LMS), to have all the key elements of the system working hand-in-hand and have easy inter-operability.

As Equilab uses Excel spreadsheets for data analysis, auditors often ask for the audit trails to evaluate data traceability, version of spreadsheets and author authentication of Equilab's Excel documents, as part of their data integrity procedures. Often, they require hard copies of the data, accepted as a physical audit trail. They also require assurance that access controls to this data are strictly controlled. The absence of these two requirements will present a data integrity compliance risk.

Waters proposed its NuGenesis LMS as a solution, comprising both the Scientific Data Management System (SDMS) and the Electronic Lab Notebook (ELN), which provides tools to support data compliance for Excel documents. The combination of the two modules of NuGenesis LMS further enhances the efficiency of Equilab's laboratory workflow and compliance with regulations for data integrity and security.

NuGenesis LMS highlights:

- Convert and enhance existing laboratory spreadsheets and documents into NuGenesis ELN forms.
- Provide a paperless solution with full audit traceability for existing worksheets and paper notebooks in the laboratory.
- Centralize and secure all laboratory related data, reports, and documents for long-term storage for use in a regulated environment.
- Spreadsheet activities are documented in ELN document audit trail to prevent unauthorized data manipulation.

No other vendor in the market currently offers a similar product, and NuGenesis clearly stood out by offering a solution that provided test results compliant with ISO 17025:2017 and GLP, particularly with regards to long-term data storage and traceability of Excel spreadsheets.

## THE IMPLEMENTATION

Equilab worked with the Waters team to deploy NuGenesis LMS in its bioanalytical laboratory and data management department. Current users include Equilab's bioanalytical manager, method development and validation manager, laboratory personnel, data management staff, and QA personnel.

Extensive support was provided by the Waters Informatics Specialist with the Excel spreadsheet template conversion to ELN forms. The converted forms offered increased ease of use and added the capability for processing an increased number of samples. Since it was implemented, NuGenesis LMS has helped Equilab improve the data integrity quality of its Excel spreadsheets in bioanalytical laboratory processes, in accordance with the ALCOA principles that ensure data integrity. As a result, it is now supporting the bioanalysis of drug concentration in biological samples for BA/BE study. The solution has also improved workflow through the reduction of repetitive data transcription.



"We are well on our way to becoming a truly global player, providing capabilities that will be acceptable by global regulators for the pharmaceutical industry. We have to thank Waters in this partnership and certainly looking forward to collaborating with them for future enhancements of our laboratory."

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AND PURNAMA DEWI YULI ASTUTI  
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## THE RESULT

Equilab offers bioanalytical capabilities with validated and accredited status. With a mission to be a global player, providing quality and accurate results in a short turnaround timeline is critical to pleasing customers and improving the lab's reputation around the world.

NuGenesis LMS, and other complementary Waters products, have proven to be very useful in helping Equilab to meet the quality expected by its customers, especially with regards to data integrity. The Excel compliance feature has provided a full audit trail that is compliant with regulatory requirements for electronic records and signatures. This ensures that Equilab now has good document control of its Excel spreadsheets for continued utilization as an essential tool for its laboratory operations.

Equilab needed to have an efficient workflow and reduce any tedious repetitions such as data transcription. Based on data evaluation generated by QA teams, The NuGenesis LMS ELN helped cut lead times on data transfers by half and has reduced paper consumption by more than half.

| Item                 | Quality lead time                   | Paper consumption        |
|----------------------|-------------------------------------|--------------------------|
| Manual data transfer | 20 working days after breaking code | Avg. 2 reams/project     |
| NuGenesis ELN        | 10 working days after breaking code | Avg. 0.5–1 reams/project |

Table 1. Adding NuGenesis ELN cut quality lead time and paper consumption in half.

## References

- For more information, visit <https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html>.

# Waters

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