Worldwide Clinical Trials

Case Study

Revolutionizing Drug Development Through Bioanalytical Excellence: Enabling Automation in Bioanalysis for Optimal Results

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Total Lab Automation (TLA) addresses critical challenges such as:

- Assay lifecycle management: mitigating issues related to analyst turnover and assay transfer.
- Significantly reduces study timeline delays by eliminating the bottlenecks associated with slow manual sample analysis.
- Minimizes study deviations by ensuring rigorous adherence to lab work processes and documentation standards.
- Dramatically cuts costs by reducing the reliance on human labor.

Validate software and equipment

The associated hardware has been validated in accordance with GLP and the protocols provided by the vendor. The software was validated in-house, adhering to the GAMP 5 Edition 2 Guidance and the FDA's "General Principles of Software Validation" guidance.

Objectives

We strive to revolutionize drug development through the advancement of automation systems, aiming to minimize manual intervention, elevate bioanalytical quality, expedite study timelines, and reduce costs.

Solutions

The bioanalytical TLA system is a combination of a liquid handler, incubator, shaker, plate washer, and plate reader, all controlled via the VENUS software. The bioanalytical assay parameters are scripted through the software. Then, the robotic system can perform all the laboratory work, including validation and sample testing.

At a Glance

Goals

- Eliminate manual lab work
- Improve bioanalytical quality
- Apply it to GCLP studies

Benefits

- 10x throughput increase
- Decrease labor costs
- Reduce study timeline(s)

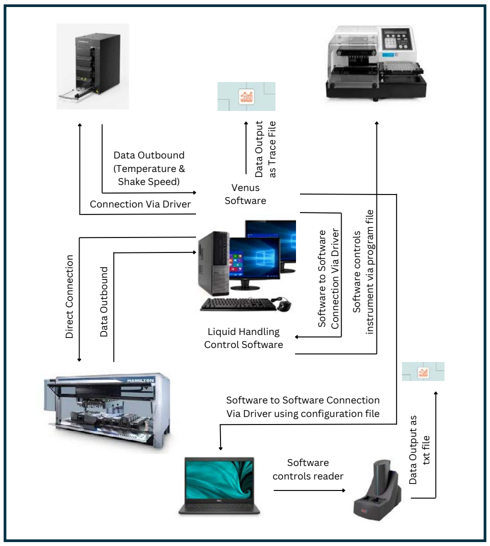

Figure 1: TLA data flow map

Enhance repeatability

A completely automated system with specific aspiration/dispense and mix settings ensures that every aspiration/dispense and mixing step is performed the exact same from one step to the next. The pressure monitoring system allows for tracking of aspiration and dispense precision and lets the user set upper and lower limits for the curve to detect any mishaps. Additionally, no variation would result from multiple analysts with different training/experience levels.

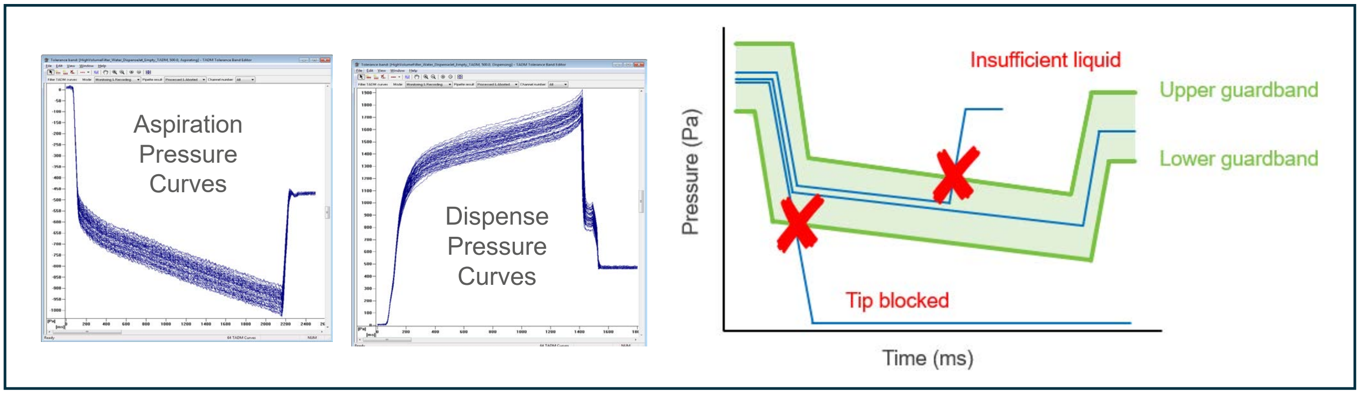

Figure 2: TLA Liquid Transfer Procedure. In order to maintain an empty tip, the tip is sustained under high pressure while submerged to a specific depth. Aspiration involves the generation of negative pressure, thereby filling the solution into the tip. Dispensation, on the other hand, necessitates the creation of positive pressure. Any abnormal pressure conditions and their related occurrences are concisely detailed. The liquid transfer is executed using varying volumes across different tip sizes.

Improve traceability

A trace file documents each step of a run from beginning to end with a time stamp and position(s). Barcoding capabilities allow it to track plate(s), individual samples, and reagents. A camera and email system are used to allow the user to track the run remotely as needed.

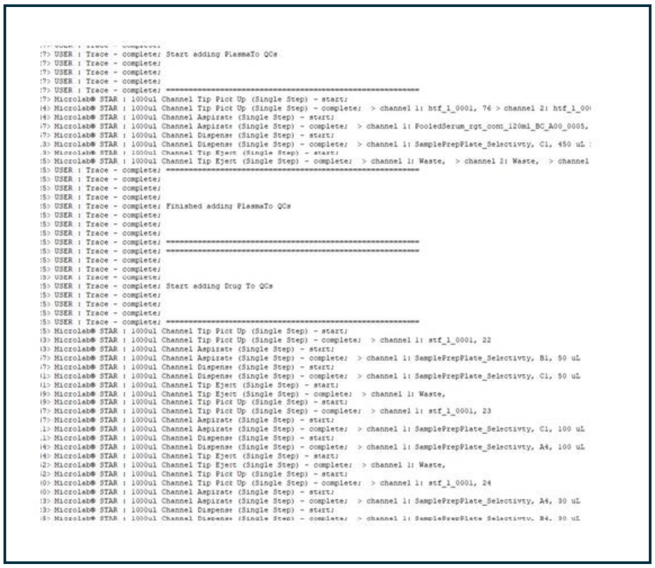

Figure 3: TLA procedure monitoring and documentation

Maximize the bioanalytical capacity

Scheduling software allows the system to accurately schedule multiple runs in parallel. This optimization leads to a 10x increase in the number of samples that can be analyzed consistently, requiring only one person to operate machinery each shift. The TLA system has the capacity to run up to 90 plates a week as opposed to one senior analyst running ten plates.

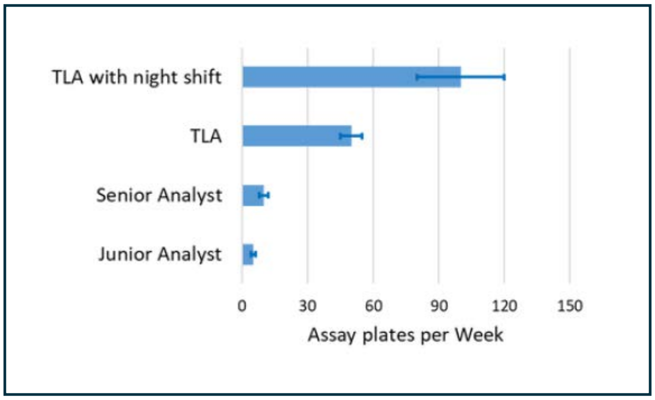

Figure 4: Bioanalytical efficiency analysis between manual and automation. TLA system is capable of performing night shift for sample testing without manual intervention.

Improve precision and accuracy

TLA development revealed that various factors influence the precision and accuracy of assay tests, including sample mixing, the duration of incubation, the sequence of sample transfer, and the settings for plate reading. Following the optimization of these parameters, the TLA system consistently displayed high levels of accuracy and precision across the tests.

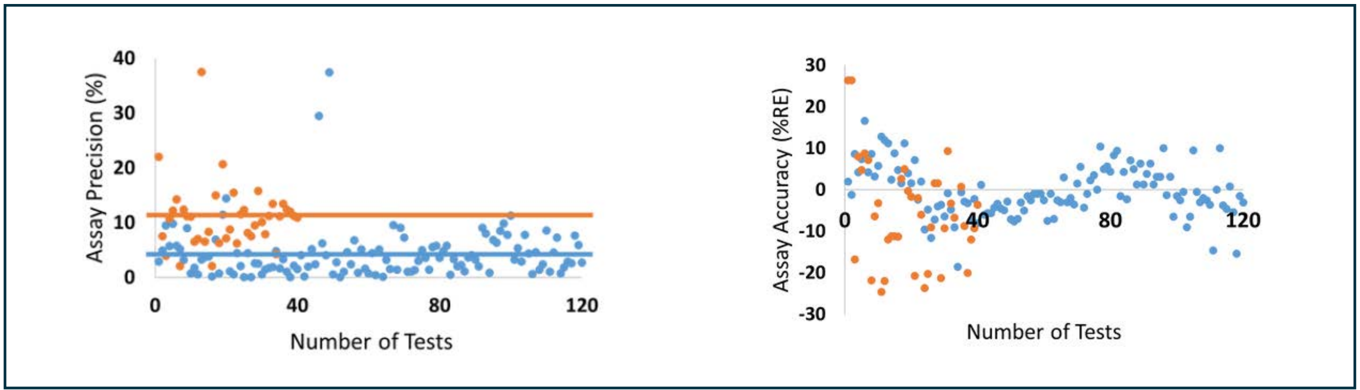

Figure 5: TLA Liquid Transfer Procedure. In order to maintain an empty tip, the tip is sustained under high pressure while submerged to a specific depth. Aspiration involves the generation of negative pressure, thereby filling the solution into the tip. Dispensation, on the other hand, necessitates the creation of positive pressure. Any abnormal pressure conditions and their related occurrences are concisely detailed. The liquid transfer is executed using varying volumes across different tip sizes.

Despite a few outliers, TLA managed to maintain assay precision within 5% for the majority of the samples. Furthermore, the data for accuracy showed a tightly clustered dispersion contained within a 10% range. In contrast, the data derived from manual assays demonstrated a significantly higher variation in both assay precision and accuracy, underscoring the advantages of TLA in maintaining consistency and reducing variability in the testing process.

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