Optimizing quality testing with LabWare and TetraScience

CUSTOMER STORY

The Challenge

Quality control (QC) scientists at a large biopharmaceutical organization conduct batch release testing, including moisture and purity assays. First, they weigh samples of the drug product and measure water content with a coulometer. Then, they weigh a second set of samples and use high-performance liquid chromatography (HPLC) to detect degradation products and impurities.

Their original workflows required extensive manual intervention, often called "human middleware" internally. They manually transcribed and transferred data between instruments and systems, relying on paper notebooks for recordkeeping (Figure 1). Ultimately, scientists would enter the data into LabWare LIMS, which generates the final report. To mitigate errors, they performed second-person verification throughout the process. Overall, these practices slowed down QC processes, compromised data integrity, and created several data silos. Inefficient testing leads to delays in delivering the product to market, resulting in increased inventory and higher costs.

The Solution

The Tetra Scientific Data and AI Cloud™ automates end-to-end data workflows through its bidirectional integration with LabWare LIMS and other software that interfaces directly with scientific instruments, including Mettler Toledo LabX, Metrohm Tiamo, and Waters Empower Chromatography Data System (Figure 2). The Scientific Data and AI Cloud collects data from these applications and transforms it into an open, vendor-agnostic format. The resulting data, known as Tetra Data, is large-scale, liquid, compliant, and purpose-engineered for release testing.

Since these workflows take place in regulated environments, the biopharma uses the Tetra GxP Package to reduce compliance risks and efforts. This package includes verification and validation documentation, among other tools, to streamline the company's GxP validation processes.

The Result

The automated data workflows greatly reduce the burden on scientists, allowing them to redirect time from manual data entry and management to increasing testing throughput. This solution also improves data integrity by minimizing the risk of human errors and deviations. It replaces paper documentation and second-scientist reviews with validated integrations and audit trails. With easily searchable data, investigations and audits become much more efficient. The upshot is faster, more reliable, and fully traceable QC processes.

By replatforming and engineering the QC data, the Scientific Data and AI Cloud optimizes the entire dataset for analytics and AI. The biopharma aims to utilize this Tetra Data to power dashboards that enable visualization and trending of chromatography data. These tools will help scientists track compliance-related information and prevent out-of-specification events.

Challenge:
QC scientists used manual-intensive data practices, slowing batch release testing.

Solution:
The Tetra Scientific Data and AI Cloud, combined with LabWare LIMS, streamlined workflows end to end through automated data replatforming and engineering.

Result:
- Faster batch release testing
- Higher productivity for scientists
- Enhanced data integrity
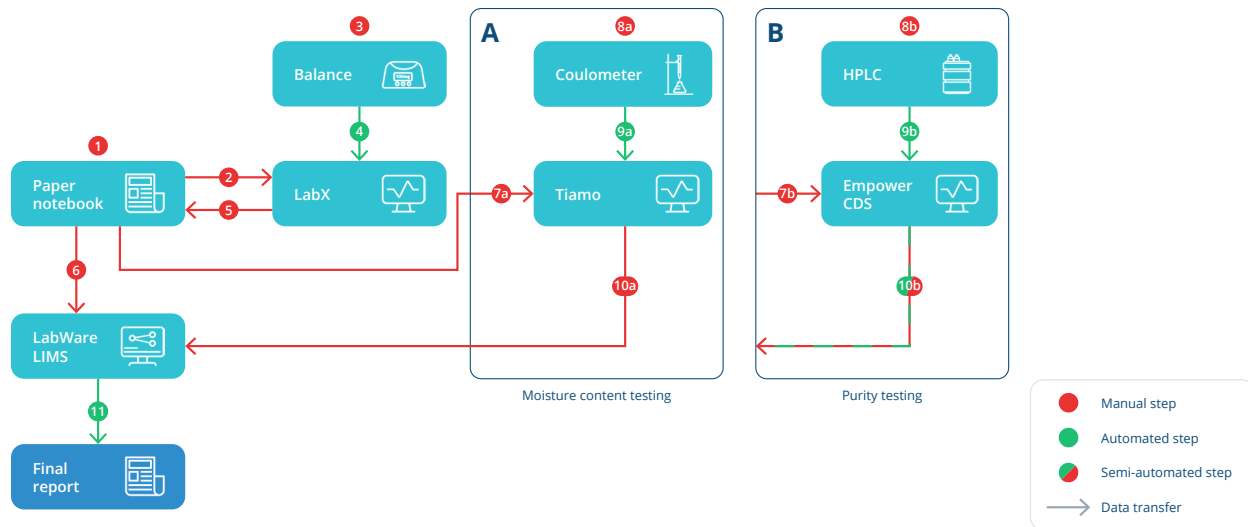- Analytics-ready data for future chromatography dashboards

Figure 1. Initial workflow for testing (A) moisture content and (B) purity.

1. Scientists record sample IDs in their lab notebook.

2. This information is entered into LabX software.

3. Scientists measure the mass of the samples.

4. The data is automatically transferred to LabX.

5. Scientists record the mass in their notebook.

6. Sample masses and IDs are manually transcribed into LabWare LIMS.

7. This information is also entered into (a) Tiamo or (b) Empower Chromatography Data System (CDS).

8. Scientists test the samples by (a) Karl Fischer titration or (b) HPLC.

9. Raw data is automatically retrieved by (a) Tiamo or (b) Empower.

10. (a) Scientists manually transfer the moisture results to LabWare LIMS. (b) Chromatographic peaks of known identity are automatically sent to LabWare; unknown peaks and column information are manually recorded in LabWare.
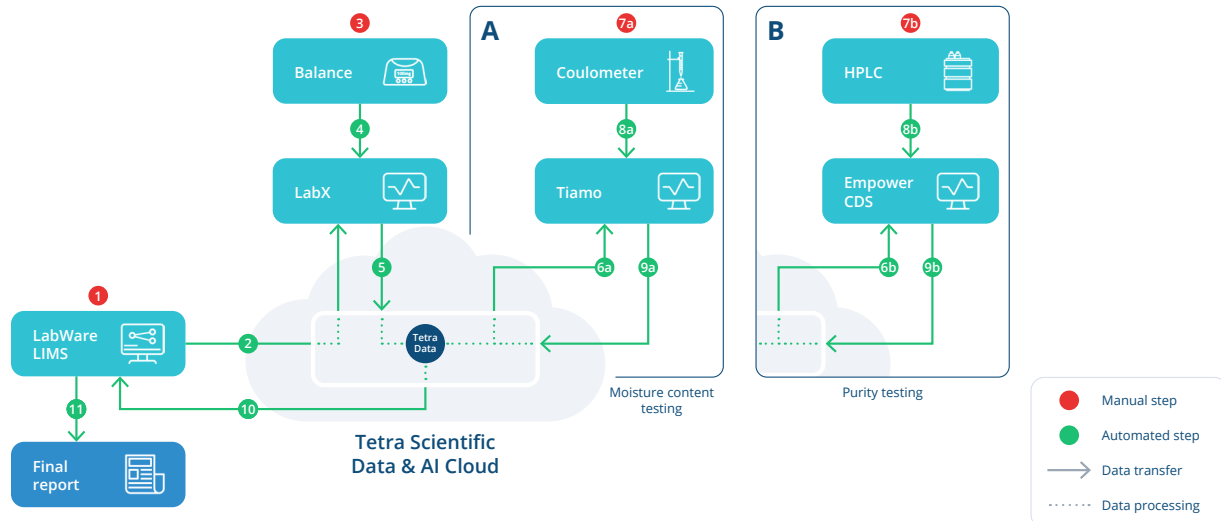
11. LabWare generates the final report.

Figure 2. Tetra workflow for testing (A) moisture content and (B) purity.

1. Scientists record sample IDs in LabWare LIMS.

2. The Tetra Scientific Data and AI Cloud automatically transfers this information to LabX via the API.

3. Scientists measure the mass of the samples.

4. The data is automatically transferred to LabX.

5. The Scientific Data and AI Cloud collects the measurement data.

6. The platform automatically engineers the sample information and sends it to Tiamo.

7. Scientists test the samples by (a) Karl Fischer titration or (b) HPLC.

8. Raw data is automatically retrieved by (a) Tiamo or (b) Empower.

9. The Scientific Data and AI Cloud collects the data from (a) Tiamo or (b) Empower and engineers it into Tetra Data.

10. The platform sends the results to LabWare LIMS.

11. LabWare generates the final report.