

Data-Driven Quality Control

CASE STUDY

THE CASE FOR THE TETRA SCIENTIFIC DATA CLOUD

Measure what matters: Chromatography data presents interesting challenges for modern life sciences organizations: Millions of samples are manually processed each year across the pharmaceutical industry. The technique underlies every step of pharmaceutical production, from research leads through post-clinical manufacturing lots. Despite its central place in the discovery landscape, chromatography suffers from a fundamental limitation: You can't easily aggregate data across multiple runs or across your diverse in-house instrumentation. Manual report creation and conversions between data formats are still the norm.

SUCCESS METRICS

Saved Time	Reduced Complexity
<ul style="list-style-type: none"> Save 2+ hours per week, per scientist of manual file transfer work Provide structured and clean data integration for other systems to consume 	<ul style="list-style-type: none"> Reduce manual errors; Results are directly calculated and derived from raw data Automation allows streamlined downstream analysis via data science applications (e.g. Streamlit apps)
Accelerated Insights	Improved Transparency and Future-Proofing
<ul style="list-style-type: none"> Improved data-driven decision making (Result is calculated and generated much faster) Harmonized, vendor-agnostic data accelerates ability to run AI/ML and data science projects on top of it 	<ul style="list-style-type: none"> Versatile pipelines are configurable and extensible to handle rich set of technologies and formats

Who Should Read this Study?

R&D IT Directors and Business Leaders; Quality Control teams in Pharmacology, Development, or Manufacturing; Scientific Project Managers, Operations Data Scientists; Lab Automation Engineers; Metabolism / Fate Study Heads



Product Focus

- Small molecule therapeutics, biomarker development, computational screening

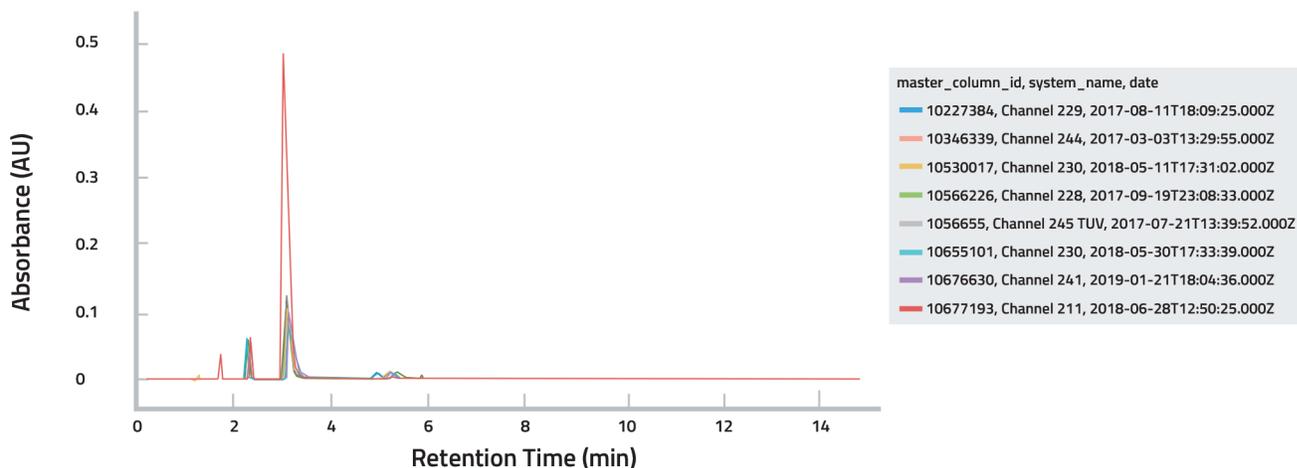
Client/ Customer

- Top 15 biopharma

KPIs / Results

- Saved 8 hours weekly in reporting;
- \$30,000 in consumables expense per HPLC; Alleviated days to weeks to rework production batches;
- Resolved inefficiencies in interdepartmental communications

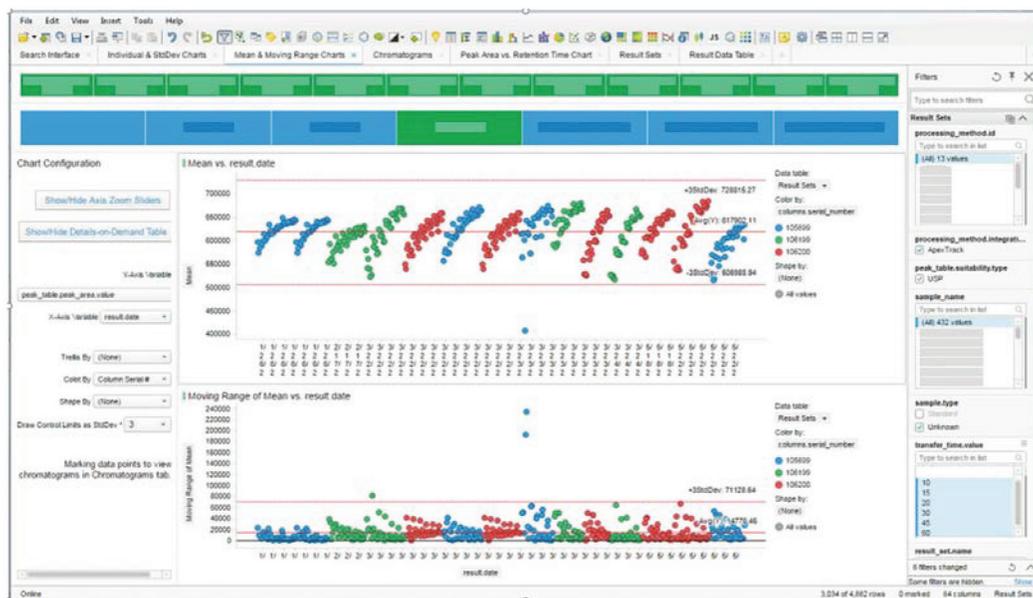
Chromatogram overlay



Speaking of column degradation - placing a final production batch onto a potentially faulty column might result in material loss, or perhaps obscure a tiny impurity in a poorly-resolved shoulder peak - leading to costly rework and missed project deadlines. What if you could monitor the health of each column in your arsenal, in near-real time, knowing when it had reached its end-of-life? What would the value be of this information - aside from ~\$30,000 in solvent and consumables per machine, per year?

Using factors such as peak area, retention time, and tailing factor from the SST, this Global Biopharma used existing runs to "predict" failures before they could occur. The graphic below shows the power of learning from existing data - simple plotting of peak mean (or any other relevant spectral parameter) over time reveals the slow drift into obsolescence.

Peak area mean value vs. time for individual columns, showing considerable drift over a 4-month period

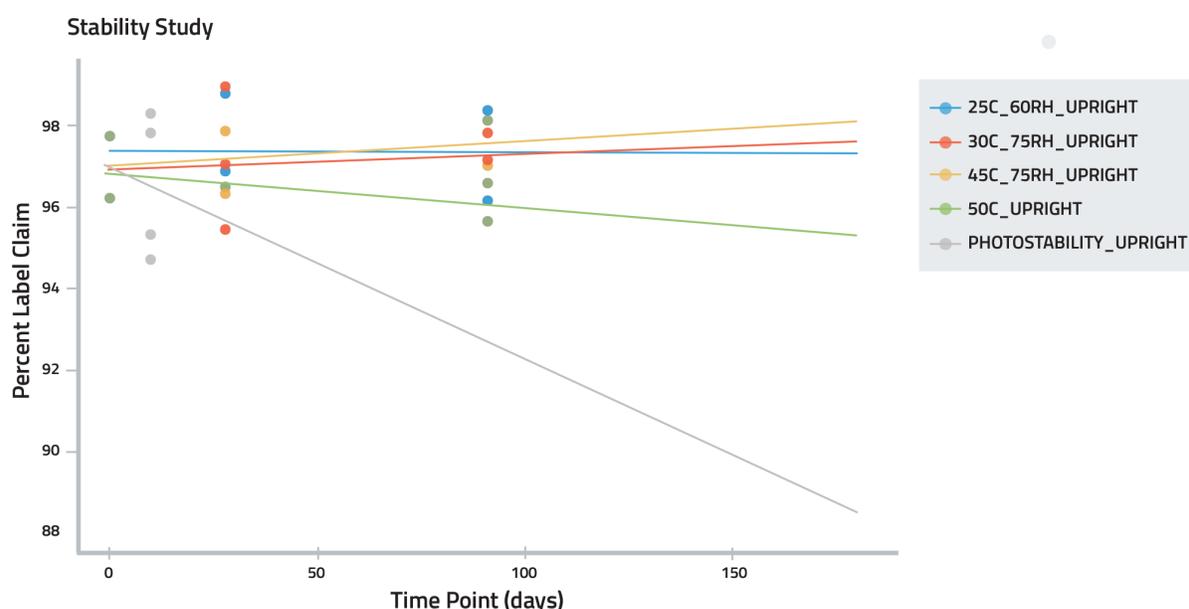


Finally, our Global Biopharma client uses the Tetra Data Platform to calculate system usage for its entire process development division, monitoring parameters like total solvent, system uptime, and run length across their chromatographic fleet. Paired with the ability to inspect specific columns by data detective work, TetraScience automates QC reporting, reduces process risk, and eliminates manual data work.

CASE 2 - SHELF-LIFE FOR ACTIVE PHARMACEUTICAL INGREDIENT (API)

Our Global Biopharma partner had also experienced issues with reporting API shelf-life: the tendency of molecules to degrade due to heat, light, water, pressure, and multiple other environmental or handling variables. Having stored and reported their data in a tabular format for years didn't permit quick, intuitive communication to other company divisions. By utilizing the Tetra Data Platform connector to ingest and harmonize all Empower data (see above), a graphical method to quickly chart observational measurements and offer predictions (fitted line) could be realized.

Desired state for shelf-life predictions: A single graphical overlay with immediate information about compound stability.



Better still: multiple such analyses could be grouped, depending on environmental conditions, batch composition, storage containers, country specs, etc.

CONCLUSION

The automation and analyses were made possible through centralized, harmonized data from Empower being available for further inquiry across the organization. This company realized manual labor savings, consumables cost savings, streamlined reporting between functions, and made data available and reusable in adherence to FAIR ideals.



TetraScience is the Scientific Data Cloud™ company with a mission to accelerate scientific discovery and improve and extend human life.

To learn how you can unlock the power of harmonized, FAIR data in the cloud with the only open, cloud-native platform purpose-built for science, visit tetrascience.com