tetrascience

Solution Brief

Quality Testing

Consistent production of safe, effective medicines requires strict adherence to product specifications. Organizations devote significant resources to quality control (QC) processes to guarantee the safety, efficacy, and quality of their products. In large enterprises, QC labs need to test and document the results for tens of thousands of samples per year. When deviations are identified and investigations follow, these efforts increase substantially.

Inherent complexity

Biopharmaceutical manufacturing varies in complexity based on the modality. More intricate systems, such as those for biologics (e.g., antibodies), cell and gene therapies, and mRNA/oligonucleotides, exhibit higher degrees of freedom, behave non-linearly, and have numerous interdependencies. As a result, identifying the root cause for out-of-specification (OOS) products requires capturing and analyzing these interdependencies across hundreds of variables. Furthermore, the data associated with deviations is generated by dozens of instrument types and models, adding complexity.

Traditional labs

In traditional labs, all this data is manually collected and reformatted. This process is extremely time-consuming and only captures a fraction of the available data. Data traceability is challenging when data is transferred for report creation or into downstream systems. Furthermore, the efforts for software validation and regulatory compliance, including data integrity and traceability, are significant. For example, manual data entry often requires review by a second scientist to ensure accuracy, and maintaining data integrity involves strict adherence to chain-of-custody protocols.

Shift to digital QC

Regardless of the modality or therapeutic focus, biopharma companies can no longer afford traditional approaches. Reducing time to patient and controlling costs demand a paradigm shift. QC needs to become digital.

Digital QC labs with mature data infrastructures consolidate all their data into an easily accessible single source of truth. They also engineer this data so it can be ingested and interpreted by applications that can run multivariate analysis, such as AI. Pairing data maturity with high-powered analytics allows organizations to leverage both historical and emerging data from every deviation instance within the lab. This accelerates deviation investigations, uncovers causal relationships to identify which variables need adjustment, and predicts future deviations. By doing so, digital QC labs for any modality—from small molecules to oligonucleotides—boost throughput and reduce lead times while improving the knowledge associated with an assay.

Tetra Scientific Data And AI Cloud

The Tetra Scientific Data and AI Cloud™ automates data workflows in the regulated biopharmaceutical space and transforms raw scientific data into compliant, liquid, purpose-engineered, and large-scale datasets. These datasets facilitate report creation, trend analysis, and predictive modeling to accelerate and improve scientific outcomes.

Data transfer

Quality testing labs performing batch release or stability tests must ensure the integrity and traceability of their data from generation to reporting. Many lab environments rely on disconnected data sources like instrument PCs, multiple chromatography data systems (CDSs), laboratory information management systems (LIMSs), spreadsheets, and analysis software. Typical data workflows require lab scientists to perform many time-consuming manual data transfers. The burden is even worse when paper-based processes are involved. This non-value-adding work makes labs inefficient and increases the risk of errors.

The Tetra Scientific Data and AI Cloud collects and centralizes data from diverse scientific data sources through industrialized, validated integrations. TetraScience has the largest, fastest-growing, purpose-built library of integrations to replatform raw instrument data, analysis results, experimental context and design tools, and data from contract manufacturing organizations (CMOs) including unstructured data (e.g., PDFs). TetraScience typically covers 80% of the data sources used by customers for small molecules, biologics, cell and gene therapies, and oligonucleotides.

This capability enables customers to fully automate their scientific data workflows, moving their data from disparate data sources into centralized cloud storage and making it accessible from commonly used applications. Scientists can maintain their existing lab workflows but no longer need to waste time on manual data transfers. This automated approach minimizes disruption for scientists while significantly increasing lab efficiency and scientific productivity, simultaneously reducing errors.

Validation and compliance

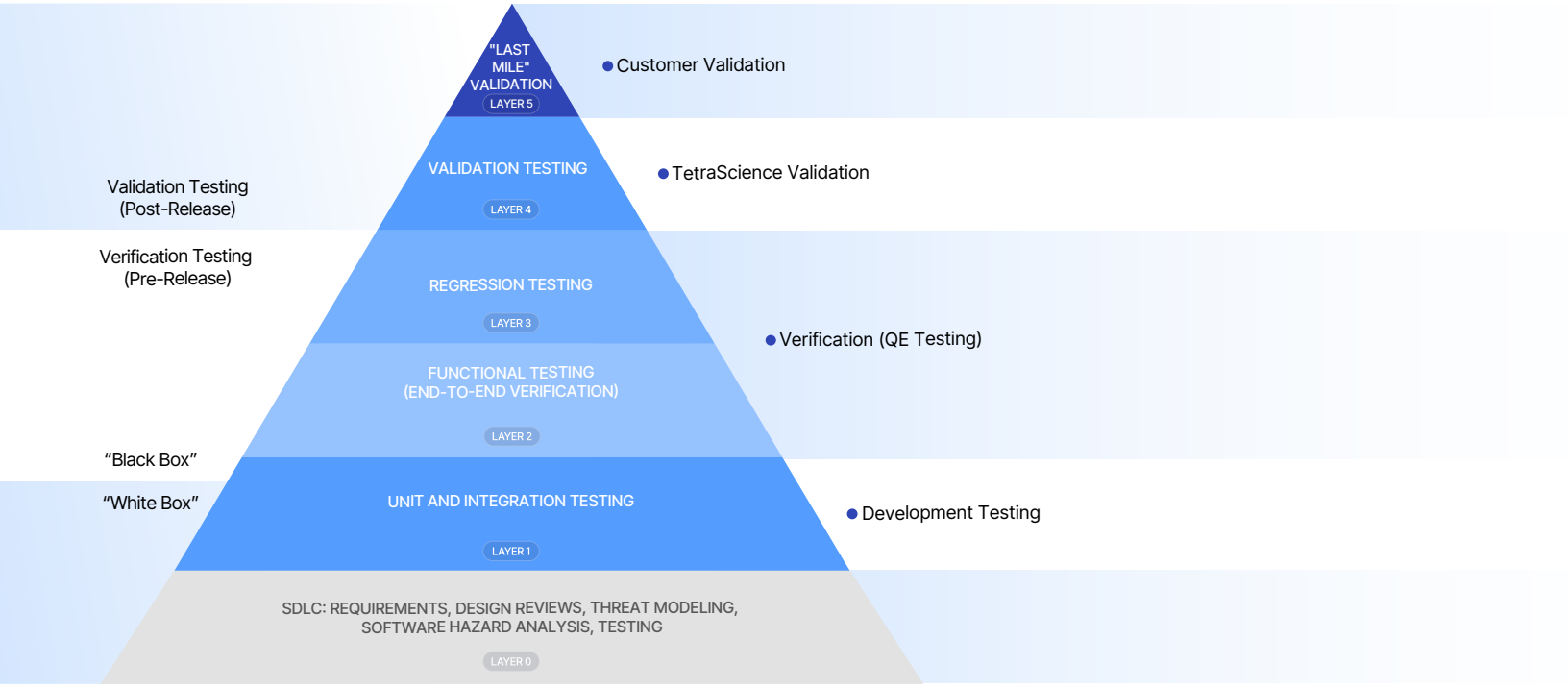
Validation and compliance, while necessary in quality testing labs, consume resources but add no value to the actual product, being considered “necessary non-value added (NNVA) activities.” Hence, organizations should minimize the cost and time spent on these activities.

TetraScience provides validated integrations for regulated environments, ensuring data integrity without the need for additional checks. Users can trust that the data they access is an exact representation of the original data. Any changes or modifications are automatically tracked through an audit trail, offering complete traceability and making the data available for reviews and audits.

Aligned with US FDA’s 21 CFR Part 11 and ALCOA++ standards, TetraScience ensures that data is accurate, secure, and traceable, while also being FAIR (findable, accessible, interoperable and reusable).

Developed through extensive customer engagement, TetraScience's GxP package reduces validation efforts by 80% by leveraging the current Computer Software Assurance (CSA) framework together with the document set that allows customers to standardize and automate industry best practices. The set of validation and verification documents is revised and reissued with every major or minor release of the platform and integrations.

The TetraScience Testing Pyramid



Report creation

In quality testing, scientific data is often used to create stability reports, batch records, quality assurance documents, and certificates of analysis (CoAs). Compiling the data for creating these reports can be time-consuming and cumbersome.

The Tetra Scientific Data and AI Cloud streamlines this process by contextualizing data with scientifically relevant metadata, such as batch ID, instrument, and method name. This metadata serves as search criteria, allowing users to quickly locate and compile the necessary data for a specific batch or method. The data can be easily found and accessed from the centralized cloud storage and reused directly in report-creation tools, including LIMS and electronic lab notebooks (ELNs). Alternatively, scientists can retrieve the data from the TetraScience user interface by entering search criteria or using customizable filters.

Control charts and trending

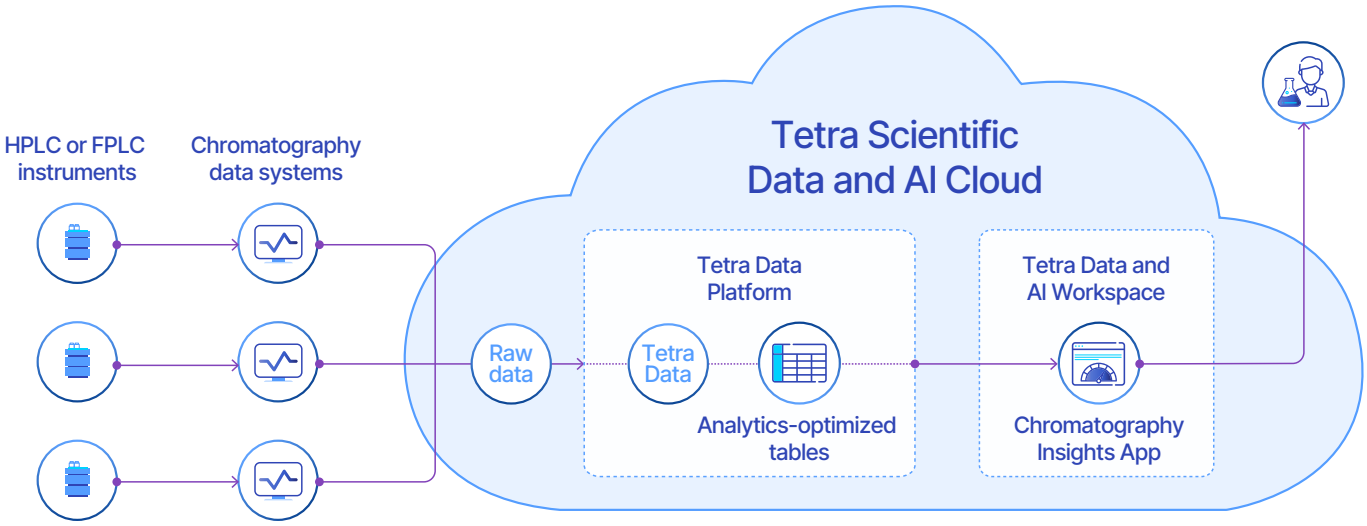
Another way quality testing experts reuse their data is for control charts and trending. Typically, scientists need to compare and analyze data from multiple vendors, relying

Search fields with typical scientific metadata.

on best-in-breed third-party tools for analysis. However, the variety of data formats generated by different instrument vendor software presents a challenge, as the heterogeneous data cannot be easily combined.

The Tetra Scientific Data and AI Cloud addresses this problem by purpose-engineering scientific raw data. With our **data pipelines**, we transform primary raw data into compliant, liquid, purpose-engineered, large-scale datasets that are analytics- and AI-ready. The resulting "Tetra Data" is in an open, vendor-agnostic, standard format, allowing scientists and data scientists to use their preferred tools for analyzing and trending QC data.

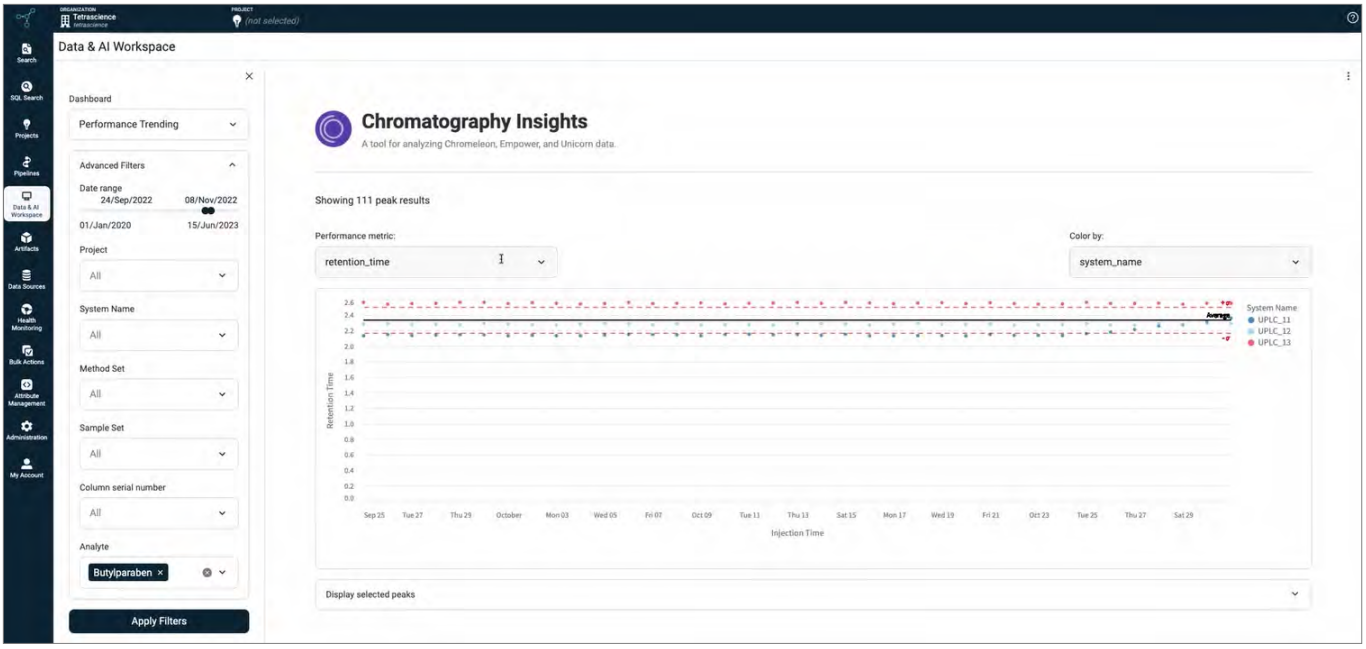
To further simplify data reuse, TetraScience has created a Data and AI Workspace that co-locates data with the applications used to analyze it. These applications can be third-party vendor software provided by the customer or Tetra Data Apps developed by TetraScience. One such app is **Chromatography Insights**, which features a performance trending dashboard that tracks data across projects, departments, or sites and enables detailed reviews of instrument results metrics. It can help reduce out-of-specification results by up to 75% by analyzing trend data and results of instruments across teams, departments, and sites. This enables the quick identification of poorly performing assays or instruments, allowing timely interventions that prevent costly downtime and troubleshooting. Another dashboard in the app monitors instrument fleet utilization. It helps optimize instrument use and identify underutilized instruments and bottlenecks in shared systems to improve lab productivity.



Deviations and investigations

Deviations happen, and when they do, it's critical to investigate and determine a root cause—a process that can be time-consuming. During this period, batches are held in quarantine, which incurs significant costs. Common causes of deviations include product degradation, influx of foreign matter, biological contamination, inadequate method or process validation, or errors related to equipment or personnel. In response, a corrective and preventive action (CAPA) must be implemented, which may involve revising standard operating procedures (SOPs) and retraining staff.

The Tetra Scientific Data and AI Cloud automates data transfer, minimizing the probability of data-related human errors. TetraScience also helps reduce process- and product-related deviations providing analytics- and AI-ready data to populate control charts and trending dashboards. This enables early detection of out-of-specification (OOS), out-of-trend (OOT), and out-of-expectation (OOE) events before they happen. A prime example is the aforementioned Chromatography Insights Data App.



Quick and easy access to data is crucial for identifying the root cause of a deviation. Centralized, contextualized data streamlines both internal and external investigations, making the process smoother and faster.

Digital QC

Organizations moving toward digitalizing their quality testing processes typically aim for more than just incremental productivity gains and error reductions in their lab workflows. They seek a comprehensive end-to-end approach that transforms the status quo. This cannot be achieved by simply implementing a software solution for the lab. It needs a "Digital QC" approach.

Digital QC applies AI/ML capabilities to make QC faster and more efficient. It helps standardize and streamline testing processes and makes it easier to find potential issues and implement corrections. To accomplish this, labs need digitalized, connected, and automated workflows alongside AI-ready data.

The Tetra Scientific Data and AI Cloud transforms data into AI-native datasets that enable AI and ML. This eliminates the need for scientists and data scientists to spend time aggregating and preparing the data. Instead, they can focus on creating the right models to answer critical questions for quality testing.

Digital QC labs can expect:

- 3x increase in sample throughput
- 80% reduction in deviations
- 90% faster investigation closure times
- 200% boost in lab productivity
- 30-40% reduction in operational costs

Examples include:

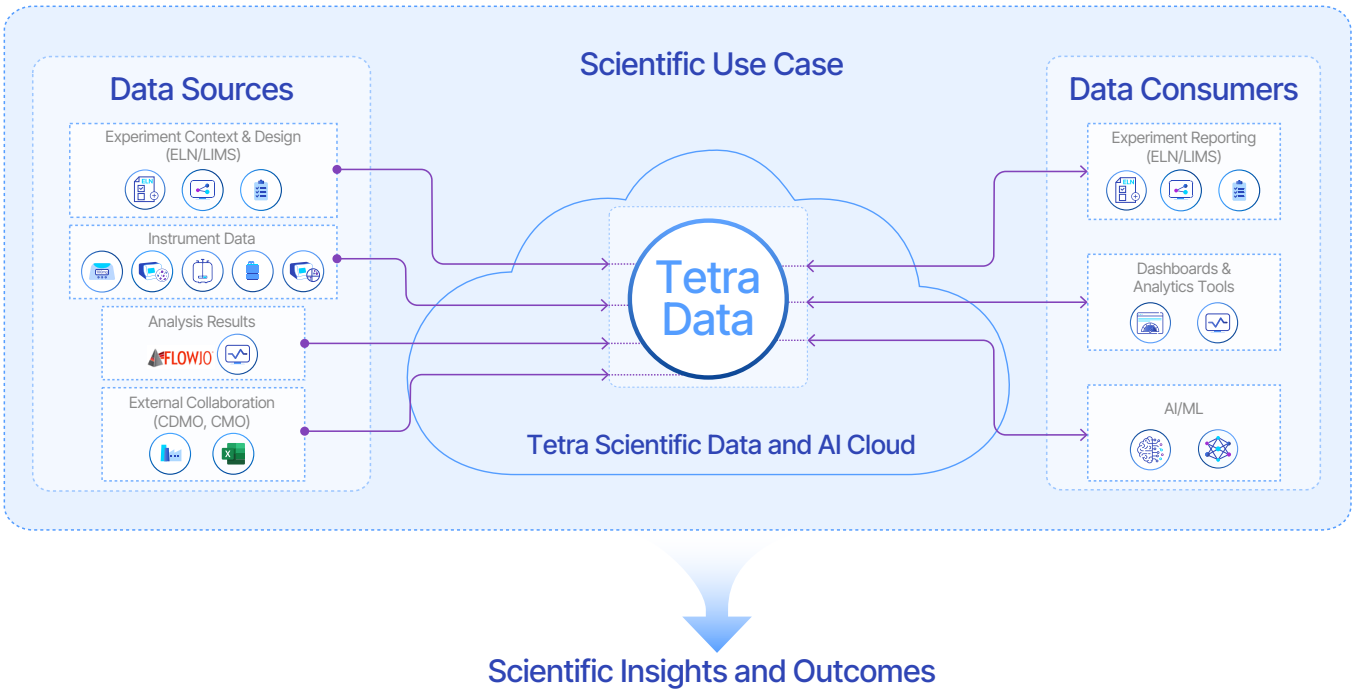
- Detecting anomalies by applying large language models to content within documents, reviews, and audit trails.
- Preventing deviations using predictive analytics to identify potential issues before they occur.
- Predicting the "expiry" dates of therapeutics based on storage temperature and other environmental factors.
- Accelerating the closure of investigations with AI-assisted root cause analysis.
- Performing real-time release testing (RTRT) or parametric release by controlling process parameters, monitoring product attributes, or both. This approach requires large volumes of historical data to train models capable of analyzing complex patterns in product and process data.

Focus on outcomes

When biopharmaceutical organizations embark on the digital QC journey, they often encounter delays, project gaps, and underwhelming outcomes. This typically occurs when the focus is solely on technology rather than the ultimate goal: achieving meaningful scientific outcomes.

The Tetra Scientific Data and AI Cloud is purpose-built with science at its core. This is reflected in the science-specific contextualization of data and a focus on **scientific use cases** to deliver well-defined scientific outcomes.

We support key scientific use cases in quality testing workflows through lab data automation, including batch release and stability for small molecules, biologics, cell and gene therapies, and oligonucleotides. Our solutions integrate with typical instruments and applications, optimize how users interact with data, manage relevant metadata, and streamline modality-specific workflows. This helps eliminate tedious and error-prone tasks while improving the user experience and lab productivity. With our Tetra Data Apps, we enable scientists to derive new insights from vast amounts of historical and current data through visualizations and analytics, forming the substrate for AI/ML. The result is faster, data-based decisions.



Summary

Biopharmaceutical organizations that adopt a data-centric, digital approach to quality testing can significantly reduce the time from sampling to product release by implementing automated, connected workflows. Across modalities, they can also gain a better data-driven understanding of their manufacturing processes with analytics- and AI-ready Tetra Data and swiftly adapt processes based on insights and predictions. This accelerates time-to-clinic and time-to-patient, reducing batch inventory, accelerating revenue realization, and fulfilling patient needs earlier. The Tetra Scientific Data and AI Cloud empowers these organizations with a digital, future-proof approach to QC.

Next steps

Contact us to discuss your scientific use case