tetrascience

Solution Brief

GxP for the Scientific Data and AI Cloud

The TetraScience approach to GxP

TetraScience employs a comprehensive approach to regulatory compliance, ensuring customer data is accurate, traceable, and secure while adhering to essential industry guidance and standards, including Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Automated Manufacturing Practices (GAMP 5 2nd edition), Food & Drug Administration (FDA) 21 CFR Part 11, FDA Computer Software Assurance (CSA) Guidance, and EU Annex 11. This approach comprises three main pillars:

- Quality Management System (QMS)
- Compliance by Design
- GxP Package

Quality Management System

TetraScience maintains an ISO 9001–certified Quality Management System (QMS) comprising the policies and procedures required to ensure a high level of product quality and continuous improvement. This QMS includes a internal audits, external certification audits, and IT governance, risk, and compliance (GRC).

Software Development Lifecycle (SDLC)

The SDLC standard operating procedure (SOP) ensures that development teams have a consistent process to follow as products are developed. The procedure includes quality checks at various stages, including software hazard analysis, verification testing, compliance review, and validation testing. These components ensure that the process is built with quality in mind, and that TetraScience product and engineering teams follow this process for every release.

Training

Employee training is an integral part of the QMS. All new employees that perform tasks affecting product quality or data integrity are assigned training to ensure understanding of policies and procedures. As these quality documents are updated, retraining is assigned as appropriate. Completion of training is monitored and tracked as a key metric for management review.

Accelerate your journey to quality and compliance

80%

reduction in validation effort

2-3x

return on investment (ROI)

$^{2}/_{3}$

reduction in deployment time

Simplify

change management

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Audits and Certifications

Internal audits are conducted on a regular basis to ensure that policies and procedures are being followed, and that documentation is robust and compliant with quality standards. Third-party audits are performed by accredited companies to maintain certifications, such as ISO-9001 (QMS), ISO-27001 (security), and SOC-2 Type II (trust). In addition, TetraScience customers who have opted for the **GxP Package**, and have GxP supplier assessment requirements, are able to perform audits of the QMS. Observations and findings are incorporated into the continuous improvement process.

Security and Trust

In addition to GxP standards, the QMS includes industry-standard software-as-a-service (SaaS) security and trust components to ensure customers' data is protected. The following areas are addressed by a combination of commercially available or TetraScience-developed tools and processes:

- Access and asset management
- Business continuity and disaster recovery
- Data classification and protection
- Monitoring and incident response
- Penetration testing
- Security policy management
- Security awareness training
- Secure software development
- Security risk management
- Third-party assessments

Compliance by Design

In addition to the QMS, TetraScience products are designed with the GxP customer in mind. Features are driven by scientific use cases, many of which take place under regulatory control. Products are designed to satisfy ALCOA++ principles, adhere to GxP data regulations and guidelines, and to comply with the FDA's 21 CFR Part 11 for electronic records. Integration, data centralization, and metadata enrichment ensure data integrity, traceability, and accountability. These functions are included in the validation testing that is done and available in the GxP Package.

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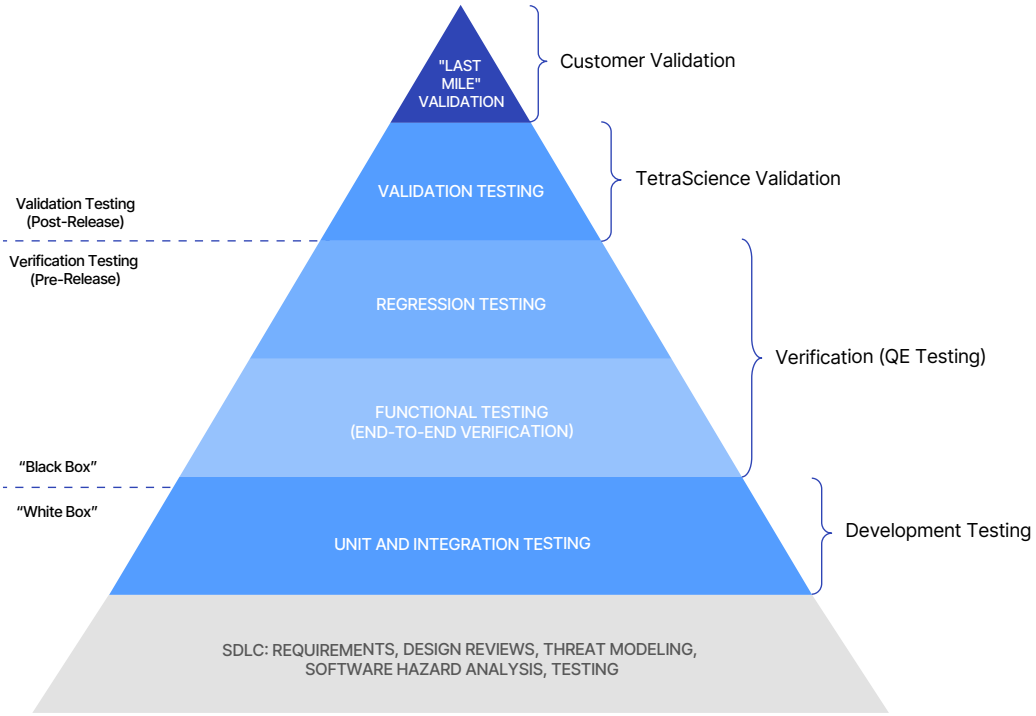
The TetraScience Testing Pyramid



Tetra GxP Package

To help customers take advantage of the efficiencies of the CSA framework, TetraScience has developed an industry-leading GxP Package that provides regulated customers an accelerated path to validation. Among the benefits are:

Verification and Validation (V&V) Document Set

A fully executed and approved document set comprising Requirements and Traceability, Validation Scripts, and Summary Reports for the following components:

- Scientific Data and AI Cloud Platform
- File-Log Agent
- Empower Agent
- UNICORN Agent
- Chromeleon Agent
- LabX Agent

These document sets are part of a growing list of productized integrations that have documentation developed. See the Roadmap section below for upcoming additions. These documents are revised and reissued with every major or minor release of the platform and integrations. For customers who have adopted state-of-the-art CSA principles, this document set can reduce their validation effort by ~80%.

> "TetraScience is ahead of the competition in regards to GxP. The Tetra GxP package looks robust. We need a vendor who does the validation with each release."
> *– Customer Success PM, Global Biotechnology Company*

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Sample Requirements and Traceability

Category	Requirement	Validation Testing
UR-2 Administration	UR-12 The system must support the ability to apply namespaces for permission management.	GX-T4 Intermediate Data Schema (IDS) and Search
	UR-13 The system must support the ability to generate service users and obtain JSON Web Tokens (JWT) for API authentication.	GX-T5 Service User Account Management
	UR-14 The system must support the ability to manage organizations and switch between them.	GX-T3 Administrative Functions
	UR-15 Password Policies (complexity, reuse, expiry, account lock, self-service reset)	GX-T3 Administrative Functions
	UR-16 The system must support configuration of the Audit Trail (on/off)	GX-T3 Administrative Functions
	UR-17 The system must support configuration of the Change Reason (on/off)	GX-T3 Administrative Functions
	UR-19 The system must allow an Administrator to Add/Edit/Disable Users and Assign Roles	GX-T3 Administrative Functions
	UR-20 The system must support the ability to download.	GX-T4 Intermediate Data Schema (IDS) and Search
	UR-21 The system must support the ability to download files in bulk.	GX-T4 Intermediate Data Schema (IDS) and Search
	UR-22 The system must encrypt data in transit.	GX-T3 Administrative Functions
UR-3 Compliance		
	UR-24 The system must be restricted to authorized users.	GX-T3 Administrative Functions
	UR-25 The system must support the retention of all historical files.	GX-T11 Pipeline Processing
	UR-26 The system must support the ability to provide detailed audit trails for user actions that occur within TDP.	GX-T2 Audit Trail
	UR-27 The system must support the ability to export audit trail data in a readable format.	GX-T2 Audit Trail
	UR-28 The system must have an option to require a reason for change for user-initiated changes, that is written to the Audit Trail.	GX T2 Audit Trail, GX-T3 Administrative Functions

Sample Validation Script

TetraScience, Inc
Tetra Data Platform

Validation Testing
DCC-4

Description:

GX-T2 **Audit Trail**

Step	Description	Expected Result
1	Verify that the 'GTX-10 File Upload & Pipeline Design' test has been executed in this test cycle prior to executing this test.	The 'GTX-10 File Upload & Pipeline Design' test has been executed in this test cycle.
2	From the hamburger menu, select Administration > Audit Trail.	Actions taken during the execution of this Test Cycle are displayed, including Entity, Entity Type, User ID, time, date, and Change Reason. (UR-26)
3	Click on 'View Change' for the entry that modi ed Labels for the le from 'GTX-10 File Upload & Pipeline Design' test, 1617625657592.json.	Change details are displayed, indicating the old value and the new value of what was changed.
4	Click on 'View Change' for the entry that modi ed Metadata and Tags for the le from 'GTX-10 File Upload & Pipeline Design' test, 1617625657592.json.	Change details are displayed, indicating the old value and the new value of what was changed.
5	Select several les by checking the checkbox at the left of each entry.	N/A
6	Click the 'Export X Selections as CSV' button and open the downloaded le.	File contains the same information as the audit trail, and is in a human- readable format. Reason for change is present in the 'after' column. (UR-27)

Test results:

Passed Jun 09, 2023 by Daniel Reed

Tested requirements:

UR-26 The system must support the ability to provide detailed audit trails for user actions that occur within TDP.

UR-27 The system must support the ability to export audit trail data in a readable format.

UR-28 The system must have an option to require a reason for change for user-initiated changes, that is written to the Audit Trail.

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> "Overall, the validation documentation is critical to our business and compliance requirements. As the experts of the application, they possess in depth knowledge of the enhancements which focuses the validation on the impacted functionality ensuring the system is fully tested. This allows us to utilize TetraScience's validation package as our internal proof the system is performing as intended." *– Head of Business Systems, Gene Therapy CDMO*

Release Cadence

GxP Package subscribers have a delayed release to production to allow for internal validation activities in their test environment.

Change Control

With each release, a GxP assessment is performed to identify GxP-relevant feature changes and ensure they are added to the validation testing and documentation. Testing evidence is provided, allowing customers to reduce their revalidation effort.

ROI

A typical system implementation and validation takes 6 months to complete and 1-2 months for subsequent change control. The cost of doing a traditional in-house validation project is considerable, given all of the roles and time required to develop artifacts from scratch. We estimate that our pre-built GxP package will produce a 2-3x return on investment (ROI) and accelerate platform availability for your scientists by 3-4 months, allowing them to shift their efforts away from validation documentation and toward the science that is their true expertise.

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Roadmap

TetraScience is continuously expanding the GxP package to include instrument-specific validation packages for productized integrations, bringing further value to the package and further reductions in customers' validation efforts.

In specific cases, TetraScience supports external testing of the Tetra Scientific Data and AI Cloud™ and software agents on live lab instrumentation. Where applicable, this testing is available as part of the respective instrument-specific package.

Summary

TetraScience delivers data replatforming, engineering, harmonization, enrichment, and data pipelines under rigorous quality controls and with high data integrity. Our product features, security principles, and alignment to the tenets of 21CFR Part 11 and ALCOA++ help ensure your data is safe, secure, accurate, and FAIR. By coupling the Tetra Scientific Data and AI Cloud with the GxP Standard Package, you can standardize and automate industry best practices throughout your development; QC; chemistry, manufacturing, and controls (CMC); and manufacturing processes.

Ready for an **80% reduction** in validation effort?

Reach out to a Tetra GxP expert

TetraScience—Enabling AI-based scientific outcomes

TetraScience is the Scientific Data and AI Cloud company with a mission to radically improve and extend human life. TetraScience combines the world's only open, purpose-built, and collaborative scientific data and AI cloud with deep scientific expertise across the value chain to accelerate and improve scientific outcomes. TetraScience is catalyzing the Scientific AI revolution by designing and industrializing AI-native scientific data sets, which it brings to life in a growing suite of next- generation lab data management products, scientific use cases, and AI-based outcomes. For more information, please visit tetrascience.com.

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FAQs for the TetraScience GxP Package

Q: What are my biopharma peers doing?
A: Forty percent of TetraScience customers are running GxP-relevant workflows in the platform today.

Q: Our procedures require that we follow a traditional Computer Systems Validation (CSV) process. Will the GxP Standard Package work for us?
A: As TetraScience has elected to align with the most recent FDA and GAMP 5 guidance around CSA, the package does not include traditional CSV artifacts, like IQ, OQ, and PQ and separate URS, FRS, etc., which are no longer considered best practice. All of the content required to demonstrate intended use is included in the consolidated documents provided. Ideally, customers can update their SOPs to align with/allow for the CSA approach, but it can still be used by simply explaining the rationale for the apparent deviation in the Validation Plan and mapping the provided CSA artifacts to their CSV framework (see *GAMP 5, Table 4.1*). For more information on TetraScience's verification and validation strategy, please visit tetrascience.com.

Q: What happens if a customer doesn't purchase the GxP Package?
A: Without the GxP Package, the customer would be responsible for the entirety of the validation effort, from developing user requirements through developing and running their own validation scripts with appropriate documentation. This would constitute a "build" vs. "buy" solution, which means the customer also undertakes the ongoing maintenance and upgrading of their built controls. TetraScience would only provide release notes. In contrast, subscribers to the industry-leading TetraScience GxP Standard Package receive a comprehensive V&V documentation set that can be leveraged by customers employing a CSA approach to validation.

Q: What are the observed benefits of electing the GxP Standard Package?
A: Customers have reduced their validation effort by up to 80%, corresponding to a 2-3x return on investment. These savings also apply to change control efforts; upon release, detailed release notes are mapped by the TetraScience compliance team directly into an updated validation package.

Q: Will I receive a certificate or other approval from TetraScience for using this platform in GxP?
A: The FDA and other regulatory bodies do not recognize a "GxP certificate" endorsing software or digital systems for GxP use. TetraScience can provide our V&V documentation to customers to leverage, but cannot "certify" them for GxP use.

Q: Does the Tetra Catalyst engagement include last mile validation?
A: While we don't currently provide validation services (i.e., creating and executing validation documentation) for the last mile, our Sciborgs do provide expertise in setting up use cases in your environment, and produce a detailed system design document (SDD) that can be used as a basis for your last mile validation. In addition, our compliance team has developed template documents for common testing activities (e.g., validation plan, configuration, end-to-end testing) to further accelerate your last mile validation efforts.

Q: How does GxP hosting work with the Tetra Scientific Data and AI Cloud?
A: Customers electing to host in TetraScience multi-tenant (MT) or single-tenant (ST) environments accrue specific benefits, including:

- The Tetra Scientific Data and AI Cloud can have multiple deployments (e.g., Dev, Test, and Prod) to allow for a staggered release in order to allow time for "last mile" validation activities
- Access to new features in your pre-production deployments as soon as the release is generally available
- Planned version updates with new functionality are released approximately four months apart, with detailed release notes published on TetraScience product documentation site
- Customers are informed ten weeks ahead of each standard deployment to provide time for internal validation processes
- New functionality is assessed for GxP impact to help customers plan for their "last-mile" validation efforts
- Patches containing non-GxP-impacting changes are released as needed, but TetraScience does not release GxP-impacting features in patch releases

Q: Can we have a short call to learn more and see sample documentation?
A: Yes! Please request a demo today.

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