tetrascience | The Scientific Data and AI Cloud

Verification and Validation Strategy

FACT SHEET

Executive Summary

This document outlines the Verification and Validation (V&V) strategy employed by TetraScience to ensure products—including the Tetra Scientific Data and AI Cloud™, agents, and connectors—perform as intended against user requirements. It provides details on all deliverables necessary to establish a validation baseline, thereby reducing validation burden significantly. It should be noted that a customer purchasing this package is still responsible for defining and ensuring the "last mile" validation of their own specific configuration, as well as any other activities required by their internal procedures.

Strategy

Quality Management System

TetraScience has an ISO 9001–certified Quality Management System to ensure the quality and reliability of our software products. This includes a software development lifecycle (SDLC) which ensures that the software can be easily validated for intended use in regulated life science environments. Processes and procedures are aligned with various GxP regulations and standards, including *21 CFR Part 211, 21 CFR Part 820, 21 CFR Part 58, 21 CFR Part 11, EU Annex 11, ISO 13485:2016, FDA Computer Software Assurance guidance, and ISPE GAMP 5, 2nd Edition.*

Supplier Assessment

TetraScience uses Amazon Web Services (AWS) Infrastructure as a Service (IaaS) to host the Tetra Data Platform (TDP). A supplier assessment was performed, consisting of an audit of relevant third-party certifications and standards, including *ISO 27001, SOC 1, SOC 2, SOC 3, ISO 9001, ISO 27701, and NIST 800:53*. The conclusion of the audit was that AWS control attestations provided are supportive of GxP compliance for SaaS delivery of the Tetra Data Platform. AWS was added to TetraScience's Approved Supplier List and will be reviewed periodically as per our Supplier Management SOP.

Infrastructure as Code

TetraScience utilizes Infrastructure as Code (IaC) for the automated provisioning of the virtual infrastructure supporting the Tetra Scientific Data and AI Cloud. IaC processes are managed via configuration management and the use of version-controlled templates. These templates dictate all of the components in the stack for each curated version, so every installation of that version can only contain components that are identical to every other installation of that version. The usage of IaC not only enables automated and consistent provisioning but also reduces the risk of errors by removing manual, human configuration. This allows for the "one qualification, many deployments" approach to be taken for standard virtualized environments, making revalidation of infrastructure unnecessary, as the entire process has already been shown to be successful. *See Appendix M11 – IT Infrastructure of GAMP 5 Second Edition for more information on Infrastructure as Code*.

TetraScience's IaC is managed via CloudFormation and Amazon Web Services (AWS) by TetraScience's DevOps and Engineering teams. IaC deployments consist of deploying a service layer and a data layer. The service layer version is the version displayed within the TDP application (e.g., v3.7.2). For consistency, both layers are versioned to be aligned on every release, even if one or the other had no changes. Upon deployment, the system verifies that both the service layer and data layer have been successful and a "Succeeded" status is shown. Successful infrastructure upgrade/installation can be easily verified by the customer by simply viewing the version upon login to their environment.

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Verification & Validation

TetraScience employs current best practices for development, verification, and validation of the Tetra Scientific Data and AI Cloud. This includes an Agile development methodology as well as modern risk-based verification and validation. These processes are in line with current regulatory and industry guidance, such as those cited above.

Note that these processes do not follow the legacy "waterfall" Computer System Validation (CSV) approach or the widely adopted—but outdated—Pharma Process Validation "IQ/OQ/PQ" terminology. Documents have been consolidated for efficiency, while still providing robust validation coverage. See ISPE GAMP5 2nd Ed. Table 4.1 for a mapping of legacy qualification terminology to current best practices.

Verification is part of the development process and comprises iterative tests of various types performed within the Agile methodology, including functional and regression testing. Validation is testing of the final release against user requirements using scripts based on user workflows. Electronic tools and automation are used wherever possible in order to maximize efficiency.

Computer Software Assurance

Recent guidance on risk-based validation has been released by both the FDA (Computer Software Assurance for Production and Quality System Software) and ISPE (GAMP 5, 2nd Edition). A significant change introduced in these guidance documents is the concept of Computer Software Assurance (CSA) as a more risk-appropriate process than the historical practice of using Computerized System Validation (CSV) as a one-size-fits-all methodology.

There are two main features of these guidance documents that reduce the burden of validation. First, they explicitly suggest that regulated companies (TetraScience customers) leverage testing executed by the supplier (TetraScience). The more robust the documentation provided, the more it can be leveraged by the customer. Second, they explicitly allow various types of less formal testing, such as ad hoc testing and unscripted testing for lower-risk functionality and/or changes. This can complement the validation testing to provide additional assurance with minimum burden.

GxP Impact Assessment

As part of the release process, all new functionality undergoes a GxP impact assessment to determine validation needs for GxP installations. Each item is assessed for its impact or potential impact on data integrity (ALCOA++ principles), applicability with respect to satisfying regulatory requirements, and applicability to GxP intended use. Those that are assessed to be GxP-relevant are added to the validation requirements and testing documentation for that release. New functionality that does not directly affect GxP, such as features added for improved usability, supportability, and performance are not included in the validation package, and reliance remains on the verification testing performed within the SDLC. Enhancements and bug fixes do not generally affect intended use for validation purposes. The outcome of this assessment is included in the release notes to aid in customer review. As with validation in general, impact and risk assessment are ultimately the responsibility of the regulated company (customer).

Releases and Change Control

New versions of the Tetra Scientific Data and AI Cloud are released ~3 times a year; agents and connectors are updated as needed and made available for elective upgrade on a release cycle separate from that of the platform and have a separate documentation set. With each Minor release (e.g., 3.6 → 3.7), new functionality included in the release is reviewed and the GxP documentation package is updated accordingly. Patch releases (e.g., 3.6.0 → 3.6.1) contain bug fixes and enhancements that do not affect intended use and, therefore, validation status and documentation. Release Notes are provided with every release to facilitate assessment under customers' change control procedures, and describe new functionality, enhancements, and bug fixes. If the new functionality section is empty (i.e., for patch releases), you should be able to accept the change with minimal effort, based on a scalable risk-based change control process.

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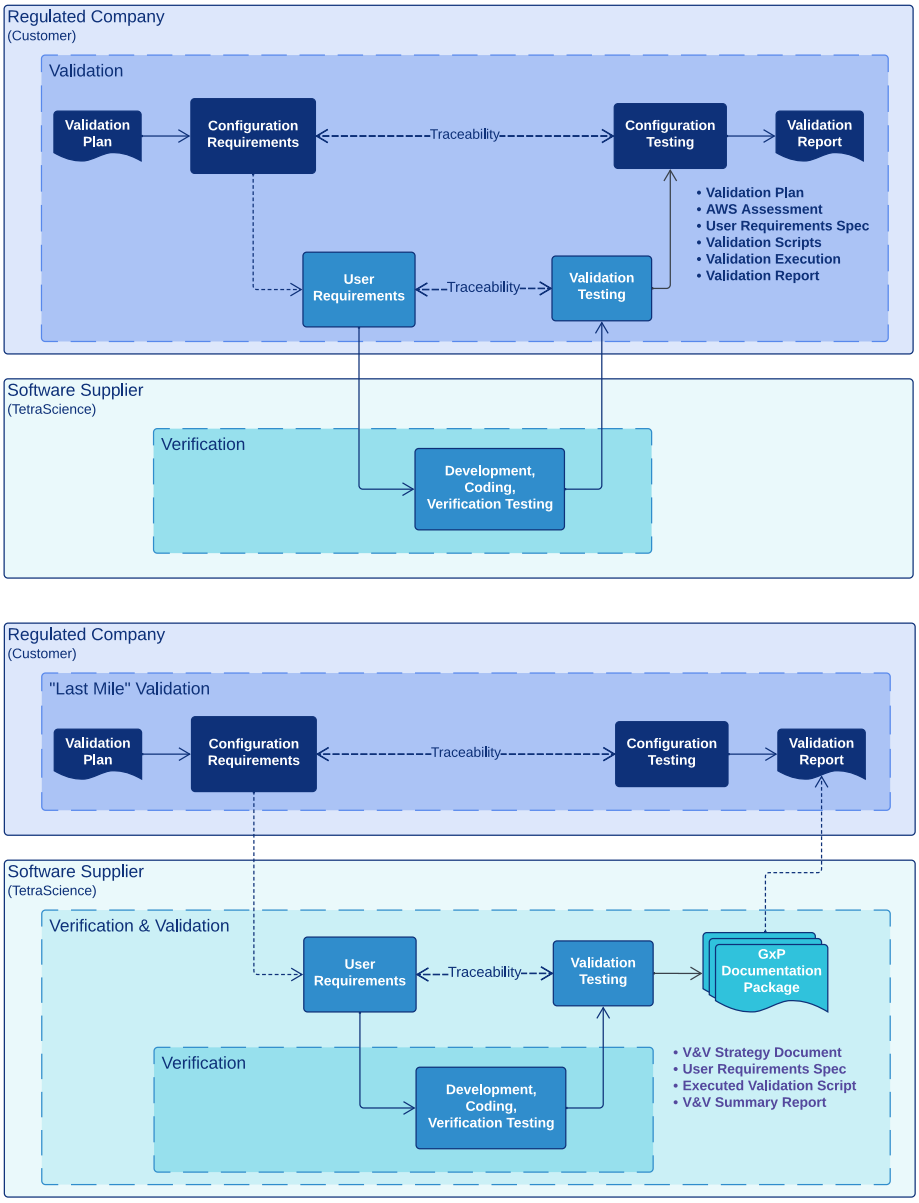
TetraScience GxP Package

In order to help customers take advantage of the efficiencies of the CSA framework, TetraScience has developed a GxP package that offers regulated customers an accelerated path to validation.

Historically, regulated companies were required to perform and document all validation activities in-house. While they could rely on supplier assessments to assure that proper SDLC practices (for design, development, and verification testing) are in place, validation was entirely the responsibility of the regulated company, as illustrated below.

The cost of doing a traditional in-house validation project is considerable, given all of the roles and time required to develop validation artifacts from scratch. TetraScience offers a GxP package that contains fully executed validation documents which demonstrate proper functioning of standard user requirements for intended use. By employing this approach, the validation burden for the platform and productized integrations is shifted to TetraScience, reducing customer validation effort by ~80-90% through leveraging of validation documentation and scalability of "last mile" validation testing (ad hoc, unscripted, etc.). We estimate that our pre-built GxP package will produce a 2-4x 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 towards the science that is their true expertise.

Verification testing (the bottom box in the diagram) is summarized in the V&V summary report, but detailed execution documentation is not included in the GxP package, as it is focused on the validation testing. As in the traditional model, verification can be assessed during a supplier assessment.



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The table below details the documents provided with the GxP package and the recommended documentation to be generated by the customer.

TetraScience GxP Package	Customer's Responsibility (Recommended)
V&V Strategy (this document)	Validation Plan
User Requirements and Traceability Matrix	Configuration Specification and Traceability Matrix
Executed Validation Scripts	Configuration Verification Script
V&V Summary Report	Validation Summary Report

Summary

TetraScience has developed this strategy to ensure that TDP meets the GxP requirements for our customers. This Verification & Validation strategy has been created with the latest guidance in mind, enabling customers to adopt the recent CSA guidance, and leverage supplier documents in order to significantly reduce validation burden.

References:
Computer Software Assurance for Production and Quality System Software (FDA)
ISPE GAMP 5, 2nd Edition

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