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Tetra Data Platform (TDP) 21 CFR Part 11 Assessment

ASSESSMENT GUIDE

Executive Summary

TetraScience provides the world's first open Scientific Data Cloud, with a mission to transform life sciences, accelerate discovery, and improve human life. Tetra Scientific Data Cloud™ enables easy access to centralized, harmonized, and actionable scientific data for the biopharmaceutical industry.

The Tetra Scientific Data Cloud, based on the Tetra Data Platform (TDP), supports use cases in biopharma, including but not limited to: screening, pre-clinical testing, model development, ADME-Tox, pilot plant synthesis, bioprocessing, manufacturing, and quality control / release testing. Regulated industries typically expect suppliers to comply with FDA Predicate Rules for Good Laboratory Practices, Good Manufacturing Practices , and Good Clinical Practices (collectively referred to as "GxP"), as well as those specific to Electronic Records, Electronic Signatures, and Computerised Systems, e.g., 21 CFR Part 11, EU Annex 11.

This technical reference document is specifically intended to assess the compliance of TDP with requirements for Electronic Records and Electronic Signatures as outlined in 21 CFR Part 11.

Overview

21 CFR Part 11 (Part 11, for short) is a Federal Regulation issued by the FDA in 1997 that defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records required by FDA Predicate Rules. Part 11 applies to drug makers, medical device manufacturers, biotech companies, biologics developers, Contract Research Organizations (CROs), and other FDA-regulated industries. It requires that they implement systems validation, audit trails, security controls, and documentation for software and systems involved in processing the electronic data that FDA Predicate Rules require them to maintain.

Applicability

The regulation is divided into three subparts:

1. **General Provisions**
2. **Electronic Records**
3. **Electronic Signatures**

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Each of these subparts outlines the controls required to establish compliance. Some of the controls are technical/automated (i.e., can be addressed through system configuration/design) and some are procedural in nature (i.e., must be implemented via policies and procedures). TDP is designed to address the technical controls in order to be Part 11 compliant by design. Procedural controls are usually the responsibility of the customer/regulated company, with some being a shared responsibility, as noted in the Assessment section.

Section	Section Title	Applicability
§11.10	Controls for Closed Systems	This section applies to all systems containing GxP Electronic Records. In scope for TDP.
§11.30	Controls for Open Systems	TDP is a cloud-based SaaS system, and as such, meets the definition of an Open System. In scope for TDP.
§11.50	Signature manifestations	There are no workflows in TDP that would require an electronic signature.
§11.70	Signature/record linking	
§11.100	Electronic Signatures - General Requirements	
§11.200	Electronic signature components and controls	
§11.300	Controls for identification codes/passwords	

Assessment

The following table outlines the requirements of Part 11 as interpreted by TetraScience, and the assessment of compliance with respect to the TDP.

Section	Requirement	Assessment	Responsibility
§11.10 Controls for Closed Systems			
§11.10(a)	System must be validated for the customer's intended use.	System Validation is the responsibility of the customer/regulated company. TetraScience does perform GxP/Part 11-compliant Verification and Validation testing as part of our Software Development Lifecycle (SDLC).	Shared
§11.10(a)	System must be able to discern invalid or altered records.	A checksum is used to verify equivalence of files imported to the system. Changes to records are captured in an audit trail.	TetraScience

Section	Requirement	Assessment	Responsibility
§11.10 Controls for Closed Systems			
§11.10(a)	System must be maintained in a validated state.	Validation Maintenance (Change Control) is the responsibility of the customer/regulated company. TetraScience partners with GxP customers to work within their Change Control process, e.g., for upgrades.	Shared
§11.10(b)	Electronic records must be available for inspection, review, and copying, in both human-readable and electronic form.	Electronic records can be viewed in the system and exported in electronic and human-readable form.	TetraScience
§11.10(c)	Records must be readily retrievable throughout the retention period.	All records are live in the system until they are archived by the customer per their procedures. Retention of archived files is the responsibility of the customer.	Shared
§11.10(d)	Access must be restricted to authorized users.	Access to the system is restricted to authorized TetraScience users. Access Management for the customer's users is the responsibility of the customer. The system is designed to use the customer's preferred method of authentication.	Shared
§11.10(e)	System must have an audit trail, recording the username, time/date stamp for user-initiated changes to GxP data, and must retain the original value.	User-initiated changes are captured in an audit trail, including username, time/date stamp, old value, new value, and reason for change. The audit trail is not editable.	TetraScience
§11.10(e)	Audit trail records must be retained.	Audit Trail records are retained in the system indefinitely.	TetraScience
§11.10(f)	System must enforce sequence of steps, as appropriate.	Pipeline configuration allows for sequencing of task scripts in the pipeline protocol.	TetraScience
§11.10(g)	System must have configurable privileges within the system.	The system has three user types with varied access privileges: Read-Only, Member, and Admin.	TetraScience
§11.10(h)	System must use device checks to determine validity of the data source.	The system uses instrument-specific protocols to import, convert, validate data. System checks verify the correct data source is connected.	TetraScience

Section	Requirement	Assessment	Responsibility
§11.10 Controls for Closed Systems			
§11.10(i)	Users must be trained.	User Training and associated records are the responsibility of the customer/regulated company. TetraScience does provide training as a service and provides customers with documentation for their records. TetraScience employees undergo training as part of our internal Quality System policies.	Shared
§11.10(j)	Company must have an e-Sig SOP.	N/A – electronic signatures are not implemented in the system.	N/A
§11.10(k)1	Manuals and System SOPs must be maintained and controlled.	User manuals are available on the TetraScience website, and are kept current with every release, as per our SDLC and documentation procedures. System SOPs are the responsibility of the customer.	Shared
§11.10(k)2	All systems documentation must be under change control.	System documentation is version-controlled per software release.	TetraScience
§11.30 Controls for Open Systems			
§11.30	Open systems must employ controls to ensure authenticity, integrity, and confidentiality of the data, including those listed above and encryption.	All data is encrypted in transit and at rest on the AWS Infrastructure.	TetraScience

Summary

TetraScience delivers data integration, harmonization, enrichment, and pipelines under rigorous quality controls and with high integrity. Our product features are designed to enable customers to validate the system for Electronic Records requirements outlined in 21 CFR Part 11. An internal assessment was performed by the Quality and Compliance group to identify any gaps in coverage of these requirements, and all relevant requirements were found to be met. Some items are a shared responsibility of TetraScience and the customer, as noted above.

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TetraScience is the Scientific Data Cloud company with a mission to transform life sciences, accelerate discovery, and improve and extend human life.

To learn more on how to optimize processes and accelerate discovery, visit tetrascience.com

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