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GXP MENTOR · TEMPERATURE MONITORING SYSTEM

21 CFR Part 11 Compliance Statement

Self-declaration by GxP Mentor (Pty) Ltd of how the GxP Mentor TMS Data Visualisation Tool supports the requirements of Title 21 CFR Part 11 for the electronic records it creates and manages.

GXP001001-SD-CS-01 · Version 1.0 · tms.gxpmentor.com

GAMP 5 Cat 5 | 21 CFR Part 11 | PIC/S Annex 11 | ALCOA+

SCOPE AND LIMITATIONS

The system. The GxP Mentor TMS Data Visualisation Tool (tms.gxpmentor.com) is a reporting and data-visualisation layer. It retrieves environmental-monitoring data from a validated source system (the iMonnit platform) through a documented API and produces consolidated, multi-sensor reports and trend analysis for quality review.

Validated state. The system has completed the full computerised-system validation lifecycle (DQ, IQ, OQ and PQ) to GAMP 5 (Second Edition) Category 5. Validation Certificates are issued as per change and validation cycles, and the system is maintained under formal change control.

What this statement is not. Deploying the GxP Mentor TMS Data Visualisation Tool does not, by itself, make an organisation 21 CFR Part 11 compliant. The GxP Mentor TMS Data Visualisation Tool provides Part 11 controls for the electronic records it creates and manages. The raw sensor readings remain in the validated source system, which maintains its own Part 11 compliance. The customer's quality management system and standard operating procedures govern procedural controls and the use of electronic signatures.

SECTION 11.10 CONTROLS FOR CLOSED SYSTEMS

Requirement	Status	How the GxP Mentor TMS Data Visualisation Tool meets it
(a) Validation for accuracy, reliability, intended performance and the ability to discern altered records	• Compliant	Full DQ, IQ, OQ and PQ lifecycle, GAMP 5 Category 5, maintained under the current Validation Certificate. Changes run under formal change control; audit trails expose altered records.
(b) Accurate and complete copies in human-readable and electronic form	• Compliant	Reports render as PDF (human readable) and export as CSV (electronic); a per-sensor ZIP contains raw CSV and PDF.
(c) Protection of records for ready retrieval throughout the retention period	• Compliant • Source system	Reports are read-only; data is held in PostgreSQL with row-level security; deactivated accounts are retained. Quality and validation records are retained for a minimum of the life of the system plus five years (GXPM-SOP-001). Retention of the raw source readings is a function of the validated source system.
(d) Limiting system access to authorised individuals	• Compliant	Unique email and password per individual; role-based access per organisation and per page; two-tier lockout; 15-minute idle timeout.
(e) Secure, time-stamped audit trails that do not obscure prior entries	• Compliant	The audit log records action, before-and-after values, user, email and timestamp for create, update and delete, and for verify, sync, send, preview, lockout and unlock. Lockout and unlock were added specifically for Section 11.10(e). Entries are append-only in normal use.
(f) Operational system checks to enforce permitted sequencing of steps	• Where applicable	Operations are gated by role and workflow state where applicable to the reporting functions the system provides.
(g) Authority checks so that only authorised individuals perform actions	• Compliant	Role-based permissions (admin and standard user); privileged actions are restricted; insufficient-privilege attempts are logged.
(h) Device (terminal) checks	• N/A	Not applicable to a web-based application.
(i) Education, training and experience of persons using the system	• Customer SOP	Customer responsibility. GxP Mentor supplies the User Manual and in-app guidance; new users are onboarded by email and set their own password on first sign-in.
(j) Written policies holding individuals accountable for signed actions	• Customer SOP	Customer responsibility, governed by the customer's own standard operating procedures.
(k) Controls over systems documentation	• Compliant • Customer SOP	GxP Mentor maintains versioned, change-controlled validation and system documentation; the customer controls distribution of its own copies under its SOPs.

• Compliant - met by the TMS • Customer SOP - procedure is the customer's • Source system - the validated source EMS • N/A - not applicable to the TMS

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HOW THE TMS SUPPORTS PART 11

Authenticity

Access requires a unique email and password per individual with role-based permissions. The system performs consistently as validated. Reports are generated read-only, so altered or invalid records can be discerned against the source.

Confidentiality

Unique credentials, role-based access per organisation and per page, and logical multi-tenant isolation prevent access by unauthorised users. Each client organisation sees only its own data.

Integrity

Records the TMS creates (reports, audit log and configuration) are protected. Reports are produced as fixed PDF and CSV copies; data is held in PostgreSQL with row-level security; sensor readings are never edited in place.

Audit and change control

Every create, update and delete writes a time-stamped before-and-after entry with the acting user to the audit trail (ALCOA+). Logins, login attempts, report downloads, scheduled sends and account lockouts are also recorded.

SECTIONS 11.50 AND 11.70 SIGNATURE MANIFESTATIONS AND RECORD LINKING

TMS-generated reports carry a review and approval sign-off block. Each block states its meaning (Reviewed By or Approved By) and provides fields for the signer's Name or Initial, Signature and Date. Signatures are applied by hand on the report, or through the customer's own Part 11-compliant electronic-signature process. The TMS does not itself apply Subpart C electronic signatures. Because each report is a fixed PDF, an applied signature is bound to that specific report record.

SUBPART C ELECTRONIC SIGNATURES (SECTIONS 11.100 TO 11.300)

Requirement	Status	How the GxP Mentor TMS Data Visualisation Tool meets it
11.100 Each signature unique to one individual and not reused	• Customer / source	The TMS does not apply Part 11 electronic signatures. Access uses a unique email and password per individual (a unique sign-in email is enforced). Where electronic signatures are required, they are governed by the customer's process or the source system.
11.200 Two distinct identification components (ID and password)	• Access control	Sign-in uses email and password (two components). This controls access; it is not represented as an electronic-signature mechanism.
11.300 Controls over identification codes and passwords	• Compliant	Unique ID and password combinations; admin-managed lifecycle (change, reset, revoke); two-tier failed-login lockout (5 in 15 minutes, 10 in 24 hours) with admin unlock; password reset via the registered email; privileged-action attempts are logged.

TABLE 1 AUDIT-TRAIL ENTRIES

Event	Captured	Store
Record create, update or delete	Action, before-and-after values, user, email, timestamp, record, organisation	**audit_log**
Report download (preview) or scheduled send	Action, user, email, timestamp, record	**audit_log**
Account lockout or unlock	Action, user, email, timestamp (Section 11.10(e))	**audit_log**
Successful sign-in	User, organisation, role, timestamp	**login_audit**
Sign-in attempt (success or failure)	Email, outcome, timestamp	**login_attempts**
Scheduled report email	Status, recipient, timestamp, message id	**email_delivery_log**

DECLARATION

GxP Mentor (Pty) Ltd declares that the GxP Mentor TMS Data Visualisation Tool provides the controls described in this statement in support of 21 CFR Part 11 for the electronic records it creates and manages, and that these statements are accurate as they relate to the validated GxP Mentor TMS Data Visualisation Tool and its current Validation Certificate.

Signed by:
A. Nerwich
A7268BFC1CCF468...

2026/10/16 | 09:58:31 SAST

Ari Nerwich
Principal Validation Scientist and Director, GxP Mentor (Pty) Ltd

Date

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