



• GXP MENTOR •

OFFICIAL CERTIFICATION

Certificate of Validation

COMPUTERISED SYSTEM VALIDATION
GAMP 5 CATEGORY 5
VERSION 8

This is to certify that the computerised system identified below

GxP Mentor TMS Data Visualisation Tool

tms.gxpmentor.com

has successfully completed the full Computerised System Validation lifecycle (DQ / IQ / OQ / PQ) in accordance with GAMP 5 (Second Edition) Category 5 for bespoke software, has been maintained under formal change control, and has now completed Change Qualification CQ-05 covering fifteen items across data-layer security hardening, access control, auth + session hardening, frontend security posture, outbound integrity, and operational verification. The validated state reaffirmed under VC-07 (04 August 2026) is hereby reaffirmed and the system is approved for continued routine production operation in a regulated pharmaceutical environment.

CHANGE QUALIFICATION · CQ-05 · 26 AUGUST 2026

Change Qualification GXP001001-CQ-05 (fifteen items across change set CR-2026-08-04-001) successfully executed and closed. Developer 26/26 D-test suites PASS (1,375 assertions). System Owner UAT 14/14 evidence packs PASS. Two items formally CANCELLED (CC-19; SEC-08-A-1); one item formally DEFERRED (T1-05 Enforce phase) to a subsequent Change Qualification. 21 Scope Notes and ~150 adversarial-review findings applied under Cat 5 100% no-partial-fix discipline. Zero deviations from the signed protocol.

GAMP 5 CAT 5

21 CFR PART 11

PIC/S ANNEX 11

ALCOA+

ICH Q1A(R2)

USP <1079.2>

4 / 4

PHASES COMPLETE

50 / 50

BASE CSV TEST
CASES

99 / 99

CQ-01...05 TESTS

1375 /
1375

D-TEST ASSERTIONS

~150 /
~150

ADVERSARIAL
FINDINGS CLOSED

0

OPEN NCS

Signed by:

A. Nerwich

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Ari Nerwich

Principal Validation Scientist & Director
GxP Mentor Pty Ltd

Signed electronically via DocuSign on 26/08/2026 · Certificate of Completion constitutes the audit trail for this electronic signature

VALIDATED
GAMP 5
CATEGORY 5
BESPOKE