AI in GxP Readiness Review

For quality organisations where AI is already at work: drafting deviations, suggesting CAPA, reviewing chromatography, flagging trends, or sitting inside a vendor product nobody has yet called AI.

WHO THIS IS FOR

You have AI in use in QA or QC, or it is weeks away. Some of it arrived through vendors, some through keen teams. Nobody has written down which systems exist, what each is allowed to do, and who signs for its output. An inspector will ask. The April 2026 FDA warning letter (320-26-58) was about exactly that gap: an AI agent wrote GxP documents and nobody in the quality unit reviewed them.

WHAT YOU GET: A WRITTEN REPORT IN 4 PARTS

An inventory of AI in use
every system, including those inside vendor products and copilots, with a risk tier for each.

An ownership statement per system
what it is claimed to do, where the claim stops, and who in the quality unit signs for its output.

The evidence gap
against the draft EU GMP Annex 22, Annex 11, 21 CFR Part 11, GAMP 5 second edition and the FDA CSA guidance, in plain language.

A fix list with owners
in the order that reduces inspection exposure fastest, with the first 90 days mapped.

HOW THE 2 WEEKS RUN

Week 1. A 60-minute kick-off with the sponsor. Document and system access. 3 to 5 interviews of 45 minutes each with the people who own the systems, the data and the approvals.

Week 2. Analysis and the written report. A 60-minute read-out with the sponsor and whoever they want in the room. The report is yours to put in front of an inspector, an auditor or a board.

What it asks of your people: 2 to 3 hours in total, spread over the 2 weeks. The review runs remotely. A site day can be added at actuals if you want one.

₹2,50,000 plus GST · fixed fee

The fee is fixed whatever the review finds. It stays valid for 30 days from the date this outline is sent. A one-page quotation with terms follows your yes, and work starts on the kick-off date we agree.

THE 12 QUESTIONS THE REVIEW ANSWERS

1. Which AI is in use today, including inside vendor products and copilots?
2. Who approved each one, and is that approval recorded?
3. What risk tier does each system sit in, and who signs at that tier?
4. What is each system claimed to do, and where does the claim stop?
5. Where does a human review the output, and is that visible in the record?
6. What data trained or tuned it, and is that data representative of your operation?
7. Is the test data independent of the training data?
8. What evidence exists that it works as intended, and would an inspector accept it?
9. How is drift monitored, and what triggers retraining or withdrawal?
10. How are vendor model updates controlled?
11. What does the audit trail capture for an AI-assisted decision?
12. Could your quality unit answer FDA's question from letter 320-26-58: who reviewed and cleared the AI output?

WHAT HAPPENS AFTER THE READ-OUT

Most reviews end with 3 to 6 fixes that a team can close itself and 1 or 2 that need help: setting up the AI governance so every new use gets a tier, an intended use and an owner; validating the applications already live; and training the team to do the next one without me. Each comes with a scope and a fee. Nothing is assumed.

Fix the findings yourselves	**No fee**
Advisory retainer: I act as your Head of Quality IT and AI governance, agreed monthly hours, independent review, inspection support. 6-month minimum.	**₹2,50,000 a month plus GST**
Project work scoped from the report: governance set-up, validation of live AI applications, CSA transition, or independent review through a go-live	**Quoted from the report**
Team training: Validating AI in GxP, or CSV to CSA with the DRIVE method, 1 day, up to 30 people	**Quoted on request**

WHO RUNS IT

Sachin Bhandari ran Quality IT and GxP compliance for Sun Pharma across 40+ sites for nearly 9 years, then led quality digital work at Boehringer Ingelheim and UCB, where he put AI into live GxP quality systems. He has validated 20+ AI applications in live GxP use and taken 9 of them through health-authority inspection, 6 FDA and 3 MHRA, with zero compliance observations. He contributed to the EU GMP Annex 22 industry review, sits on the GAMP Global Steering Committee, and wrote Validating AI in GxP: A Practitioner's Guide.

To start: reply to the email this came with, or write to sachin.bhandari@trustbridge-compliance.com. Tell me the trigger and the month it needs to be sorted by, and I will send the quotation and 2 kick-off dates. · trustbridge-compliance.com