Inspection Readiness Review: computerised systems

For a site expecting an inspection in the next 12 months, where the computerised systems, the data integrity controls and the CSV paperwork have not been looked at together by someone who has sat on the other side of the table.

WHO THIS IS FOR

Unannounced FDA inspections of Indian sites are now routine, and the revised Schedule M expects computerised systems to be validated and their data controlled. At the same time the CSV programme has grown heavier than the systems it protects: every system gets the same treatment whatever its risk, the backlog grows, and QA capacity goes into paperwork. This review looks at the systems, the data and the paperwork together, the way an inspector will, and tells you what to fix first and what to stop doing.

WHAT YOU GET: A WRITTEN REPORT IN 4 PARTS

The inspector's view of your systems
the inventory, the validated state, data integrity controls and audit trail review for your critical systems, judged the way an inspector judges them.

A right-sized validation approach
critical thinking first, testing scaled to risk using GAMP 5 second edition and CSA thinking, and vendor evidence used properly, so effort goes where the risk is.

The question bank
what an inspector will ask about your computerised systems and what you will show, for your 3 most critical systems, with the gaps named.

A 90-day plan with owners
the SOP changes, the pilot systems, and the decisions that need a signature.

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 systems are in the validated state, and does the inventory match reality?
2. Would your 3 most critical systems pass an unannounced inspection tomorrow, and what would you show?
3. How much of the test effort goes to high-risk functions, and how much to habit?
4. Where is scripted testing used because the SOP demands it rather than the risk?
5. Do you use vendor evidence, and how is it assessed?
6. How long from requirements to go-live for a typical system, and where does the time go?
7. What do your SOPs allow: unscripted, exploratory, ad-hoc testing?
8. Who makes the risk decisions, and are they recorded with rationale?
9. What has an inspector asked about computerised systems in the last 3 inspections?
10. How is periodic review done, and is it current?
11. What is the data integrity picture: audit trail review, access control, backups?
12. How are cloud and SaaS systems handled?

WHAT HAPPENS AFTER THE READ-OUT

Most reviews end with a plan the team can run itself and 1 or 2 things that need help: rewriting the validation SOPs to allow the lighter approach, coaching the team through the first 2 pilot systems, and training the wider group in the DRIVE method for CSV to CSA. 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. He has led paperless validation across 40+ sites, supported 300+ regulatory inspections with zero critical findings, sits on the GAMP Global Steering Committee, and teaches the DRIVE method for the CSV to CSA transition.

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