Validation Readiness Review

For an ERP, LIMS, MES, eQMS or CDS going live in the next 6 months, where the integrator is booked, the date is set, and validation is where the timeline will quietly slip.

WHO THIS IS FOR

A new system is going in. The project plan has a line called validation, owned by someone who also has a day job. The vendor says its package is validated. The integrator says testing is your side. Six weeks before go-live, the validation plan is still a draft and the test scripts are being written from the vendor manual. That is the pattern that moves go-live dates, and it is avoidable if the questions are asked now.

WHAT YOU GET: A WRITTEN REPORT IN 4 PARTS

A validation approach fit to the go-live date
risk-based and scaled, using GAMP 5 second edition and the FDA CSA guidance, with the scripted and unscripted testing split decided.

The intended use and GxP assessment
which functions are GxP, which are not, and what that means for the effort.

A vendor evidence plan
what to take from the vendor and integrator as evidence, what to test yourselves, and what to refuse.

The people and data plan
who approves, who tests, who owns data migration and legacy records, and a week-by-week order to the go-live.

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. What is the go-live date, and what has to be in the validated state by then?
2. Which functions are GxP, and which are not?
3. What is the vendor supplying as evidence, and has anyone read it?
4. What is the split between scripted and unscripted testing, and who decided it?
5. Who signs the validation plan and the summary report?
6. How is data migration validated, and who owns the legacy records?
7. How are configuration and customisation controlled during the project?
8. What are the Part 11 and Annex 11 controls: audit trail, e-signature, access?
9. What does the integrator own and what do you own, in writing?
10. How will change control run from day one after go-live?
11. What is the periodic review plan, and who owns it?
12. What happens to the legacy system, its data and its records?

WHAT HAPPENS AFTER THE READ-OUT

Most reviews end with a validation approach the project can run itself and 1 or 2 things that need help: an independent reviewer through to go-live, a data migration validation, or a hand on the change control set-up for the first 90 days after go-live. 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 validated LIMS, eQMS, ERP (including SAP S/4HANA), MES and CDS at enterprise scale, supported 300+ regulatory inspections with zero critical findings, 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