TRUSTBRIDGE COMPLIANCE

OUTLINE · FIXED FEE · 2 WEEKS

AI and CSA Gap Assessment

In 2 weeks you find out where your validation would struggle in front of an inspector. You also get a plan that puts the fixes in order of risk, with the effort each one takes.

The problem

Most Heads of Quality I talk to have 1 system that worries them. Sometimes it's an AI pilot that went live faster than the procedures around it. It might be an eQMS validated years ago, under a policy that has since been rewritten. Or leadership wants the whole CSV estate moved to CSA, and the team needs a clear place to start.

I read the system and the CSV policy it was validated under together. The policy sets one expectation, the system was often validated to another, and that mismatch is where most findings come from. When the gap is in the policy, other systems validated under that policy probably have it too.

Who it's for

- You lead Quality, QA IT or validation at a pharma, biotech or CDMO company.
- You have an AI pilot, or an AI feature inside a GxP system, and you want to know what the draft EU GMP Annex 22 would expect of it.
- You run an eQMS or another validated GxP system and want an independent read of its validation package before an inspector gives you one.
- Your CSV policy is moving to CSA, and you want to know what has to change first.

The 2-week plan

The clock starts on the day I have your documents and access. The scope is 1 system, your CSV policy and up to 6 procedures that sit under it.

Week 1

KICK-OFF AND DOCUMENT REVIEW

- A 60-minute call to agree the document list, the standards and what High, Medium and Low mean. Settling this on day 1 gives us one standard for the whole report.
- I read the validation package, your CSV policy and the procedures under it.
- The baseline is GAMP 5 Second Edition, EU GMP Annex 11, 21 CFR Part 11 and the data integrity guidance from MHRA, WHO and PIC/S.
- For an AI system I add the draft EU GMP Annex 22 and the ISPE GAMP guidance on AI. For a move to CSA I add the FDA guidance on Computer Software Assurance.

Week 2

INTERVIEWS, READ-OUT AND FINAL REPORT

- 3 to 5 interviews of about 45 minutes with the people who use the system.
- I see the system in use, by screen share or on a day at your site. The documents tell me what was meant to happen, and the interviews tell me what happens on a normal Tuesday.
- You get the draft report, and we walk through it together in a 60-minute read-out.
- I issue the final report with your comments in it, inside the 2 weeks.

What you get

- A written gap report. It opens with a summary of about 2 pages, in plain language, for your leadership.
- A gap register with every finding ranked High, Medium or Low for its impact on patients, product quality and data integrity. Each entry shows the evidence I read, the clause I measured it against and what I recommend.
- A remediation plan. It says what to fix now, what to close within 90 days and what can wait for the next periodic review. Every action has an owner and an effort estimate.
- A short note on which other systems in your estate are likely to carry the same gaps, and a plain statement of anything I couldn't evidence.

If you want, I issue it as a controlled document with a number and a version, which you can show an inspector as evidence of an independent assessment.

What I need from you

Documents

The validation package, any vendor documents you hold, and your CSV policy with the procedures under it.

Access

Read access to the system, or a guided walkthrough over screen share. A day at your site is your choice.

People

3 to 5 people for interviews, and 1 contact who can unblock access. About 2 to 3 more hours of your team's time.

₹4,50,000
plus GST at 18%, for clients in India

USD 9,000
for clients outside India

Price and terms

- The fee is fixed for 1 system, your CSV policy and up to 6 procedures under it.
- It stays the same however many gaps I find.
- Anything beyond that scope goes in a written change note before the work starts.

What comes after

Most teams want help closing what the report finds. That's the remediation programme. I price it on the findings, once you've read them, so the quote matches the work your own report shows. You're free to take the plan and run it with your own team.

About Sachin Bhandari

I do the work myself. I've spent 25+ years in pharma quality IT and digital quality, with global roles at Sun Pharmaceuticals, Boehringer Ingelheim and UCB, and my career record is 300+ inspections, zero critical findings. I validated 20+ AI applications in live GxP use (deviations, queries and CAPA support among them), and took 9 of them through health-authority inspection, 6 FDA and 3 MHRA, with zero compliance observations. I sit on the GAMP Global Steering Committee, I contributed to the EU GMP Annex 22 (AI) industry review, and I wrote *Validating AI in GxP Environments: A Practitioner's Handbook*.

Write to me or call me to fix a start date.

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