SERVICES FOR LIFE SCIENCES COMPANIES · NOVEMBER 2026

Validation, AI governance and training for life sciences companies

Quality and IT leaders in life sciences now get 2 kinds of question. Inspectors want to see that computerised systems are validated in proportion to their risk, which is the thinking behind Computer Software Assurance. Leadership teams want to know how AI in a GxP process is approved and kept under control. We help your teams answer both with evidence an inspector can follow, and we stay with you after go-live.

Advisory, validation and training for life sciences companies, led by one person who has done the work inside global pharma.

Sachin Bhandari leads every piece of advisory work and teaches every programme himself. Where a programme needs hands for execution, such as drafting IQ and OQ protocols from your specifications, TrustBridge's partner firms work on his framework, and he stays accountable for the advice.

TRAINING

Leadership Orientation page 3
Transitioning from CSV to CSA page 4
Validating AI in GxP page 5
Data Integrity and Inspection Readiness page 13

ABOUT US

How an engagement runs page 2
About Sachin Bhandari page 14
Customers, partners and contacts page 15

CONSULTING

Readiness Review page 6
AI QMS setup and monthly support page 7
Validation of AI applications page 8
CSV to CSA transformation page 9
Computerised systems validation page 10
Enterprise Paperless Validation page 11
Quality digital transformation page 12
The book and the Practitioner Pack page 13

Start with the piece that fits the problem you have this quarter

Each service stands on its own. Some clients start with a Leadership Orientation or a Readiness Review. Others start with the training for their validation, QA and IT teams. Each step makes the next one quicker, because your people already share the method.

HOW WE WORK WITH YOU

How an engagement runs

Most clients start with one piece and add the next when they're ready. Each step stands on its own, and each one makes the next step quicker because your people already share the method.

1	**Leadership Orientation** A 2.5-hour session for your leadership on the current regulatory position for AI and computerised systems in GxP. You agree where to focus first, and the fee is credited against the work that follows.	**LED BY** TrustBridge
2	**Training** Your validation, QA and IT teams learn the method they'll use day to day: risk-based CSA for computerised systems, and the TRUST lifecycle for AI.	**LED BY** TrustBridge
3	**AI QMS setup** We adapt a ready set of AI governance SOPs and templates to your QMS. Each AI system then has a procedure to be approved, tiered and validated against.	**LED BY** TrustBridge
4	**Validation of your applications** Each application is tiered by risk and intended use, then validated with a plan, protocols and evidence sized to that risk.	**LED BY** TrustBridge. Sachin sets the strategy and reviews the evidence. Execution partners draft and execute the protocols on his framework.
5	**Keeping them validated** Drift monitoring, hallucination management, periodic review and change control keep each system inside its validated state long after go-live.	**LED BY** TrustBridge. Your team or an execution partner runs the monitoring and changes. Sachin reviews them under the retainer.

What TrustBridge Compliance brings

Advisory and training, led in person by Sachin Bhandari. That covers validation strategy, risk tiering, the AI QMS, independent review of validation evidence, inspection readiness and the 2 training programmes. TrustBridge is independent and product neutral, so its advice is about your risk alone.

How execution is staffed

When a programme needs hands, such as drafting IQ and OQ protocols from your functional specifications or running and documenting the testing, the execution comes from TrustBridge's partner firms, who work on Sachin's framework. Your validation gets the people to execute it and a senior advisor who reviews every piece of evidence and stays accountable to you.

WHY LEADERSHIP TEAMS ARE ASKING NOW

FDA has already written to a firm about its use of AI

On 2 April 2026 FDA issued warning letter 320-26-58, the first to cite AI use in drug manufacturing, under the heading "Inappropriate Use of Artificial Intelligence in Pharmaceutical Manufacturing". The firm had let an AI agent write its GxP documents and then relied on the AI's account of what the regulations required, before anyone in its quality unit had reviewed them. FDA's position is that any output from an AI agent must be reviewed and cleared by an authorised person in the quality unit. Trained reviewers and a governed AI QMS are how a company shows an inspector that this control is in place.

TRAINING · START HERE

Leadership Orientation

A 2.5-hour session that gives your leadership team one shared picture of what regulators now expect of AI and computerised systems in GxP. Sachin keeps it in plain language and relates it to your own systems, so the discussion ends with decisions your team can act on.

WHO IT'S FOR
Heads of quality, IT, operations and product, and the leaders who approve AI and validation budgets. Up to 30 people.

HOW LONG IT TAKES
2.5 hours, live online or at your site.

WHO LEADS
TrustBridge. Sachin Bhandari runs the session himself.

What we do

- Explains the current position on Computer Software Assurance, draft EU GMP Annex 22, the EU AI Act and Part 11, and what each one asks of you
- Walks through FDA warning letter 320-26-58 of April 2026 and the control it points to
- Takes a short readiness snapshot of your own AI use and validated systems
- Agrees the 2 next steps that matter most for your organisation

What you get

- A shared view across your leadership of where you stand today
- Your readiness snapshot, which you keep whatever you decide next
- The 2 next steps in writing, in the order we'd take them
- A clear picture of which training or engagement fits your teams first

A QUESTION CLIENTS ASK

What happens to the fee if we go ahead?

It's credited in full against the first programme or engagement you take on, so a leadership team that decides to proceed pays nothing extra for the session.

RELATED SERVICES

The natural next steps are the training programmes on pages 4 and 5, or the Readiness Review on page 6.

TRAINING

Transitioning from CSV to CSA

A practical programme that moves your team from document-heavy validation to risk-based Computer Software Assurance. Sachin teaches it through his DRIVE framework and adapts the examples to your own systems before the session.

WHO IT'S FOR
Validation and CSV leads, QA and QC, IT compliance and data integrity owners, automation engineers, and the reviewers who sign off validation. Up to 30 people per batch.

HOW LONG IT TAKES
1 day or 2 days, delivered in person at your site.

WHO LEADS
TrustBridge. Sachin Bhandari teaches every session.

What we do

- Teaches DRIVE as a sequence of 5 decisions: start from intended use, let risk decide the testing, choose the assurance approach (scripted, unscripted or supplier evidence), keep the evidence that is enough, and sustain the change
- Grounds the method in the FDA CSA guidance, GAMP 5 Second Edition, EU Annex 11 and 21 CFR Part 11
- Takes one worked case through the whole framework so your team sees the method working end to end

What you get

- A team that can rate a requirement by its impact on patient safety and product quality, and choose the right testing for it
- Confidence in using supplier evidence
- A lean evidence set an inspector will accept, with full traceability kept
- CSA templates and checklists your team keeps and reuses, and a certificate of participation for each person

4.8 out of 5 from 60 participants at Sun Pharma, who rated the CSV to CSA day for how useful it was to their own work.

A QUESTION CLIENTS ASK

Can the day use our own systems?

Yes. Sachin adapts the examples to your systems before the session, and mixed rooms of validation, QA and IT people work well.

RELATED SERVICES

For CSA built into your own procedures and rolled out across your sites, see CSV to CSA transformation on page 9.

TRAINING

Validating AI in GxP

A programme that teaches your team to validate AI and machine learning in a GxP setting and keep it valid after go-live. Sachin teaches it through his TRUST framework, with one case running through the whole day so the method is seen working end to end.

WHO IT'S FOR
QA, validation, IT, data science and product teams, and anyone who will need to defend an AI system in an inspection. Up to 30 people per batch.

HOW LONG IT TAKES
1 day or 2 days, delivered in person at your site. The 2-day version adds a live project on one of your own AI use cases and a mock inspection.

WHO LEADS
TrustBridge. Sachin Bhandari teaches every session.

What we do

- Works through TRUST: tier the risk, requirements and intended use, understand the data, substantiate with evidence, and track in operation
- Uses one worked case, an AI agent that triages deviations, from first classification to monitoring in service
- Covers draft EU GMP Annex 22, the FDA CSA guidance, Part 11, Annex 11 and the EU AI Act as tools for real decisions

What you get

- A team that can classify an AI system by risk and decide who signs
- Intended use statements that set the limits of the validation
- The skills to judge training data quality, lineage and test data independence
- An AI validation plan and evidence pack your team knows how to build, and drift monitoring that keeps the system valid
- A certificate of participation for each person

> **4.7 out of 5** from 57 participants at Sun Pharma, who rated the AI in GxP day for how useful it was to their own work.

A QUESTION CLIENTS ASK

Which format should we choose?

The 2-day version is the stronger choice when an AI use case is already live or about to go live, because day 2 works on that use case directly.

RELATED SERVICES

AI QMS setup on page 7, and validation of AI applications on page 8.

CONSULTING

Readiness Review

A fixed-scope review of your validation and inspection readiness over 2 weeks. Sachin looks at your validation records, your procedures and the way your systems are used day to day, then gives you a written report you can act on and defend.

WHO IT'S FOR
Quality, IT and validation leaders with an inspection on the horizon, a new AI use case to defend, or a validation approach they want tested by an outside expert.

HOW LONG IT TAKES
2 weeks, fixed scope, agreed with you before the review starts.

WHO LEADS
TrustBridge. Sachin Bhandari carries out the review himself.

What we do

- Agrees the scope with you: the systems, sites or AI use cases to look at
- Reads the validation packages and governing procedures against the same yardstick an inspector would use
- Talks with the people who run and use the systems, so the review reflects day-to-day practice
- Rates each finding by risk and sets out the order to address them

What you get

- A written report with every finding tied to its evidence and the requirement it relates to
- A risk rating for each finding that you can defend in the room
- A plan in the order the risk calls for, sized to your team
- A closing discussion with your leadership on the report

The review comes from someone who has stood on the quality side of the inspection table. Sachin has supported 300+ inspections with zero critical findings, in front of FDA, EMA, MHRA, PMDA and other authorities, so the questions in the review are the ones inspectors ask.

A QUESTION CLIENTS ASK

What do you need from us before the review starts?

A named contact, the list of systems or AI use cases in scope, and access to their validation records and procedures. We agree all of this in the first conversation.

RELATED SERVICES

The report says which of the services on pages 7 to 12 would close each gap, if any are needed.

CONSULTING

AI QMS setup and monthly support

When AI enters a GxP process, your QMS needs procedures for it. TrustBridge has a ready AI QMS of 13 SOPs, 50 templates and 19 quick reference guides. We adapt it to your existing QMS and your own terminology, so it fits the procedures your people already use, and then stay on hand through a monthly retainer.

WHO IT'S FOR
Companies using or planning AI in GxP processes, and QA and IT owners who need a procedure set an inspector can follow.

HOW LONG IT TAKES
Setup is a one-time piece of work, sized to your QMS. After that, a retainer of 10 hours a month, for the term we agree with you.

WHO LEADS
TrustBridge. Sachin Bhandari leads the setup and the retainer.

What we do

- Reviews your current QMS and maps where AI governance needs to sit
- Adapts the SOPs, covering the AI validation lifecycle, use case intake and classification, risk assessment and testing, monitoring and drift response, retraining, generative AI use, data governance, supplier oversight, periodic review and retirement
- Adapts the templates and quick reference guides, and walks your owners through how each one is used
- Under the retainer, supports new use cases, change decisions, evidence reviews and inspection preparation

What you get

- 13 SOPs, 50 templates and 19 quick reference guides adapted to your QMS
- Procedures your team owns from day one
- 10 hours of Sachin's time each month under the retainer

A QUESTION CLIENTS ASK

Do we have to replace our existing SOPs?

The AI SOPs are added to your QMS and refer to your current procedures where the two overlap, so the rest of your QMS stays as it is.

RELATED SERVICES

Validating AI in GxP training on page 5, and validation of AI applications on page 8.

CONSULTING

Validation of AI applications

Each AI application is validated in proportion to its risk, inside a governance framework that decides who approves what. Sachin designs that framework with you using his AI Governance Stack, then TrustBridge sets the validation approach and signs off the evidence while execution partners draft and execute the protocols on his framework.

WHO IT'S FOR
Companies taking AI into deviations, CAPA, complaints, laboratory review or other GxP processes, and AI vendors whose customers need validation evidence.

HOW LONG IT TAKES
It depends on the risk tier and the number of applications. You get a plan with dates after the first tiering session.

WHO LEADS
TrustBridge. Sachin sets the approach and signs off the evidence. Execution partners draft and execute the protocols on his framework.

What we do

- Designs your AI governance with the AI Governance Stack: regulatory spine, reference architecture, 4-tier risk classification, governance operating model, validation master plan and live monitoring
- Classifies each application by risk and intended use, and decides who is accountable
- Sets acceptance criteria and checks the data the model learned from
- Drafts and executes IQ, OQ and performance testing sized to the risk tier
- Sets up drift monitoring, hallucination management for generative AI, periodic review and change control after go-live

What you get

- An AI governance framework with clear decision rights
- A risk classification record for each application
- A validation plan, executed protocols and a summary report an inspector can follow from intended use to the final decision
- Monitoring that keeps each system inside its validated state

This is work Sachin has done in live operations. He has 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.

RELATED SERVICES

AI QMS setup on page 7, and Validating AI in GxP training on page 5.

CONSULTING

CSV to CSA transformation

This is the consulting version of the CSV to CSA move, for companies that want the new method built into their own framework, procedures and templates and rolled out across their sites. Sachin led this change across a global manufacturing network at Boehringer Ingelheim, and he uses the same DRIVE framework here.

WHO IT'S FOR
Heads of validation, QA and quality IT who want risk-based assurance as the way their company validates, across every site.

HOW LONG IT TAKES
Scoped to the number of sites and systems. We agree the plan and timeline with you before work starts.

WHO LEADS
TrustBridge. Execution partners join where templates need to be applied to live projects.

What we do

- Builds the risk logic that decides testing depth, using the 5 DRIVE decisions
- Rewrites your CSV policy, SOPs and templates for risk-based assurance
- Sets the rules for using supplier evidence and unscripted testing
- Plans and supports the rollout across sites, with training for reviewers and approvers
- Applies the new method to a first set of live projects so your team sees it work

What you get

- A CSA framework that fits your quality system
- Updated procedures and templates, ready for approval
- A rollout plan across your sites
- Reviewers and approvers trained in the new method
- Worked examples from your own systems

Sachin has worked on CSA since before FDA published its draft. He co-authored the ISPE GAMP India SIG whitepaper on Computer Software Assurance in July 2021, and later led the move to CSA across a global manufacturing network.

A QUESTION CLIENTS ASK

Can we start with one site?

Yes. A single site and a few systems make a good first phase, and the rollout plan then takes the method to your other sites.

RELATED SERVICES

Transitioning from CSV to CSA training on page 4, and computerised systems validation on page 10.

CONSULTING

Computerised systems validation

Validation of the systems your GxP operations run on, across the full lifecycle, with data integrity built in from the first specification. Sachin sets the strategy and reviews the evidence, and execution partners working on his framework do the drafting and testing. He stays accountable for the evidence.

WHO IT'S FOR
Companies implementing, upgrading or migrating LIMS, eQMS, MES, ERP or laboratory and manufacturing equipment.

HOW LONG IT TAKES
Scoped per system or programme. We agree the plan and timeline with you before work starts.

WHO LEADS
TrustBridge. Sachin sets the validation strategy and reviews the evidence. Execution partners draft and execute the protocols.

What we do

- Validates LIMS, eQMS, MES, ERP and other GxP systems, including upgrades, migrations and system retirement
- Writes the URS, risk assessments, traceability and IQ, OQ and PQ protocols, and executes them
- Qualifies equipment with Modular Qualification Architecture: shared building blocks are qualified once, and each new site or unit is tested only for what differs
- Builds 21 CFR Part 11, Annex 11 and ALCOA+ data integrity controls into the design

What you get

- A complete validation package for each system
- Executed protocols and a summary report
- Less repeated qualification effort for equipment across sites
- Evidence an inspector can follow on their own

Sachin knows the main GxP platforms well, including Veeva Vault, TrackWise, MasterControl, LabWare, LabVantage, STARLIMS, Körber PAS-X, Siemens Opcenter and SAP S/4HANA, across manufacturing, laboratory, quality and enterprise systems.

A QUESTION CLIENTS ASK

Can you work with our existing validation templates?

Yes. We use your templates and procedures where you have them, and bring ours where you need them.

RELATED SERVICES

CSV to CSA transformation on page 9, and Enterprise Paperless Validation on page 11.

CONSULTING

Enterprise Paperless Validation

A design for running the whole validation lifecycle on a validated electronic platform: specifications, risk assessments, test evidence, electronic signatures and the audit trail, all in one place. At Sun Pharmaceutical Industries, Sachin built the paperless validation platform that took 40+ sites off paper, removing about 6M paper records a year and improving validation cycle time by up to 45%.

WHO IT'S FOR
Companies running validation on paper or hybrid records, and those choosing or rolling out a digital validation platform across several sites.

HOW LONG IT TAKES
A programme scoped to your sites and systems. We agree the plan and timeline with you before work starts.

WHO LEADS
TrustBridge. Sachin designs the lifecycle and the governance. Execution partners bring the technology and the execution.

What we do

- Designs the digital validation lifecycle and the rules that govern it
- Sets requirements for the platform and supports its selection
- Validates the platform against 21 CFR Part 11 and Annex 11
- Moves templates and live projects onto the platform, and plans the rollout across sites

What you get

- A digital validation lifecycle your sites follow the same way
- A validated electronic platform with signatures and audit trail in place
- Evidence that's ready the moment an inspector asks for it
- A rollout plan across your sites

Here's what changes for your teams. Reviews and approvals happen in the system, signatures are electronic and the audit trail is complete from the first specification, so your team can produce any piece of evidence on the day an inspector asks for it.

A QUESTION CLIENTS ASK

Do regulators accept a fully electronic validation record?

Yes, when the platform itself is validated and the record meets 21 CFR Part 11 and Annex 11, with controlled electronic signatures, a complete audit trail and evidence a reviewer can follow.

RELATED SERVICES

Computerised systems validation on page 10, and quality digital transformation on page 12.

CONSULTING

Quality digital transformation with QMS 2.0

Moving deviations, CAPA, change control and complaints from paper or local tools into one eQMS, designed around the decisions those processes support. Sachin has run this at enterprise scale, with an eQMS used by about 15,000 people and quality digitalisation programmes that reduced rejection and rework by up to 80%.

WHO IT'S FOR
Quality leaders running paper or mixed quality processes, and companies bringing several sites onto one eQMS.

HOW LONG IT TAKES
A programme scoped to your processes and sites. We agree the plan and timeline with you before work starts.

WHO LEADS
TrustBridge. Execution partners support the technology side where needed.

What we do

- Agrees one core process set for deviations, CAPA, change control and complaints, with any local variations named and governed
- Designs the eQMS around that process set
- Builds one quality data layer so KPIs mean the same thing at every site
- Plans go-lives so every site stays inspection ready, and adds validated AI assistance where it helps

What you get

- One quality process set across your sites
- An eQMS design and rollout plan
- Quality KPIs your leadership can compare and act on
- A validated, inspection-ready quality system

QMS 2.0 has 4 layers. A connected quality data layer is at the base. Above it is the eQMS core for deviations, CAPA, change control, complaints and audit, then a validated automation and AI layer for the high-volume steps, and quality KPIs that show trends early.

A QUESTION CLIENTS ASK

Do all sites have to work exactly the same way?

Every site follows one core process set. Where a site needs a local variation, it is named, given an owner and reviewed.

RELATED SERVICES

AI QMS setup on page 7, and Enterprise Paperless Validation on page 11.

TRAINING AND LICENSED PRODUCTS

Other training and products we offer

These 2 one-day programmes run in the same way as the main training, taught live by Sachin with examples adapted to your systems. The book and the Practitioner Pack are licensed products your teams can work from every day.

Data Integrity and ALCOA+ — 1 DAY

WHO IT'S FOR

QA, laboratory and operations teams. Up to 30 people per batch, delivered in person at your site.

WHAT IT COVERS

- What inspectors check first, and why
- How to handle hybrid paper and electronic records
- Audit trail review that's quick and focused on risk
- ALCOA+ applied to your own records

Inspection Readiness for Digital Systems — 1 DAY

WHO IT'S FOR

Anyone who will face an inspector or a customer auditor on computerised systems or AI. Up to 30 people per batch.

WHAT IT COVERS

- How inspectors approach computerised systems and AI
- Mock-inspection drills on your own systems
- The evidence that answers an inspector's questions quickly

WHO LEADS THE WORK

About Sachin Bhandari

Sachin Bhandari is the founder and Principal Consultant of TrustBridge Compliance. He has spent 25+ years in pharma quality IT and digital quality, nearly 20 of them in validation and CSV, most of it leading global teams inside large pharmaceutical companies. He leads every TrustBridge engagement himself, from the first conversation to the last deliverable.

25+	300+	40+	1,500+
years in pharma quality IT and digital quality	inspections, zero critical findings	sites taken onto paperless validation	trainings delivered

GLOBAL ROLES

Sun Pharmaceutical Industries Global, headquartered in Mumbai	Global Head of Quality IT, Digital Transformation and GxP Compliance. Sachin built the paperless validation platform that took 40+ sites off paper, removing about 6M paper records a year and improving validation cycle time by up to 45%.
Boehringer Ingelheim Global	Global Head of CSV and Equipment Qualification. Sachin led the move from traditional CSV to Computer Software Assurance across the global manufacturing network, aligned to GAMP 5 Second Edition, EU GMP Annex 11 and 21 CFR Part 11.
UCB Global	Head of Quality Digital Industrialization and Business Process Owner for Quality IT.

SYSTEMS SACHIN HAS VALIDATED

Manufacturing	Laboratory	Quality	Enterprise
MES, electronic batch records, SCADA and PLC	LIMS, chromatography data systems, ELN and instruments	eQMS, document management and learning management systems	ERP including SAP S/4HANA, RIM, clinical and serialization

Standing in the industry

- Member of the Global GAMP Steering Committee
- Co-author of the ISPE GAMP India SIG whitepaper on Computer Software Assurance (July 2021), written before FDA published its CSA draft
- Former Director of ISPE India and former Chair of the GAMP India Steering Committee
- Speaker at 70+ global forums, and author of 25+ whitepapers
- Confirmed speaker at KENX AI in GxP Europe in Amsterdam and at the Scilife Quality Summit 2026, both in October 2026

The book

Sachin wrote *Validating AI in GxP Environments: A Practitioner's Handbook*. It works through the real problems a practitioner meets when validating AI in a GxP setting, with 19 chapters, 28 templates and the inspection questions a team should expect. Several organisations hold team licences so their quality and validation people work from the same playbook.

How he works

Sachin is independent and product neutral. When a programme needs hands, the execution comes from TrustBridge's partner firms, and Sachin stays accountable for the advice.

CUSTOMERS AND PARTNERS

Organisations that work with Sachin

These organisations have brought TrustBridge in for training or advisory work, licensed the book for their teams, or work alongside TrustBridge as partners. Other clients, including a Big Four firm, a global CDMO and a global nutrition company, stay unnamed.

TRAINING AND ADVISORY CLIENTS

SUN PHARMA · ARCHIMEDIS DIGITAL · Caliber (Deliver More. Deliver Excellence) · sciagen · Alkem Laboratories

TEAM LICENCES OF THE BOOK

celito · Compliance Associates · LabInformatics · onevector · Sai

WHERE SACHIN SPEAKS AND PUBLISHES

KENX (Knowledge Exchange Network) · Scilife · EBM (Eminence Business Media) · Pharmaceutical Online

IN THEIR WORDS

> *"Today's session, you gave us several valuable perspectives to reflect upon, along with clear and actionable takeaways that we can work on. The content presented effectively captured the essence of industry standards, emerging practices, and the latest trends shaping the rapidly evolving world of AI."*
>
> **Caliber leadership team**, Caliber Technologies

> *"The session challenged us to rethink traditional validation approaches through risk-based decision making, critical thinking, data integrity principles, audit trail review, and the practical application of CSA concepts within analytical laboratories."*
>
> **Analytical scientist**, Quality Control team, a global nutrition company

> *"This is a hand book that can be used for quick references and will help in training fellow colleagues."*
>
> **Girish Ghatge**, VP Quality and Compliance, One Vector

> *"Thank you for the detailed comparison. More than I expected. I really appreciate it."*
>
> **Victor Zurita**, President and CEO, Compliance Associates

HOW TO GET STARTED

Pick the service that fits the problem in front of you. Write to Sachin and we'll find a time that suits your team.

TRUSTBRIDGE COMPLIANCE

Sachin Bhandari
Founder and Principal Consultant
sachin.bhandari@trustbridge-compliance.com
trustbridge-compliance.com

PHONE AND LINKEDIN

+91 99714 90103
linkedin.com/in/sachinbhandari
Jaipur, India