ONE-DAY TRAINING PROGRAMME · 8 HOURS · ONSITE OR LIVE VIRTUAL

Transitioning from CSV to CSA

Move a validation organisation from document-driven CSV to risk-based Computer Software Assurance. Less paper, faster systems, and a stronger inspection story than the binders ever gave you.

3
CSV to CSA transformations delivered end to end

45%
validation cycle-time improvement achieved on enterprise programmes

300+
regulatory inspections supported, with zero critical findings

WHY NOW

CSA stopped being a debate in 2025

FDA's Computer Software Assurance guidance was finalised in September 2025 and updated in February 2026 to align with the QMSR. GAMP 5 second edition is the working standard. ICH Q9(R1) set expectations on how you make risk decisions. Regulators no longer ask for more documentation, they ask whether you thought. Most organisations have read all of it and still validate the way they did in 2015.

WHO IT IS FOR

Everyone who has to agree before the paper shrinks

Validation and CSV teams, QA reviewers and approvers, IT and system owners, data integrity leads, and the quality leadership who carry the risk. Put the doers and the approvers in one room. CSA adoption fails when you train practitioners and not QA, because the reviewer still asks for the screenshots the new method removed. Up to 30 people in one sitting.

THE PROBLEM WE SOLVE

Three reasons CSA programmes stall after the kick-off deck

Risk is assessed, not used
Teams fill in a risk assessment, then test everything anyway. The rating changes no downstream decision.

Nobody will sign the reduction
Practitioners will happily test less. No approver puts their name on it without a defensible rationale.

Unscripted testing is misread
Teams treat it as testing without records. Done properly it produces better evidence than a script.

Delegates take a real validation package of their own, typically a LIMS, eQMS or ERP change, and rebuild it in the room. Then they defend what they removed, first to a challenger playing the QA approver, then to one playing the inspector. That two-sided challenge is where the behaviour changes. Where a client cannot share a live package, we bring a prepared one.

WHAT WE TEACH

DRIVE: five decisions that move an organisation from CSV to CSA

1 Intended use first
"What is this for, and what could go wrong?"

2 Risk that decides
"Which functions are high risk, and so what?"

3 Assurance strategy
"Scripted, unscripted, or the vendor's evidence?"

4 Evidence that is enough
"What do I keep, and what do I stop making?"

5 Sustaining the change
"How does this survive the next audit and hire?"

DRIVE is a sequence of decisions, not a document set. Each stage settles a question before the next one is safe. We run one of your own systems through the whole sequence, so delegates leave with a worked example in their own vocabulary.

THE AGENDA

Built around what the room has to stop doing on Monday

THE PROGRAMME		09:00 to 17:00 · 8 hours · onsite or live virtual · up to 30 people
09:00	**Why is our validation so heavy?**	Where the documentation habit came from, and what guidance never asked for.
09:45	**What did CSA actually change?**	FDA CSA, GAMP 5 second edition and ICH Q9(R1) against Part 11 and Annex 11.
10:45	**What is this system for?**	Intended use and patient impact, written for your own system.
11:30	**Which functions are high risk?**	Risk that selects the assurance activity, worked in teams.
13:30	**Scripted, unscripted or exploratory?**	Choosing the method per function, and the record unscripted testing produces.
14:45	**What can I rely on from the vendor?**	Supplier assessment, and using vendor evidence without inheriting their gaps.
15:45	**What evidence is enough?**	Lean records, the screenshot question, and the rationale an approver can sign.
16:30	**What are we stopping?**	Each delegate names one practice to retire, and what replaces it.

RECOMMENDED UPGRADE · ADD DAY TWO

Day one teaches the method. Day two turns it into your SOPs. Teams rework a real package of their own end to end, defend it to QA and then to a mock inspector, write the SOP, template and approval matrix changes in the room, and leave with a pilot plan carrying success measures and a named owner per action. Approvers leave willing to sign a lighter package, not just aware of it. Take it when you are standing a CSA programme up rather than explaining it, and whenever we deliver onsite.

WHAT EACH PERSON WALKS OUT WITH

- Write intended use that drives the assurance effort
- Run a risk assessment that changes what gets tested
- Design and record unscripted testing defensibly
- Judge and leverage supplier evidence
- Write the rationale that lets an approver sign a lighter package
- Name what to stop producing, and defend it to an inspector

WHAT IS INCLUDED

- Live delivery by Sachin Bhandari, onsite or as a virtual cohort
- The DRIVE toolkit: intended use, risk, assurance and lean evidence templates
- Rework of a real package of yours, or a prepared one if yours cannot be shared
- Recording for virtual cohorts, and a certificate of participation
- A pre and post competency check
- A follow-up question and answer window

WHAT THE ORGANISATION GETS, STATED PLAINLY

Systems go live sooner

Programmes run this way have cut validation cycle times by up to 45 percent.

QA capacity comes back

Reviewers stop reading screenshots and start reviewing risk, the work only they can do.

A better inspection story, not a thinner one

A defensible rationale reads stronger than a binder nobody can explain.

The change survives the pilot

SOPs, templates and the approval matrix move with the method, so CSA becomes the default.

DELIVERY AND LOGISTICS

What booking one actually involves

Format

Onsite at your site, or delivered as a live virtual cohort. Virtual widens reach across sites; onsite adds the energy and the tailoring of a room.

Group size

Up to 30 people in one sitting. Further sittings are arranged separately.

Lead time

A tailored proposal within one working day. Dates are held on a released purchase order or advance, and most sessions deliver within four to six weeks of booking.

Tailoring

Built on yours. Sessions work on your system inventory, your SOPs and your inspection history, and teams leave with output they can use the next working day.

QUESTIONS WE ARE USUALLY ASKED

Is it generic, or built on our systems?

Built on yours. Sessions work on your system inventory, your SOPs and your inspection history, and teams leave with output they can use the next working day.

How fast can a date be confirmed?

You receive a tailored proposal within one working day. Dates are held on a released purchase order or advance, and most sessions deliver within four to six weeks of booking.

What do participants take away on paper?

The working templates for the framework taught, the worked case built in the room, and a certificate of participation. Virtual cohorts also receive the recording.

YOUR TRAINER

Sachin Bhandari

Founder and Principal Consultant, TrustBridge Compliance. Sachin has spent 25 years in pharma quality IT. He built the DRIVE, Enterprise Paperless Validation and QMS 2.0 frameworks, delivered three CSV to CSA transformations end to end, and took 40+ sites paperless. He sits on the Global GAMP Steering Committee and wrote *Validating AI in GxP: A Practitioner's Guide*. He teaches practitioners and briefs boards, often in the same room.

Next step. See all three in-house programmes, what each day covers and what a session costs, and ask for a date. A tailored proposal follows within one working day.

trustbridge-compliance.com/book-a-training