LEADERSHIP ORIENTATION · 2.5 HOURS · LIVE ONLINE OR ONSITE

AI & Digital Quality

A short session that puts your leadership team on one shared understanding of the regulatory ground under AI in GxP, and of the decisions you are already making without it. No pre-reading, no homework, and nothing you have to be technical to follow.

300+
regulatory inspections supported, with zero critical findings

Annex 22
contributor to the EU GMP industry review of the AI annex

Author
Validating AI in GxP: A Practitioner's Guide

WHY NOW

You are already running AI in GxP

AI and machine learning are almost certainly in use in your organisation already, whether or not anyone has logged them as such. They sit inside vendor platforms, in features switched on by a supplier update, and in tools a team adopted to save time. The first honest step is to write that list down. Most sites find more than they expected.

WHO IT IS FOR

The people who own the risk, not the paperwork

Site heads, VPs and Heads of Quality, CIOs and CDOs, managing directors, and the product or function leads whose teams are putting AI into a GxP decision path. Your validation and CSV people are welcome, and the session is built for the decision maker. Up to 30 people in one sitting.

THE PROBLEM WE SOLVE

Your CSV was built for software that behaves the same way every time

It changes after release
A learning system can change after you sign it off, so a validation done once no longer describes what the system does today.

You cannot read its logic
The reasoning is not written down in a specification you can test line by line, the way you inspect code.

Its behaviour is inherited
Behaviour comes from the data the model learned on. A gap in that data becomes a gap in the system that no amount of functional testing will reveal.

None of this means your CSV was wrong. It means AI adds three questions your CSV was never designed to ask. You are not choosing between a cost and no cost. You are choosing when, and on whose timetable, you do the work.

WHAT WE TEACH

TRUST: the five decisions, at the level a leader needs them

T	R	U	S	T
Tier the risk	**Requirements & intended use**	**Understand the data**	**Substantiate with evidence**	**Track in operation**
"What tier is this, and who signs?"	*"What are we claiming, and where does it stop?"*	*"Can we trust the data it learned from?"*	*"What evidence earns the validated state?"*	*"How do we keep it inside the envelope?"*

Governance decides whether a system may exist. TRUST earns and keeps its validated state. The double T is deliberate: the sequence opens and closes on "can you trust this system", which is the question every inspector is really asking.

THE AGENDA

Two and a half hours, with a break, and no pre-reading

THE PROGRAMME		2.5 hours · live online or onsite · up to 30 people in one sitting
0:00	**Welcome and objectives**	Session goals and ground rules, and where this sits against the full practitioner programme.
0:05	**Where AI validation now shows up commercially**	How customer quality teams evaluate AI features during vendor selection, and the effect on review timelines and deal cycles. The mirror image for a manufacturer: what your own customers and inspectors will ask you.
0:20	**The regulatory landscape, current and forthcoming**	In force or final: EU Annex 11, 21 CFR Part 11, FDA CSA, the FDA and EMA joint AI principles, the EU AI Act. Forthcoming: the EU Annex 22 final, the Annex 11 revision, and the FDA AI credibility framework. Effective dates are mapped against your own timelines, because a purchase order is often the earliest point of enforcement.
0:40	**The TRUST framework**	The five-stage lifecycle worked end to end on a real case: tier the risk, bound the requirements and intended use, understand the data, substantiate with evidence, track in operation. The governance model that sits above it.
1:10	**Break**	Fifteen minutes.
1:25	**Applied to your own systems**	The assessment questions run against your AI features or platforms, with strengths and gaps read against Annex 22, FDA CSA and GAMP 5. See the note below on what this segment needs from you.
1:55	**The maturity roadmap**	The capability layers, from a documented intended use through to an evidence pack you could hand to a customer or an inspector, and how to sequence them.
2:05	**Discussion and next steps**	Open questions, and the inputs that shape a full training agenda if you take one.

WHAT THE 1:25 SEGMENT NEEDS FROM YOU

That segment can only run on your own systems if three things reach us a week beforehand: product or system information for the AI features in scope, the current validation and quality documentation, and the governance structure showing who decides and who signs. Without it, we teach the same assessment questions against a comparable platform and your team applies them internally afterwards.

WHAT THE ROOM LEAVES WITH

- A shared vocabulary across quality, IT and the business
- An honest list of where AI already sits in your GxP processes
- The three questions AI adds that your CSV never asked
- A view of which regulations bite, and when
- Agreement on who signs at each risk tier
- A sequenced roadmap, not a shopping list

WHAT IS INCLUDED

- Live delivery by Sachin Bhandari, online or onsite
- Slides shared with every participant afterwards
- The assessment questions applied to your own systems
- A maturity roadmap your team keeps
- A follow-up question and answer window
- Recording permitted for your internal use

THE ROAD AFTER THIS

The practitioner programme

TRUST taught hands-on over a full day, with the agenda tuned by this session.

A readiness assessment

An independent validation-readiness review of the systems you named.

The AI layer in your QMS

The validation framework built into your own quality system.

Ongoing advisory

A standing arrangement, at the point it earns its place.

WHY A BUDGET HOLDER SIGNS THIS

The conversation stops being theoretical

Leaders who can name their own AI exposure make decisions in weeks instead of deferring them.

One vocabulary across the business

Most AI governance failures are handover failures between quality, IT and the business, not technical ones.

A defensible position before it is tested

The work is the same whether you do it now or during an inspection. Only the timetable changes.

The natural first step

Teams graduate from here into the full practitioner programmes with a mandate already agreed.

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.

YOUR TRAINER

Sachin Bhandari

Founder and Principal Consultant, TrustBridge Compliance. Sachin has spent 25 years in pharma quality IT. He wrote *Validating AI in GxP: A Practitioner's Guide*, the field's first practitioner handbook, and contributed to the EU GMP Annex 22 (AI) industry review. He has validated 20+ AI applications in live GxP use, deviations, queries and CAPA support among them, and taken 9 of them through health-authority inspection, 6 FDA and 3 MHRA, with zero compliance observations. 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