FIRESIDE CHAT · LIFE SCIENCES QUALITY

From compliance to proactive insight.

Governing AI-integrated eQMS — and what it unlocks for life sciences quality.

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ABOUT YOUR LEAD PANELIST

Mandy Gervasio – Transforming Quality into a Decision & Governance System

- Enterprise quality & risk executive with 20+ years in biotech, pharma, and medtech
- Builds practical, scalable quality systems aligned with real-world operations
- Focuses on connecting quality, risk, and data to improve decision-making
- Designs fit-for-purpose governance models—less reactive, more effective
- Deep experience in outsourced and complex global environments
- Led senior roles across sponsor & CDMO organizations
- Built quality infrastructure and global partner governance from the ground up
- Expertise in commercial readiness, combination products, audits & inspections
- Advises executives on risk-based, growth-focused regulatory strategies
- Creator of *Automating Quality* podcast & speaker on AI in regulated environments

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Quality systems have moved through four eras — each shift expanded what compliance had to govern.

PAPER	ELECTRONIC ON-PREMISE	SaaS / CLOUD	AI-INTEGRATED

1997	2000s	2014	2024 - 2026
21 CFR Part 11	**Validated on-premise eQMS**	**Cloud / SaaS eQMS**	**AI-integrated eQMS**
Electronic records and signatures get federal teeth.	Servers, scanned PDFs, audit-ready document control.	Multi-tenant, browser-based, vendor-validated.	PCCP, QMSR & CSA finalize risk-based, AI-aware rules.

Each era kept the prior controls and added new objects to govern. AI does this again — at the level of the model itself.

Sources: 21 CFR Part 11 (1997); SOLABS QM10 (2014); FDA PCCP (Dec 2024); QMSR final rule (Feb 2024, effective Feb 2026); FDA CSA final guidance (Sep 2025).

AI moves the eQMS from a system of record to a system of inference.

YESTERDAY

System of record

- Captures what happened
- Periodic review, manual triage
- Compliance is the goal
- Insight requires effort

TODAY

System of inference

- Predicts what's likely next
- Continuous, AI-assisted triage
- Compliance is the floor
- Insight is the default output

The same data the eQMS already holds becomes a live decision input — but only if governance keeps up.

Source: Discussion framework prepared for fireside chat.

Six FDA and harmonized frameworks shape governance for AI-integrated eQMS today.

Framework	Year / status	What it tells AI-integrated eQMS
21 CFR Part 11	1997, in force	Electronic records and signatures — still the foundation for any eQMS data trail.
21 CFR Part 820 → QMSR	Effective Feb 2026	Replaces most of Part 820 with ISO 13485:2016 by reference; risk-based by design.
Computer Software Assurance (CSA)	Final Sep 2025	Risk-based assurance for production / quality system software; SaaS and AI explicitly in scope.
AI-Enabled Device PCCP	Final Dec 2024	Pre-authorize defined post-market modifications with a modification protocol and impact assessment.
Good Machine Learning Practice	2021 (10 principles)	Joint FDA / Health Canada / MHRA principles for ML in medical devices — widely cited for AI in regulated quality workflows.
ICH Q9(R1)	Revised 2023	Quality risk management — the lens through which AI-system risk should be evaluated.

None of these were written for AI in eQMS — but together they already require what AI demands: risk-based, traceable, defensible.

Sources: FDA.gov; Federal Register notices; ICH; Health Canada / MHRA / FDA joint principles (2021, 2025).

AI integration introduces four failure modes the legacy eQMS was never designed to govern.

Model drift

Performance degrades silently as data, products, and processes change. There is no equivalent in document control.

Opaque data lineage

Decisions depend on training and reference data — but who validated, sourced, and refreshed it, and when?

Auto-classification risk

AI may mislabel deviations, complaints, or CAPA — quietly distorting trend reports and audit narratives.

Continuous learning vs. validated state

If the model updates itself, what exactly is validated — the model, the version, or the framework?

These don't replace document control. They sit on top of it — and require new artifacts of evidence.

Sources: ICH Q9(R1); EU AI Act (high-risk systems); FDA GMLP guiding principles; industry interviews.

Governance must extend from document control to system control.

Dimension	Document-control governance	AI-system governance
Unit of control	Document version	**Model version + dataset**
Review cadence	Periodic (annual)	**Continuous monitoring**
Approval signal	Signed signature	**Signed + drift threshold**
Audit trail	Who edited what	**Who decided + why the model said so**
Change control	Change request	**Change request + retraining record**
Failure detection	Found in audit	**Found in real time**

Same standards of evidence. Different objects of control.

Sources: 21 CFR Part 11; QMSR (effective Feb 2026); FDA CSA guidance (Sep 2025); GAMP 5 (2nd ed.).

Done well, governed AI turns the eQMS into an early-warning system.

Use case	What AI does	Proactive output
CAPA	Cluster deviations, complaints, and lab investigations	**Surface emerging issues before they trend**
Training	Predict gaps from role changes and access patterns	**Pre-empt non-conformance before audit findings**
Supplier quality	Aggregate signals across deviations, audits, inspection	**Flag at-risk suppliers ahead of qualification reviews**
Audit readiness	Score documentation and process state continuously	**Make readiness a metric, not a six-week sprint**

Analytics shifts the work from explaining the past to shaping the next 30 days.

Sources: Illustrative use cases drawn from public client examples and industry interviews.

Under CSA, vendor evidence is a first-class input — your job is to assess and complement, not duplicate.

CSA principle	Practical translation for SaaS eQMS users
Leverage vendor evidence	SOC reports, ISO certifications, SDLC artifacts, vendor validation packs.
Risk-based assurance	Test what your intended use changes — not the vendor's platform.
Continuous monitoring	Use vendor dashboards plus your own override and drift triggers.
Service-level agreements	Put change-control and AI-update terms in writing, with notice windows.

The vendor and the user share assurance — neither owns it alone.

Sources: FDA CSA final guidance (Sep 2025); ISPE GAMP 5 (2nd ed.) cloud and SaaS chapters; FDA on service agreements as assurance.

Quality is becoming a continuous, predictive, regulator-ready system property.

FROM

Periodic

↓

TO

Continuous

Every check is always-on — drift, training, audit readiness, supplier signal.

FROM

Reactive

↓

TO

Predictive

Analytics see failure modes earlier — before they become deviations or recalls.

FROM

Defending

↓

TO

Demonstrating

Evidence is generated, not assembled. Submissions become machine-readable on demand.

FROM

Cost center

↓

TO

Competitive edge

Quality enables faster speed-to-market with confidence — the moat, not the brake.

The destination isn't more controls — it's controls that produce insight as a by-product.

Sources: Industry direction informed by FDA Case for Quality, CSA, QMSR/ISO 13485, and EMA / EU AI Act trajectory.

A pragmatic first 90 days: inventory, ownership, controls.

30 DAYS

INVENTORY

- Catalog AI/ML touchpoints in the eQMS today and on the roadmap.
- Distinguish vendor-supplied features from internally configured logic.
- Flag any GxP-impacting decisions the system makes or assists.

60 DAYS

OWNERSHIP

- Stand up a model / decision registry — versions, dates, owners.
- Assign cross-functional ownership: QA + IT + RA + process owner.
- Define human-in-the-loop intervention points, with override rights.

90 DAYS

CONTROLS

- Update SOPs to reference CSA and AI-specific controls.
- Operationalize drift and monitoring thresholds in the system.
- Run the first audit-readiness assessment of the new governance.

Three months from now, you should know what AI does, who owns it, and how it's controlled.

Source: Synthesized starter framework — adapt to your organization's risk profile and existing controls.

TAKEAWAY

Governance isn't the brake on AI-integrated eQMS. It's what lets you go fast.

If the binder is what you defended,

the model is what you'll defend next.

Same standard of evidence — different objects of control.

DISCUSSION

- Where does AI in your eQMS create the most defensible quick win?
- Who owns model oversight today — quality, IT, or no one yet?
- What would you stop doing if the system flagged it first?

Context-Project-Scope

Context

- Mid-size biotechnology company
- Transitioning from clinical to commercial scale
- Increasing deviation volume across GMP operations
- Manual triage causing delays and inconsistency

Project & Scope

- AI embedded in EQMS
- Classifies deviations (minor/major/critical)
- Supports prioritization and routing
- Used by QA across clinical and manufacturing

Assessment Approach

- Applied AI Governance Diagnostic Toolkit
- 6 domains evaluated
- Scoring scale: 0–4
- Focus on control over time

1. Intended Use & Risk Framing (Score: 3.2 Green)

Control	Score	Risk	Artifact	Gap	Action
Question of interest defined	4	🟢	Intended Use Statement	None	None
Context of use defined	3	🟢	COU Spec, Workflow Map	Edge cases not fully defined	Add prohibited-use scenarios
GxP impact classified	3	🟢	Risk Assessment	Limited patient linkage	Expand patient risk linkage
Failure modes identified	3	🟡	FMEA	Misuse scenarios incomplete	Expand misuse scenarios
Performance criteria defined	3	🟢	Validation Plan	Justification weak	Strengthen justification

2. Data Integrity & Governance (Score: 2.5 Yellow)

Control	Score	Risk	Artifact	Gap	Action
Data sources defined	3	🟢	Data Inventory	Legacy sources unclear	Clean inventory
Data lineage traceable	2	🟡	Data Flow Diagram	Partial traceability	Implement full lineage tracking
Dataset segregation	3	🟢	Dataset Register	Minor gaps	Enforce versioning SOP
Representativeness	2	🟡	Sampling Rationale	Bias not assessed	Add bias analysis
Data controls (Part 11)	3	🟢	Part 11 Assessment	Audit trail gaps	Improve audit logging
Output traceability	2	🔴	Traceability Matrix	Cannot fully reconstruct decisions	Build full traceability chain

3. Model Validation & Credibility (Score: 2.8 Yellow)

Control	Score	Risk	Artifact	Gap	Action
Model documented	3	🟢	Model Description	Limited explainability	Improve documentation
Metrics aligned to use	3	🟢	Validation Plan	Threshold rationale weak	Refine thresholds
Edge case testing	2	🟡	Test Protocol	Limited stress testing	Expand edge cases
Independent review	3	🟢	QA Approval	None	None
Credibility justification	3	🟢	Credibility Assessment	Limited narrative	Strengthen justification
Vendor model transparency	2	🟡	Vendor Docs	Black-box limitations	Improve vendor transparency

4. Deployment & Oversight (Score: 3.0 Green)

Control	Score	Risk	Artifact	Gap	Action
Workflow defined	3	🟢	SOP	Minor gaps	Refine SOP
Roles defined	3	🟢	RACI	Training inconsistency	Standardize training
Human oversight	3	🟢	Review Matrix	Not always enforced	Audit compliance
Over-reliance risk	2	🔴	Training Material	Users trust too much	Add bias training
Version control	4	🟢	Version Log	None	None
Change control	3	🟢	Change SOP	Slow updates	Streamline process

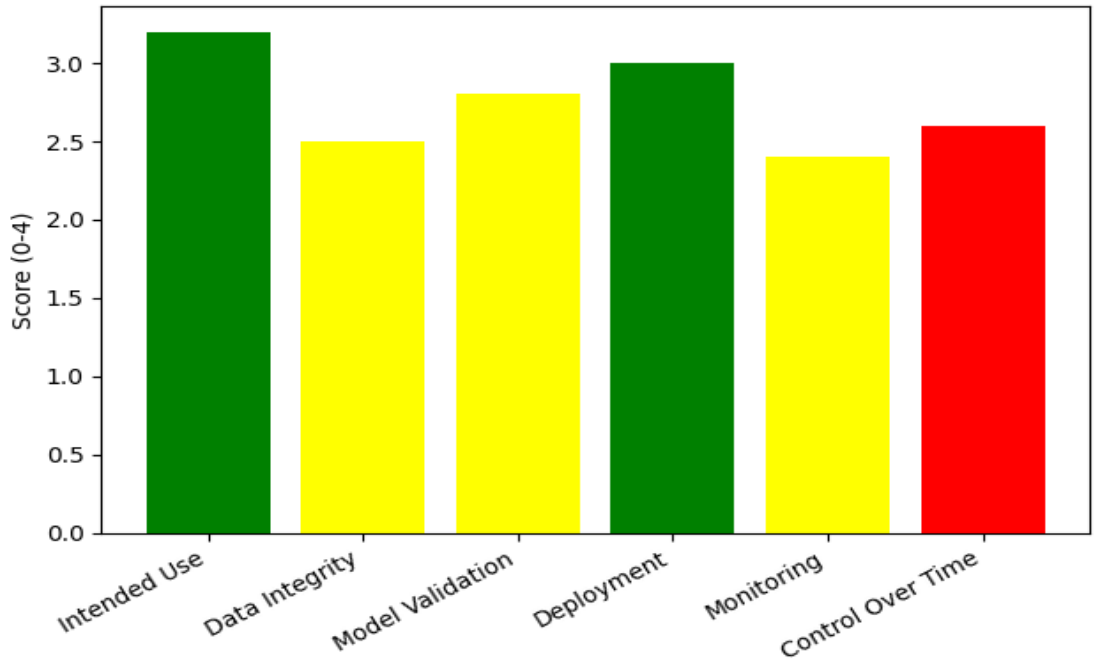
5. Monitoring & Lifecycle (Score: 2.4 Yellow)

Control	Score	Risk	Artifact	Gap	Action
Performance monitoring	2	🔴	KPI Dashboard	No drift metrics	Add drift indicators
Periodic review	3	🟢	Review SOP	Not frequent	Increase cadence
Deviations trigger CAPA	2	🟡	CAPA SOP	Weak linkage	Strengthen triggers
Revalidation approach	2	🟡	Validation SOP	Undefined triggers	Define thresholds
Feedback loops	3	🟢	Audit Tracker	Slow feedback	Improve cycle time
Metrics tailored	2	🟡	Monitoring Plan	Generic metrics	Customize metrics

6. Control Over Time (Score: 2.6 GATING FAILURE)

Control	Score	Risk	Artifact	Gap	Action
Owner assigned	4	🟢	Governance Charter	None	None
Detect degradation	2	🔴	Dashboard	No drift detection	Implement monitoring
Explain changes	2	🟡	RCA	Weak traceability	Improve RCA
Act on change	3	🟢	CAPA	Slow execution	Improve responsiveness
Maintain validated state	2	🔴	Review Records	Not demonstrated	Formalize lifecycle validation
COU reassessment	2	🟡	Governance Minutes	Not periodic	Define schedule
Change classification	3	🟢	Change Matrix	Incomplete	Expand categories

Domain Scores with Risk Levels



Overall Results

- Overall Score: 2.76
- Maturity Level: Controlled
- Final Status: NOT IN CONTROL
- Reason: Control Over Time < 3.0

Key Strengths

- Clear intended use and risk framing
- Structured validation approach
- Defined workflows and governance
- Strong configuration/version control

Key Gaps

- Weak data lineage traceability
- Limited drift detection capability
- Inconsistent lifecycle monitoring
- Risk of user over-reliance

Top Risks

- Model performance degradation over time
- Inability to fully reconstruct decisions
- Automation bias in QA users

Priority Actions

- Implement drift monitoring & alerts
- Enhance traceability (input → output → decision)
- Strengthen human oversight training
- Define revalidation triggers

Key Insight

- System appears controlled at deployment
- But lacks lifecycle robustness
- Common in scaling biotech organizations
- Control over time is the critical gap

Conclusion

- AI can add value in biotech EQMS
- But requires strong lifecycle governance
- Shift from validation → continuous control
- Next step: implement monitoring & governance enhancements