



Continuous Intelligent GxP Audits (cIGA)

“The Smart Engine Behind Vendor Compliance Audits”



INTRODUCTION

xLM's Continuous Intelligent GxP Auditor (cIGA) changes how life sciences organizations conduct vendor audits. Traditional vendor audits are manual, inconsistent, and limited by SMEs availability. cIGA replaces these with AI-driven intelligence, standardized questioning, and real-time compliance validation.

More than a tool, cIGA is a platform, methodology, and digital audit workspace that enables regulated organizations to:

- Conduct structured, standardized GxP audits through intelligent AI agents
- Interview vendors asynchronously without calendar constraints
- Validate responses and evidence in real time
- Generate defensible compliance scores and audit-ready reports
- Run multiple vendor audits simultaneously with minimal human input

With built-in regulatory alignment and continuous learning, cIGA lets organizations audit faster, smarter, and at enterprise scale without compromising compliance or readiness.



VISION FOR cIGA



cIGA transforms vendor audits from episodic, manual exercises into continuous, intelligent compliance workflows. We believe GxP audits should be:

- Continuous: Not one-time events.
- Standardized: Not dependent on individual auditors or teams
- Automated: Not driven by manual interviews and reviews
- Traceable: Not fragmented across emails, spreadsheets, and documents

In today's complex regulatory and digital ecosystem, organizations require:

- Vendor audits that scale with growing ecosystems
- Real-time visibility into compliance gaps and risks
- Consistent interpretation of GxP expectations
- Audit processes that reduce SME dependency while increasing rigor

cIGA aligns vendor oversight with modern regulatory expectations and AI operating models.



OUR PROCESS

► Discovery & Audit Scoping

We assess the audit domain, regulatory context (GxP), and vendor risk profile. Audit scope, domains, and knowledgebases are pre-configured.

► AI-Led Vendor Interviews

AI Auditor Agents conduct structured, text/voice-based interviews with vendors using standardized GxP-aligned questions and adaptive follow-ups.

► Review, Approval & Reporting

SMEs review audit outcomes via dashboards. Audit-ready PDF reports with embedded evidence generate automatically.

► Knowledgebase Configuration

Regulatory requirements, audit frameworks, SOPs, and domain-specific controls form a structured knowledgebase powering intelligent questioning.

► Real-Time Response & Evidence Validation

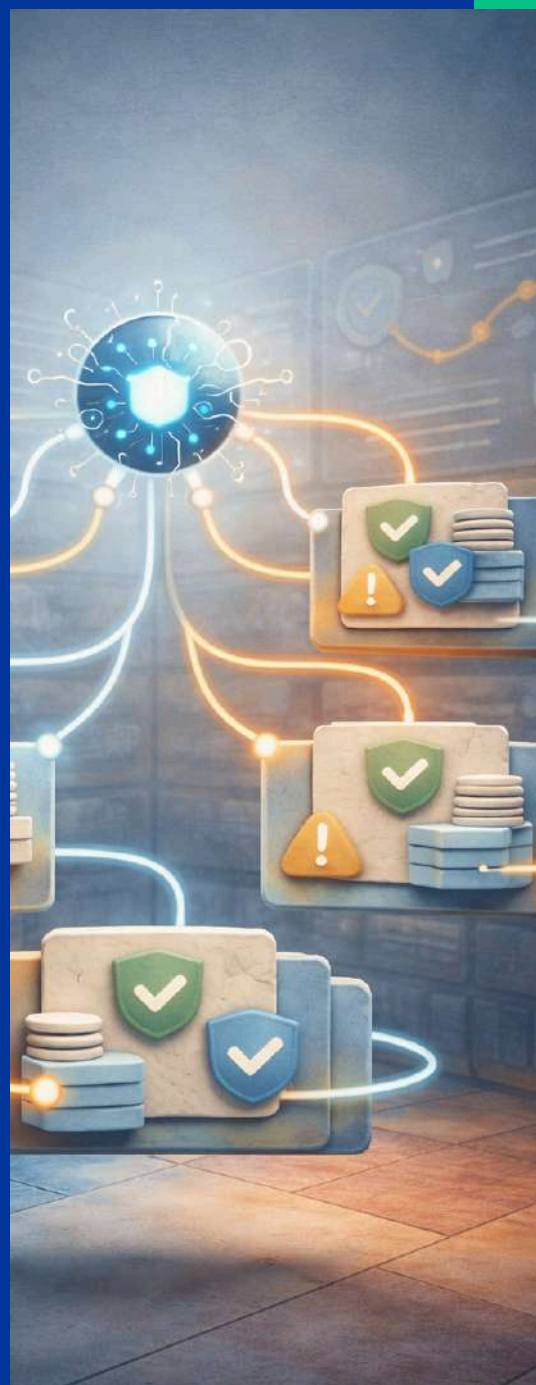
Validator Agents evaluate responses and evidence against regulatory expectations, assigning compliance scores and identifying gaps instantly.

► Continuous Learning & Reuse

Audit insights feed back into the knowledgebase, improving future audits and enabling consistent, repeatable vendor assessments.

INTELLIGENT FEATURES

- **Agentic Audit Orchestration**
AI Manager Agents coordinate audit workflows, question sequencing, progress tracking, and parallel vendor audits.
- **Standardized GxP Questioning Engine**
Auditor Agents retrieve domain-specific questions and generate context-aware follow-ups to ensure full compliance coverage.
- **Real-Time Compliance Scoring**
Validator Agents score responses on a 1–5 scale (Critical to Satisfactory), providing immediate visibility into risk and gaps.
- **Evidence-Aware Validation**
AI validates uploaded documents using semantic search and retrieval, ensuring defensible, evidence-backed assessments.
- **Live Audit Dashboards**
Administrators track audit status, KPIs, risk indicators, and completion metrics in real time.



VALUE MATRIX

Aspect	Traditional Vendor Audits	cIGA by xLM	ROI Impact
Audit timeline	Weeks to months	Days	70%+ time reduction
SME dependency	High (Auditors)	Minimal (Approvals only)	80% SME effort reduction
Audit consistency	Auditor-dependent	Fully standardized	100% coverage assurance
Compliance insight	Post-audit	Real-time	Immediate risk visibility
Evidence handling	Manual review	AI-validated	Zero audit prep time
Scalability	One audit at a time	Parallel audits	Enterprise scale audits
Audit Scheduling	Limited Time slots/ Scheduling Nightmare	24x7 accommodating vendor expert's busy schedules	5x faster audits/ 3x more sessions

ABOUT US

xLM is a trusted managed application provider enabling FDA-regulated organizations to modernize compliance, quality, and IT operations.

With decades of domain expertise and a technology-first mindset, xLM helps companies scale digital transformation without compromising on validation, traceability, or audit-readiness.

Our Other Applications

▶ Continuous Intelligent Validation (cIV)

▶ Continuous Predictive Maintenance (cPdM)

▶ Continuous Environmental Monitoring System (cEMS)

▶ Continuous Temperature Mapping (cTM)



Our stack incorporates intelligent and responsible AI into all our managed services. From Predictive Analytics to Software Validation, our apps are pre-built with best practices so that they can be deployed within days or hours.



Intelligent Application Provider

All our apps are delivered as managed apps. We do the heavy lifting so that you can focus on building your business



Intelligent and Responsible AI

Through our partnership with IBM, all our AI centric apps are delivered with cLCG (Continuous Life Cycle Governance)



White Glove Service

Our team does more than 95% of the heavy lifting. All we need from you are approvals



Extensive App Portfolio

xLM leverages its robust partner ecosystem to deliver over 15 managed apps and it is growing



Delivered Validated

All our managed apps are delivered “validated”



21 CFR Part 11/Annex 11/FDA CSA Compliant

Ensures all our managed services are compliant out of the box



High Data Integrity Assurance

Our services guarantee accurate, reliable and resilient data across all our managed apps

[Get Started](#)

