MODICUS PRIME

Are You in Control of Your AI?

Questions Every Life Science Organization Should Ask to Ensure Regulatory Compliance

1 Enterprise Visibility and Use Case Control

Question: Do you know what AI tools are currently in use across your organization, who is using them, and whether they've bypassed AI assurance in GxP processes?

Answer: AIMS serves as your centralized inventory and single source of truth. It tracks AI use cases and contexts of use across the organization, ensuring that models entering GxP workflows are accompanied by the proper governance controls.

2 Regulatory Findings and Audit Readiness

Question: Are you concerned about receiving regulatory findings due to autonomous AI agents acting without audit-ready evidence?

Answer: AIMS captures technical artifacts and risk-based decisions, giving inspectors complete, traceable proof of compliance throughout the entire AI lifecycle.

3 Multiple AI Systems, Functions, and Ownership

Question: How do you maintain a unified state of control when AI tools operate across disparate quality systems, data science tooling, and business applications?

Answer: AIMS ensures a state of control across AI systems that integrates with existing business applications (e.g., LIMS, MES), QMS (Quality Management System), MLOps infrastructure (e.g., Cloud, MLFlow). It unifies compliance across your entire tech stack without forcing you to replace core infrastructure.

4 Model Drift and Lifecycle Oversight

Question: How do you account for AI model drift or probabilistic behavior that could potentially compromise product quality or patient safety over time?

Answer: AIMS provides continuous lifecycle management. It can be configured to monitor AI performance, flags model drift, and tracks retraining or system updates so your AI models remain under a state of control.

5 Supplier AI Governance

Question: How can CDMOs and CMOs scale supplier oversight for third-party AI models, from foundational model providers to cloud hyperscalers?

Answer: AIMS simplifies supplier governance by standardizing supplier risk assessments, and supporting compliance across all external AI tools entering your GxP pipeline.

6 Eliminating Wasteful Iterations and Negative ROI

Question: Are you worried about negative ROI and resource drain caused by redundant initiatives and AI deployments?

Answer: AIMS manages each AI system, from context of use to audit readiness. It reduces deployment friction, wasteful iterations, and protects your return on AI investments.

7 Cross-Functional Friction (e.g., IT, Quality, Data Science)

Question: How do you bridge the communication gap between Data Science teams building models and Quality/Compliance teams enforcing GxP standards?

Answer: AIMS connects technical data science artifacts to standardized regulatory evidence. It bridges IT, Quality Assurance, and Data Science teams into one unified workflow, ensuring stakeholder alignment with compliance objectives.

8 Multi-Site Regulatory Compliance

Question: How do CDMOs and pharma companies ensure uniform AI compliance across manufacturing sites with varying regional regulations?

Answer: AIMS delivers a scalable compliance framework adaptable to regulatory standards (e.g., FDA, EMA). It supports consistent quality controls and audit readiness across all facilities worldwide from a single platform.

For more information about Modicus Prime's AIMS software solution or to schedule an AIMS demo scan the QR code below or contact us at:
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