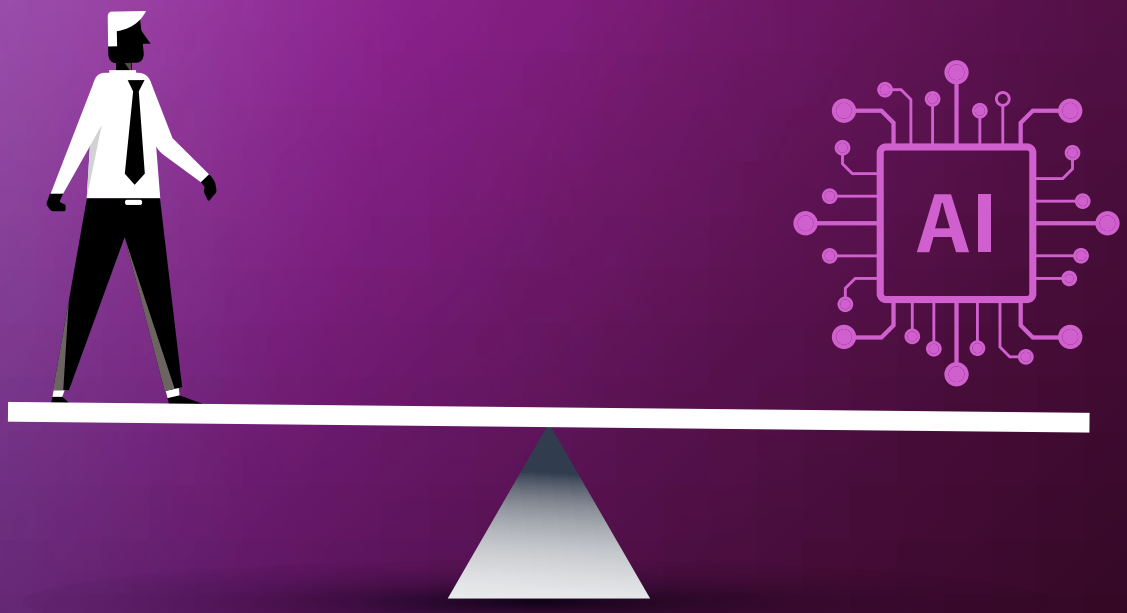
Industry Brief

Ensuring AI Compliance in Life Sciences: 5 Critical Requirements

MasterControl™



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5 AI Compliance Requirements Table of Contents

AI can add $100 billion in value to life sciences industries, according to McKinsey.[1]

Only 9% of life sciences professionals know U.S. and EU AI regulations well.[2]

Introduction

As a life sciences manufacturer, there's mounting pressure to integrate artificial intelligence (AI) across the product lifecycle and capitalise on the opportunities this technology presents to the industry. Organisations face the complex challenge of balancing innovation with regulatory compliance.

Safe and effective adoption of AI can require rigorous evaluation. You must be confident that AI capabilities that are (1) built in-house by your company or (2) are built by a vendor you are partnering with uphold the highest standards of compliance, product safety, data integrity, and patient protection.

Adding to that is the complexity of regulations and guidelines. Guidance and protocols continue to evolve globally, causing uncertainty among life sciences professionals around standards and compliant AI adoption.

In this evolving regulatory environment, uncertainty can cause hesitation and a "wait and see" approach for AI adoption. However, with the right trusted partner, you can confidently accelerate your adoption of AI, and benefit sooner from the time savings, improved efficiencies, and other advantages that come with strategic usage of AI in your processes. Life sciences manufacturers' operational needs and compliance requirements are at the core of MasterControl's approach to AI development. As guidance from global regulatory bodies evolves, we also continue to evolve to ensure we build secure AI tools that help you save time and work more efficiently, without sacrificing compliance.

By focusing on the five key areas we've identified below you can ensure the AI you are evaluating to integrate into your quality and manufacturing processes meets regulatory requirements. At MasterControl, we understand the effort and time/resource investment required to thoroughly evaluate AI for regulatory compliance. That's why we've done the work for you with the AI tools we build and release. MasterControl ensures we are addressing these five areas with our AI development so that life sciences manufacturers can easily and confidently adopt our compliant AI into their processes.

1. Data Integrity and Electronic Records

Best Practice

In life sciences manufacturing, data integrity is the foundation of product quality and patient safety. When implementing AI tools and/or systems, for example, manufacturers must ensure compliance with 21 CFR Part 11 for electronic records and signatures, while also adhering to EU GMP Annex 11 for computerised systems and the broader principles outlined in PIC/S PI 041-1 guidance on data integrity, among other global regulations.

Successful implementation requires system access controls with unique user identification and comprehensive audit trails. These audit trails must capture who made changes and when, along with the reasoning behind modifications – a critical aspect for any systems, including those that incorporate AI, where decisions may impact product quality.

Industry leaders implementing AI have found success by establishing dedicated data governance committees or councils that oversee AI data management practices. These committees or councils typically implement risk-based approaches to data integrity, focusing resources on critical data that directly impacts product quality and patient safety. Regular system audits, coupled with automated data verification processes, help ensure ongoing compliance with regulatory requirements.

In Practice at MasterControl

All AI tools available from MasterControl are built on our secure agentic AI platform, a system of customised large language models (LLMs), services, and programmatic agents all governed and administered by MasterControl. The platform adheres to 21 CFR Part 11 and EU GMP Annex 11 requirements and supports the principles outlined in PIC/S PI 041-1. We make sure data stays within our platform architecture and never goes to a third-party for processing.

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2. Assessing Fit for Use

Best Practice

AI development drives a need to think outside of traditional processes. The usage of AI tools must be evaluated for their fit with your business and your unique use cases within existing processes, or in the creation of new processes. This requires a verification of functionality for individual tools and an assurance that the foundational platform architecture those tools are built on is validated and compliant. In addition to that verification of intended use, human oversight is essential to guarantee the content, recommendations, and any other outputs that are generated enhance processes.

In supporting this approach, the evolving U.S. Food and Drug Administration (FDA) guidance on Computer Software Assurance (CSA) and AI/ML-Based Software, combined with GAMP 5 Second Edition principles, provides a framework for critical thinking and ensuring AI systems are fit for their intended use while maintaining regulatory compliance.

In Practice at MasterControl

MasterControl large laguage model (LLM)-powered tools are built upon our robust, validated platform infrastructure that adheres to stringent regulatory requirements including 21 CFR Part 11 compliance. This strategic approach combines the flexibility of verified tools with the security and compliance of a validated foundation, offering life sciences companies the best of both worlds.

AI tools released by MasterControl go through a rigorous testing process to confirm they function as specified. Prior to being released in production settings, MasterControl AI tools are deployed in test environments to ensure top performance, verify compatibility with the MasterControl platform, and identify and fix any bugs. Ultimately, the rigorous testing processes conducted on our AI tools lead to higher-quality products and a better user experience.

In addition to diligent testing, MasterControl also trains LLMs for relevancy for life sciences users. That means technical industry language, regulatory requirements, complex procedures, and more are more likely to be understood by MasterControl's owned models, increasing the accuracy of AI output compared to more general models not specifically trained for life science use cases.

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3. Transparency and Explainability

Best Practice

Recent FDA guidance on AI/ML in medical products emphasises the critical importance of "explainable AI," requiring manufacturers to demonstrate clear understanding and traceability of AI-driven decisions that impact product quality and patient safety.

Regulatory bodies, including the European Medicines Agency (EMA) and the FDA, are increasingly focusing on the interpretability of AI. This stems from the fundamental good manufacturing practice (GMP) principle that critical decisions affecting product quality must be traceable and justified. For life sciences manufacturers, this means implementing AI systems that can provide clear explanations of their decision-making and/or recommendation processes.

"Human in the loop" is a critical approach for oversight of AI systems to ensure understanding. Human review of data and content accuracy and the interpretation of insights or content generated is essential to ensure and enhance accuracy and reliability. Ultimately, having a human in the loop helps ensure the highest quality output that is most useful in helping with process improvement.

In Practice at MasterControl

At MasterControl, we are committed to AI-driven tools with transparent outputs so users can review and modify/accept as needed. All tools built by MasterControl are designed with a human-in-the-loop approach. Nothing replaces the oversight of a knowledgeable person who may direct input and should approve output for LLMs.

When AI tools like MasterControl's are founded on a human-in-the-loop approach, all content generated, recommendations provided, and other outputs should be reviewed for accuracy by a human expert on that subject matter.

For example, when a user generates training exams with Exam Generator, they are able to review, regenerate, or directly modify or edit the question, correct answer, and incorrect answers for a multiple-choice question to ensure accuracy and relevance. This human review is a quick, valuable check that builds confidence in then implementing the exam into your training process to test for comprehension on critical content in a standard operating procedure (SOP).

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4. Risk Management

Best Practice

Risk management for AI systems in pharmaceutical manufacturing must align with ICH Q9 principles while addressing the unique challenges posed by artificial intelligence. The dynamic nature of AI systems requires a more sophisticated risk management approach across all life sciences industries that considers both traditional quality risks and AI-specific concerns such as algorithm bias, hallucinations, and data quality dependencies.

Successful risk management programmes typically begin with a comprehensive risk assessment that evaluates potential impacts across the entire product lifecycle. This includes consideration of direct product quality impacts, potential effects on patient safety, data integrity risks, and compliance implications. Organisations should document their risk assessment and maintain evidence of systematic risk evaluation for each AI implementation.

Regular risk reviews should assess both the performance of the AI system and the effectiveness of established control measures. Organisations should also establish and document clear procedures for system failures, including defined thresholds for when to revert to manual processes. These plans should be regularly reviewed and updated to ensure they remain effective as systems evolve.

In Practice at MasterControl

MasterControl prioritises the performance of models. We continuously monitor the market for the best open-source LLMs and carefully select the models that best fit the needs of our end users. Next, we make modifications to optimise those models for a specific type of task, then make the models our own.

In addition to customising and fine-tuning models specific to life sciences use cases, we use post-processing. Post-processing, among other guardrails, helps to mitigate the risk of an AI model hallucinating.

Finally, when warranted, we check AI-generated content for HIPAA/PII compliance.

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5. Data Privacy and Security

Best Practice

In an increasingly connected manufacturing environment, data privacy and security for AI systems must comply with both industry-specific regulations (such as 21 CFR Part 11) and broader data protection requirements like the EU's General Data Protection Regulation (GDPR) law or other regional privacy laws. This dual compliance requirement creates unique challenges for life sciences manufacturers implementing AI solutions.

Successful data privacy and security programmes typically implement multiple layers of protection for sensitive data. This includes robust encryption for data both at rest and in transit, granular access controls, and comprehensive audit trails of data access and usage.

In Practice at MasterControl

MasterControl is the custodian of our customers' data, so everything from input to processing throughout our agentic AI platform (including LLMs) to storage remains strictly under our control. This means routing and storing of data within our platform is compliant with industry standards and regulations.

The AI imperative for life sciences cannot be ignored. Save hundreds of hours and thousands of dollars with safe adoption of tools that help to augment, or even re-think, your processes. However, the rigorous evaluation of tools prior to implementation can delay those benefits. Partnering with a vendor who has expertise with both AI development and regulatory compliance streamlines your ability to experience those efficiencies.

Learn more about MasterControl's AI tools on our website or speak with one of our experts to learn what our AI tools can do for your organisation.

About MasterControl

MasterControl Solutions Inc. is a leading provider of cloud-based quality, manufacturing, and asset management software for life sciences and other regulated industries. For three decades, our mission has been the same as that of our customers – to bring life-changing products to more people sooner. MasterControl helps organisations digitise, automate, and connect quality, manufacturing, and asset management processes and has a proven track record of improving product quality, reducing costs, and accelerating time to market. Over 1,100 companies worldwide use MasterControl to streamline operations, maintain compliance, manage critical assets and equipment, easily analyse and interpret large amounts of data, and visualise business insights in real time.

For more information, visit www.mastercontrol.com.

References:

1. "Generative AI in the pharmaceutical industry: Moving from hype to reality," McKinsey & Company, Jan. 9, 2024.
2. "Trendspotting: Predictions for Bio-IT World in 2025," Bio IT World, Jan. 7, 2025.