

RiskCortex & Biopharma Institute Launch Groundbreaking AI Compliance Expert-in-the-Loop Certification for Life Sciences

The first industry-designed accreditation dedicated specifically to the safe, compliant, and human-supervised use of AI across the life sciences sector.

PARAMUS, NJ, UNITED STATES, March 24, 2026 /EINPresswire.com/ -- Biopharma Institute, in

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Carolyn Troiano, Compliance & Quality Authority Lead at RiskCortex

partnership with RiskCortex, is proud to announce the launch of the [AI Regulatory Compliance: Expert-in-the-Loop \(EIL\) Certification Program](#) - Empowering Experts to Guide AI. This is a first-of-its-kind professional certification designed to help life sciences organizations harness the power of artificial intelligence while maintaining regulatory control, compliance integrity, and human accountability.

As AI rapidly transforms pharmaceutical, biotechnology, medical device, and clinical research operations, organizations face increasing pressure to adopt advanced technologies without compromising compliance, validation standards, or regulatory trust. The new Expert-in-the-Loop

Certification Program addresses this urgent industry need by preparing quality, validation, and regulatory professionals to serve as the critical human authority guiding AI use in regulated environments.

Developed by industry leaders at RiskCortex and Biopharma Institute, this innovative certification program is the first industry-designed accreditation dedicated specifically to the safe, compliant, and human-supervised use of AI across the life sciences sector. The program equips professionals with the practical knowledge, regulatory insight, and applied skills needed to oversee AI-enabled processes, reduce operational burden, strengthen decision-making, and support confident adoption of AI in highly regulated settings.

“AI can accelerate compliance work dramatically, but only when guided by skilled human experts,” said Carolyn Troiano, Compliance & Quality Authority Lead at RiskCortex. “The Expert-in-the-Loop role is essential to ensuring organizations maintain trust, data integrity, and

regulatory confidence while adopting these advanced AI technologies.”

The launch comes at a pivotal time for the industry. Regulatory agencies worldwide have intensified enforcement across 2025 and 2026, with a reported increase in FDA Drug Warning Letters and a rise in Untitled Letters compared with prior periods. This escalation reflects a broader shift toward data-driven enforcement, AI-supported inspection targeting, and increased scrutiny of data integrity, computerized systems, validation practices, and global manufacturing operations.

Program Highlights

Module 1: Introduction to AI Regulatory Compliance Management: The Expert-in-the-Loop

A complimentary program that provides foundational insight into the Expert-in-the-Loop, an evolving role of human oversight in AI-enabled compliance, critical thinking in AI-supported decision-making, and the growing challenge of the AI trust paradox.

Module 2: Basic Skills – AI Regulatory Compliance Management: Expert-in-the-Loop Professional Certification Program

This program takes participants into the evolving world of AI-driven regulatory compliance management. Learners will explore the shift from traditional Computer System Validation (CSV) to Computer Software Assurance (CSA), gaining a practical understanding of the risk-based, critical-thinking approach now shaping compliance in regulated life sciences environments. A key feature of the program is a self-directed, hands-on activity using the [RiskCortex AI regulatory intelligence platform](#), providing a practical experience using an AI tool in a compliance-focused setting.

Module 3: Advanced Skills – AI Regulatory Compliance Management: Expert-in-the-Loop Professional Certification Program

This advanced module expands on the operational and regulatory application of AI. Learners will be challenged to independently complete high-level, hands-on exercises using the RiskCortex AI regulatory intelligence platform.



The graphic features a central image of a human hand shaking a robotic hand against a dark blue background. Above this image, the text "AI Expert-in-the-Loop" is written in a large, white, sans-serif font. Below the handshake, there are two circular logos. The left logo is white with a red and grey shield-like emblem and a red laurel wreath. The right logo is a circular seal with a blue and purple border, containing a grid of blue and purple dots and the text "CERTIFIED" at the top and "EXPERT IN THE LOOP" at the bottom.

AI Expert-in-the-Loop

AI Regulatory Compliance: Expert-in-the-Loop (EIL) Certification Program - Empowering Experts to Guide AI

Module 4: Specialty Skills – AI Regulatory Compliance Management: Expert-in-the-Loop Professional Certification Program

In the final stage of the program, participants pursue master-level specialty training aligned to one of eight areas of professional focus described on the program webpage.

Upon successful completion of Modules 2, 3 or 4, participants will earn a professional certification as an Expert-in-the-Loop - a qualified guide to oversee and strengthen the use of AI in regulated life sciences environments.

“Regulators are using AI to identify compliance risks faster than ever before,” said Arun Parekkat, Co-Founder and CEO of RiskCortex. “This certification gives professionals the skills, judgment, and tools they need to meet modern regulatory expectations, strengthen compliance performance, and avoid costly mistakes.”

[Enrollment is now open for Module 1](#): Introduction to AI Regulatory Compliance Management: The Expert-in-the-Loop.

About RiskCortex

RiskCortex is an AI-driven regulatory intelligence and compliance platform built to help life sciences organizations reduce the risk of regulatory penalties and compliance failures. The platform provides autonomous risk assessment, continuous validation support, and real-time regulatory monitoring to help organizations strengthen compliance performance in a rapidly evolving regulatory landscape.

About Biopharma Institute

Biopharma Institute provides accredited regulatory and GxP compliance training programs for professionals and corporations across the pharmaceutical, biotechnology, clinical research, and medical device sectors. Its programs are designed to strengthen workforce capabilities across regulatory, quality, validation, and compliance disciplines.

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