AI Assurance for GxP™

Keeping AI-supported regulated work under meaningful human control

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The proposition

AI is entering regulated life-science work faster than assurance practice is maturing. Technical validation, data integrity, cybersecurity, supplier controls, SOPs and training remain necessary. They do not, by themselves, show that people can recognise weak output, challenge it, act independently when needed and recover safely when the technology changes or fails.

RHIEOS treats assurance as a continuing organisational capability rather than a one-time compliance event.

The central question

Can the organisation still detect, challenge and recover when the AI is wrong?

What good assurance should preserve

- Clear intended use: what the AI may do, what it may not do, and where human judgement remains required.
- Accountability: named people with the competence, authority and independence to review, challenge, override, pause or escalate.
- Evidence over claims: enough information to understand supplier responsibilities, system behaviour, change and limitations.
- Human capability: critical professional skills remain usable rather than fading through repeated automation.
- Ongoing control: monitoring, change management and recovery remain effective after deployment, not only at go-live.

What this public summary does - and does not do

This summary explains the RHIEOS assurance position at a high level. It does not disclose the underlying rubric, mnemonics, test sequence, maturity model, scenario library, scoring/evidence logic, detailed templates, supplier-control method, implementation architecture or commercial packaging.

Where it applies

The approach is intended for AI-supported work where errors, over-reliance, weak oversight or loss of professional capability could affect patient safety, product quality, data integrity, trial integrity, regulatory compliance or other important outcomes.

- Pharmacovigilance and medical information
- Clinical operations and data review
- Quality and manufacturing support
- Regulatory and medical writing
- Supplier and outsourced-service oversight
- Other GxP-relevant workflows where human judgement remains material

How it relates to existing quality systems

RHIEOS does not propose a replacement for GxP quality management, validation, training or AI governance. The aim is to strengthen the parts that depend on sustained human judgement and clear organisational control. Existing QMS, LMS, validation, risk-management and governance records remain authoritative.

A practical test

If an organisation cannot explain who can stop the AI-supported process, what evidence supports its use, how important human skills remain current, and what happens when conditions change, the oversight claim is incomplete.

Status and limits

AI Assurance for GxP™ is a RHIEOS working practice for discussion, testing and development. It is not a regulation, standard, certification scheme, validated method or substitute for legal, regulatory, quality, safety or validation judgement.

The detailed RHIEOS AI-assurance rubric and Skill-Capability AI Assurance Toolkit remain proprietary working material unless expressly released.

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