DIA LEARNING

Agentic AI in Pharmacovigilance: From Operator to Supervisor

8-9 November 2027 | 13:00-17:30 CET | Virtual Live



Overview

Agentic AI has arrived in pharmacovigilance. Systems that read safety correspondence, build cases, code events and draft assessments are moving from pilots into production, and the job of the pharmacovigilance professional is changing with them: from executing the work to supervising the machines that execute it. Supervision is a different skill from execution, and almost nobody in the field has been trained for it.

This virtual live training course gives pharmacovigilance professionals the vocabulary, the mental model and the practical tools to oversee AI agents competently and compliantly.

Participants learn how an agent actually works, where it fails and why those failures are hard to see, how to review agent output with a defensible sampling and escalation plan, how to apply credibility assessment and validation thinking to a non-deterministic system, and what has to change in SOPs, roles and KPIs when the work is delegated.

The course is hands-on. Every participant works in a browser-based sandbox with a representative ICSR intake agent, breaks it, supervises it and writes its credibility plan. It is taught by a physician with direct experience of building and operating agentic pharmacovigilance systems and of defending them in front of auditors and inspectors. EU and US regulatory expectations are treated side by side throughout.

Learning Objectives

At the conclusion of this virtual live training course, participants will be able to:

- Define agent, tool call, trace, guardrail, eval and golden set, and explain how an agent loop runs
- Classify pharmacovigilance tasks as delegate, delegate with checkpoint, or keep human, with reasons
- Recognise the pharmacovigilance-specific failure modes of AI agents, including silent omission, and name the control that catches each
- Review a batch of agent output using thresholds, risk-based sampling and escalation rules, and measure their own oversight quality
- Draft a context-of-use statement, model-risk rating and credibility assessment plan for one pharmacovigilance task, and map it to EU and US expectations
- Describe the changes to SOPs, roles, KPIs and training records that supervised-agent workflows require

Who Will Attend

This virtual live training course is designed for Pharmacovigilance professionals whose roles are shifting towards oversight of AI-assisted or AI-executed processes:

- Case processors and case-processing leads
- Medical reviewers
- PV quality and compliance staff
- Local safety officers
- QPPVs and deputies
- PV system owners and business analysts

No technical background is required; a 20-minute pre-course primer brings participants with no prior AI exposure to the same starting point.

Instructor

Jan Petracek
CEO
iVigee Services
Czech Republic

Key Topics

- Agent anatomy: the loop, tools, memory, traces and non-determinism
- Where agents fit in the PV value chain and where they fail
- Human-in-the-loop, on-the-loop and out-of-the-loop supervision, human-in-command concept
- Risk-based sampling, confidence thresholds, escalation and audit trail
- Credibility assessment framework and validation of non-deterministic systems
- EMA and FDA expectations side by side: reflection paper, AI credibility framework, EU AI Act, CSA, Annex 11 and Part 11
- Agentic architecture patterns and where the human checkpoint belongs
- Change management: SOPs, roles, KPIs, training records and the psychology of delegation

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DAY 1 — UNDERSTANDING AGENTS

13:00 WELCOME AND INTRODUCTION

- Course arc: operator today, supervisor tomorrow
- Sandbox check: every participant logs in and runs the agent once on a sample email

13:30 SESSION 1

WHAT AN AGENT IS AND HOW IT WORKS

- An agent is a language model plus instructions, tools, memory and a goal, running in a loop: perceive, reason, act, observe
- How agents differ from RPA, rules engines and chatbots
- The ten terms you will hear from engineers: token, context window, system prompt, tool call, orchestrator, guardrail, trace, eval, golden set, drift
- Why the same input can give a different output, and why that is a property to be controlled rather than a defect to be fixed
- Hands-on Lab 1 (breakout rooms): Break the agent. Edit the agent's instructions, remove its MedDRA tool, re-run three times, read the trace and report what varied and what was confidently wrong

14:45 BREAK

15:00 SESSION 2

WHERE AGENTS FIT IN PV, WHERE THEY FAIL, AND WHAT REGULATORS SAY

- The PV value chain from intake to aggregate reporting: delegate, delegate with checkpoint, keep human
- A failure taxonomy for PV: hallucination, omission, silent failure, drift, automation bias, prompt injection, personal-data leakage
- EU and US side by side: EMA reflection paper on AI in the medicinal product lifecycle and the EU AI Act; FDA framework for AI credibility in regulatory decision-making and Computer Software Assurance; Annex 11 and 21 CFR Part 11; GVP Modules VI and IX, 21 CFR 314.80 and ICH E2B(R3); EMA–FDA joint principles
- Group exercise (shared whiteboard): sort the tasks of a case-processing flow into the three columns and defend the reasons

16:14 BREAK

16:20 SESSION 3

THE SUPERVISOR'S TOOLKIT

- Human-in-the-loop, on-the-loop and out-of-the-loop, human-in-command, and how the right mode shifts with task risk and system maturity
- Reading a trace: what to look for, what to ignore
- Confidence thresholds, escalation rules and risk-based sampling instead of 140% review
- Metrics a supervisor owns: field-level accuracy, recall and coverage, hallucination rate, escalation rate, turnaround
- Feedback loops and the audit trail: who signed, what was recorded, what an inspector reconstructs

17:00 DISCUSSION AND Q&A

- Bridge assignment for Day 2: observe one of your own working days, note three tasks you would delegate and one you would never delegate, and bring one decision you found hard to make because you did not trust an input

17:30 END OF DAY 1

DAY 2 — SUPERVISING AGENTS

13:00 RECAP AND BRIDGE-ASSIGNMENT DEBRIEF

- The agent loop, the failure taxonomy and the supervisor's toolkit in ten minutes
- Quick round: which tasks the group would delegate and why the answers differ

13:15 SESSION 4

HANDS-ON LAB 2 — SUPERVISE A SHIFT

- Each participant receives a queue of ten agent-processed synthetic cases with source documents and a time budget; five contain planted errors
- Decide accept, correct or escalate for every case; decisions are scored for precision and recall as a supervisor
- Debrief: what most participants missed, the sampling plan that would have caught it, and what the agent's confidence scores did and did not signal

14:05 BREAK

14:15 SESSION 5

CREDIBILITY ASSESSMENT AND VALIDATION

- The credibility framework step by step: question of interest, context of use, model risk as influence × consequence, credibility assessment plan, execution, adequacy judgment; roots in ASME V&V 40
- Mapping it onto CSV and CSA, the GAMP 5 AI appendix and Annex 11
- Validating a non-deterministic system: golden datasets, acceptance criteria, performance qualification that never ends, change control for model and prompt changes, continuous monitoring
- The five questions an inspector will ask
- Hands-on Lab 3 (breakout rooms): draft a question of interest, context-of-use statement, model-risk rating and evidence list for the sandbox agent, then compare it with the evidence the sandbox actually provides

15:25 BREAK

15:40 SESSION 6

DESIGN STRUCTURES AND CHANGE MANAGEMENT

- Architecture patterns in plain language: single agent, orchestrator and workers, evaluator and optimiser, human checkpoints as design elements
- Role redesign and a competency framework for supervisors; rewriting SOPs so that "verify" means something specific
- KPIs that measure quality of oversight rather than cases per day; training records; the psychology of delegation: anxiety, over-trust, under-trust, deskilling
- Group exercise (breakout rooms): rewrite three steps of a case-processing SOP for a supervised-agent workflow

16:20 DISCUSSION, Q&A AND COURSE CLOSE

- Open questions from both days
- Taking it home: one thing to learn, one process to change, one conversation to have

17:30 END OF THE VIRTUAL LIVE TRAINING COURSE

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REGISTRATION FORM

Agentic AI in PV | Virtual Live Training Course | # 27544
8-9 November 2027 | 13:00-17:30 CET

DIA LEARNING

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

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INDUSTRY/REPRESENTATIVE	€ 1'035.00 ❑	€ 1'150.00 ❑	€ 1'410.00 ❑
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