The Institute of Applied AI

CPD ACCREDITED

MICRO DIPLOMA

# Applied Generative AI

Judgement before tools. Capability before compliance.

For pharma and life sciences manufacturing teams

- 4 modules, 12 contact hours
- Generative AI and machine learning
- In person, on site
- Regulatory position dated to delivery

WHY NOW

# AI is already on site.
# Can you stand over every AI-assisted decision?

Most sites now have Copilot or similar tools in daily use, alongside machine learning that has run quietly in operations for years. The regulators have noticed.

The EU AI Act requires organisations to make sure the people using AI have sufficient AI literacy. The HPRA is now a designated authority under Ireland's AI legislation, alongside its GMP inspection role. And the draft EU GMP Annex 22 sets out what inspectors will expect for AI used in GMP activities.

Most AI training teaches tools. People learn to prompt, but not when to use AI, when not to, and how to check what comes back. That gap shows up in an inspection.

**This programme builds the judgement first. The tools follow.**

REGULATORY POSITION AS AT 21 OCTOBER 2026

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|---|---|
| In force | **EU AI Act, as amended by the AI Omnibus** (Regulation (EU) 2026/1744, July 2026). The Article 4 AI literacy obligation applies to organisations using AI. |
| In force | **Regulation of Artificial Intelligence Act 2026** (Ireland, July 2026). The AI Office of Ireland is operational and the HPRA is a designated competent authority. |
| Draft | **EU GMP Annex 22, Artificial Intelligence.** Final text targeted for the fourth quarter of 2026, with the position on generative AI under review. Annex 11 and Chapter 4 are being revised alongside it. |
| Published | **FDA and EMA Joint Guiding Principles for Good AI Practice** (January 2026). A shared direction of travel, not a checklist. |
| Draft | **FDA draft guidance on AI to support regulatory decision making for drugs** (January 2025). Not yet finalised, with no committed date. |
| Good practice | **ISPE GAMP Guide: Artificial Intelligence** (2025). Industry guidance on lifecycle and validation. |

The programme is refreshed to the position on the day of delivery.

THE FOUR MODULES

# One programme.
# Four questions worth answering.

AI is already in use on site. Most people cannot yet say when it should be used, whether the answer can be trusted, what the rules allow, or how to take a use case forward safely. Each module closes one of those gaps.

## 01 From Blind Habit to Intentional Co-Partner

*Does the human process matter here?*

Most people use AI for speed and could not say what they checked. Participants learn to decide where AI belongs in their own work, to think first and consult the tool second, and to account for what they accepted and rejected. The site gains people who can stand over their AI-assisted work.

JUDGEMENT AND CRITICAL THINKING

## 02 The Intelligent Foundation

*Can AI reliably do this?*

AI gives confident answers and no way to judge them. Participants learn how AI produces an answer, where it fails, and why the data behind it matters. The site gains a shared vocabulary and people who can question a tool or a vendor on equal terms.

AI FOUNDATIONS

## 03 Trust by Design™

*Does the governance allow it?*

Few people are sure what the rules require, or what an inspector would ask. Participants learn what the regulations say on the day, how to classify a use case on this site, and what evidence should exist. The site gains a first set of classified use cases and a clear view of who answers for them.

GOVERNANCE AND REGULATION

## 04 Your AI Advantage

*Can you stand over every AI-assisted decision you or your team have made?*

Good use cases stall because nobody owns the steps between idea and use. Participants take a real use case through the AI lifecycle: what is decided at each stage, by whom, and what record is kept. The site gains use cases that are ready to move forward under its own quality system.

THE AI LIFECYCLE IN PRACTICE

WHAT PARTICIPANTS LEAVE WITH

# Practical capability, not theory.

### Every participant leaves with

- A clear test for when AI should and should not be used
- A structured way to prompt and check what comes back
- Their own use case, classified and ready for the site's use case register
- That use case taken through the AI lifecycle with their team
- An assessed record of their capability, not an attendance certificate

### The site gains

- A shared AI vocabulary across functions, kept as a site reference that can be updated
- A common understanding of what an inspector could ask for, and who would answer
- A first set of classified use cases from across the site
- A baseline of individual and team AI maturity, from a short pre-programme questionnaire

PROGRAMME DETAILS

| | |
|---|---|
| WHO IT IS FOR | Managers, team leads and specialists across quality, QC, manufacturing operations, engineering, maintenance, supply chain, regulatory, EHS and IT. No technical background needed. Minimum two years' professional experience. |
| FORMAT | Four modules of three hours each (12 contact hours), delivered over two consecutive days or as four half days. The site chooses. |
| GROUP SIZE | 10 to 15 participants per cohort. |
| DELIVERY | In person, on site or at a hosted venue. Tool agnostic: we work with the tools the site has approved, such as Copilot or Gemini. |
| MATERIALS | Participant workbook, reference documents and exercises for each module. |
| ASSESSMENT | Portfolio based: in-session exercises, short reflections and a final lifecycle exercise, assessed against a rubric. |
| ACCREDITATION | CPD accredited through The CPD Certification Service (UK). CPD certificate on completion. |

WHERE THE MICRO DIPLOMA FITS

# Capability first.
# Then readiness.

The Micro Diploma builds the capability. What follows depends on where the site is and what it needs next.

STEP 1
**Build capability**
The Micro Diploma, for a cohort or across functions.

STEP 2
**Diagnostic**
Where the site stands against what an inspector could ask to see.

STEP 3
**Focused workshops**
On the areas that matter most for the site.

STEP 4
**AI project support**
Taking governed use cases from pilot to production.

ABOUT US

## The Institute of Applied AI

We are a Cork based company focused on one thing: helping regulated life sciences manufacturing build AI capability responsibly, and be ready to stand over it.

The Institute was co-founded by Siobhán O'Leary and Susana Marambio. Siobhán spent over a decade in leadership roles in regulated pharma manufacturing before moving into AI. She is a Certified AI Governance Professional (IAPP) and a Project Management Professional. Susana leads commercial strategy and market development.

Our approach, Trust by Design™, treats AI governance the way manufacturing already treats quality: designed in from the start, not inspected in afterwards.

CPD MEMBER
The CPD Certification Service

Certified AI Governance Professional
AIGP
iapp

**Next steps**
We scope each delivery with the site: format, cohort, examples and timing. Pricing is available on request.

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The Institute of Applied AI

**Building AI capability, responsibly.**