Artificial Intelligence and Technical Services

CIARA DUFFY

RPS BOARD MEMBER

QP & SPECIALIST PROJECTS NOVARTIS

Agenda

Introduction and Overview

Understanding AI

Machine Learning

Large Language Models

Regulatory Landscape

AI in Practice

Critical Thinking and AI

Conclusion

Career Path

Clinical Trials

MPharm Graduate 2011

Locum Community Pharmacist

Hospital Pharmacist 2012

PG Advanced Pharmacy Clinical Practice

Production Pharmacist 2014

QA Pharmacist 2016

PG Pharmaceutical technology Quality Assurance

QP Application and VIVA 2020

QP Novartis 2021

Investigational medicinal products considerations in pediatric clinical drug trials

Mandy Wan[1,2], *Samantha Carmichael*[3] *and Ciara Duffy*[4]

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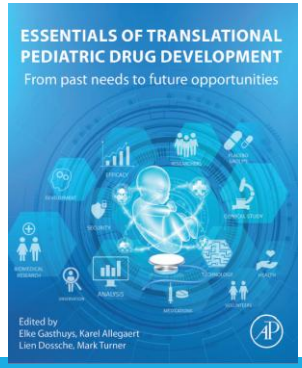


Clinical Trials
+
Commercial Products
+
Specialist Projects

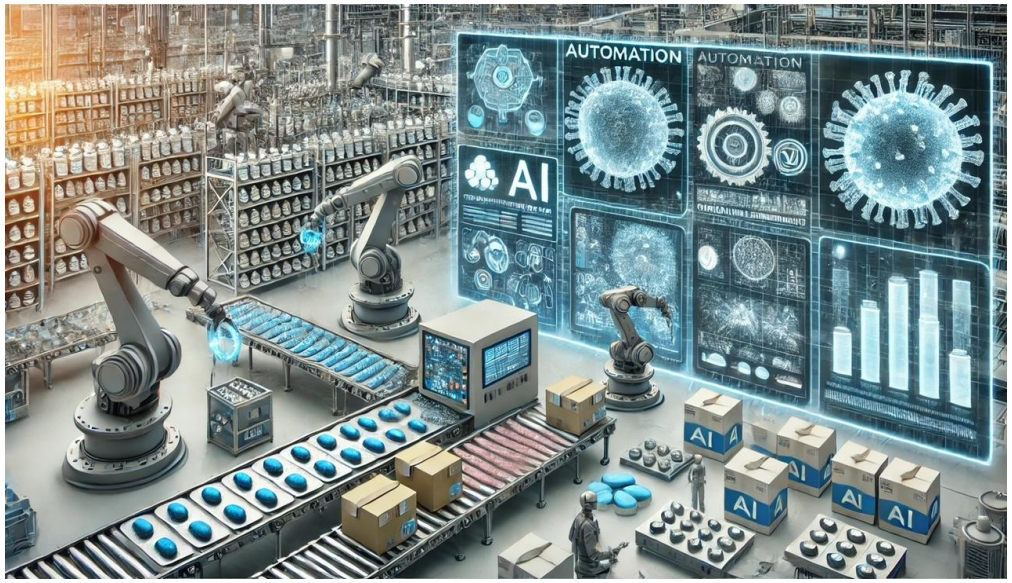
My AI Journey

ACT OR BE ACTED UPON

What is Artificial Intelligence (AI)?

AI, or Artificial Intelligence, refers to algorithms designed to mimic or simulate human cognitive abilities. This includes information processing, establishing relationships between multiple elements, learning and adapting to new concepts, making decisions, and adjusting to new situations.

Differences Between AI and Automation



AI VS AUTOMATION	AI - ARTIFICIAL INTELLIGENCE	AUTOMATION
Definition	A sector of computer science focused on creating intelligent machines that mimic human intelligence	A technique used to make a system operate automatically to accomplish repetitive tasks based on preset rules and commands
Key Capabilities	Problem-solving, speech recognition, learning, planning	Handles repetitive tasks without human intervention
Learning Ability	Has the ability to adapt and learn from new information	Lacks the ability to learn from processed data
Complexity of Tasks	Can cope with complex tasks involving decision-making or problem-solving	Best suited for straightforward, repetitive tasks
Interaction	Capable of interacting with humans and predicting user needs	Lacks human-like interaction
Data Analysis	Can analyze and interpret large volumes of data	Can process large data but lacks interpretation capability

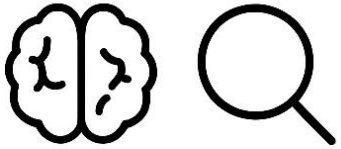
Differences Between AI and Automation

Automation
(Past & Present)

Rule-based image checks (pixels, contrast, thresholds

Example: Detecting if a vial is empty or misaligned
"If X, then Y —
no learning, just ules

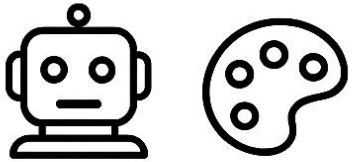
Discriminative AI
(Now)



Machine learning models trained on "good" vs "defective" vials

Example: CNN classifies particles, cracks, or label defecta
Learns from data to classify defects

Generative AI
(Emerging)

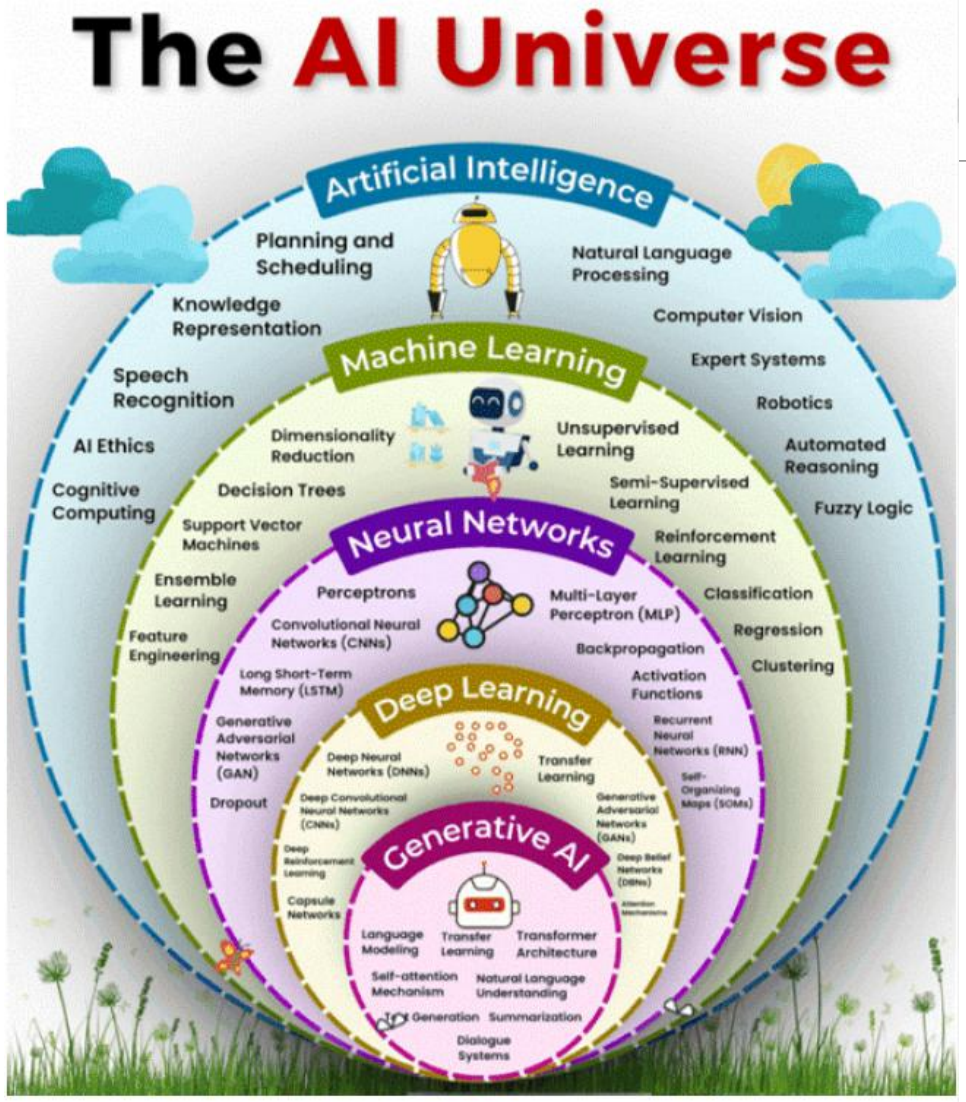


Generates synthetic defect images to improve training sets

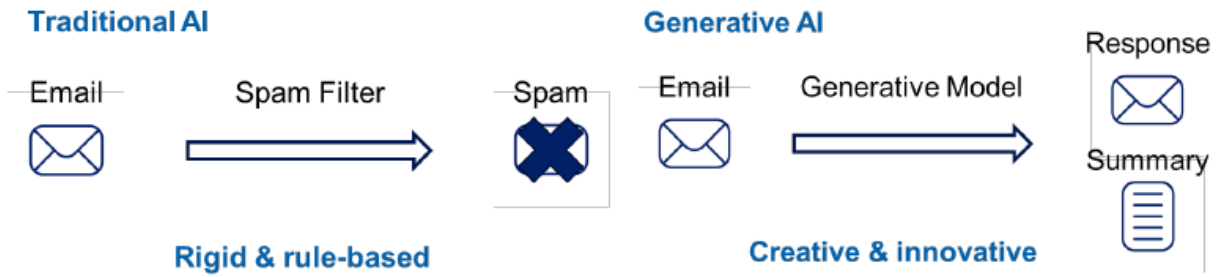
Example: Creating rare defect scenarios for validation

Creates training data, making inspection smarter

AI Terminology



AI Type	Discriminative (Narrow) AI	Generative AI
Overview	Implements predefined rules and applies machine learning for predictive analytics	Employs deep learning for tasks involving creativity and innovation, generating new, useful data from existing information
Example in Drug Manufacturing	Analyzes historical production data and optimizes assembly line operations, making real-time adjustments to enhance efficiency and reduce waste	Learns from a vast database of chemical reactions and designs and optimizes synthetic routes for drug manufacturing. It proposes the most efficient, cost-effective, and eco-friendly way to synthesize a drug
Key Applications II	Visual inspection, Monitoring, predictive maintenance	Content Generation Automation (Text, Tables), Draft Document generation,



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Artificial Intelligence Models - Examples

Model Type	What It Does	Everyday Example
Transformer-based LLM	Learns patterns in language to understand, predict, or generate human-like text	ChatGPT writing emails, Copilot drafting documents
CNN (Convolutional Neural Network)	Recognises patterns in images by scanning for shapes, edges, textures	Google Photos tagging faces, Instagram filters
GNN (Graph Neural Network)	Learns from networks (like social or molecular graphs); considers relationships between items	LinkedIn friend suggestions, fraud detection
Knowledge Graph	Connects pieces of information as relationships in a web of knowledge	Google Search showing “related people” or facts
Reinforcement Learning	Learns by trial and error -rewards success, punishes failure	YouTube recommending videos based on watch behaviour
Collaborative Filtering	Looks at what similar users liked to predict what you’ll like	Spotify suggesting songs, Netflix recommending shows
Recommendation System	Combines filters, behaviour, and rewards to make smart predictions	Amazon suggesting “People who bought this also bought…”

Machine Learning

Machine learning is a subset of artificial intelligence (AI) that involves the development of algorithms and statistical models enabling computers to learn from and make predictions or decisions based on data.

Machine Learning

- **Reinforcement Learning**

Learn to make sequential decisions to maximize rewards

Eg : Chess AI.

- **Unsupervised Learning**

Discover Patterns, relationships or groupings with unlabeled data

Eg: Recommendation system used by websites like Amazon and Netflix.

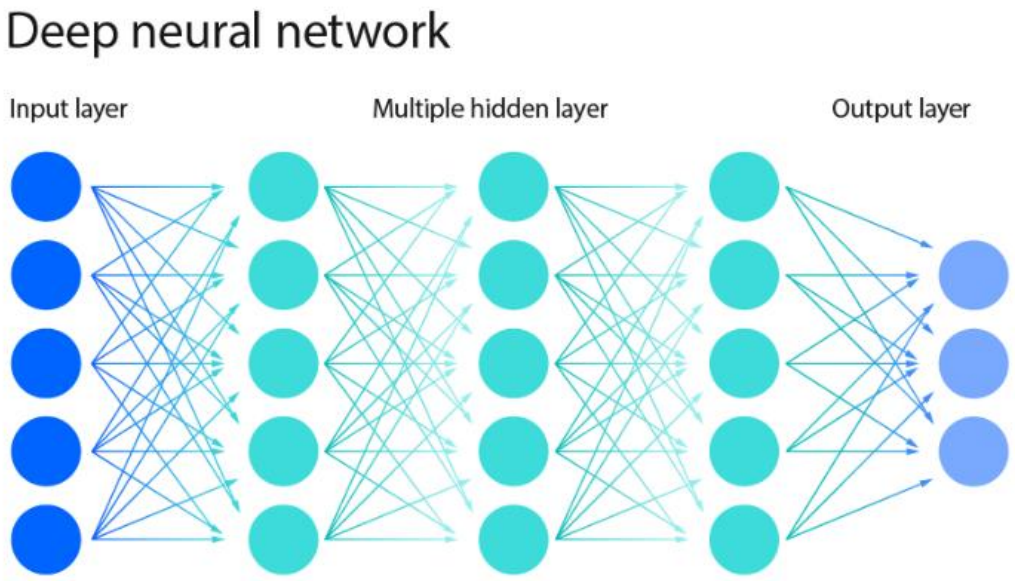
- **Supervised Learning**

Predicts or Classify based on labeled data

Labeled data with input output pair

Eg:Spam emails

Machine Learning : Neural Networks



- Neural networks are brain-inspired models that power AI to spot patterns and make decisions from data.
- Deep networks pack many layers and millions of parameters, making them powerful—but hard to explain from input to output.

Large Language Models

- LLM: A Large Language Model is a type of neural network model that has been trained on a vast amount of text data to understand and generate human language.
- LLMs can perform a variety of language-related tasks such as text completion, translation, summarization, and question answering.
- Generative Pre-trained Transformer GPT is a specific implementation of a Large Language Model developed by OpenAI Trained on large text corpora

ANTHROP\C

Limitations and Risks of Large Language Models (LLMs)

Unpredictable Outcomes: Reliance on probability models can produce unexpected results.

Lack of Transparency: Hidden layers in deep neural networks are difficult to interpret.

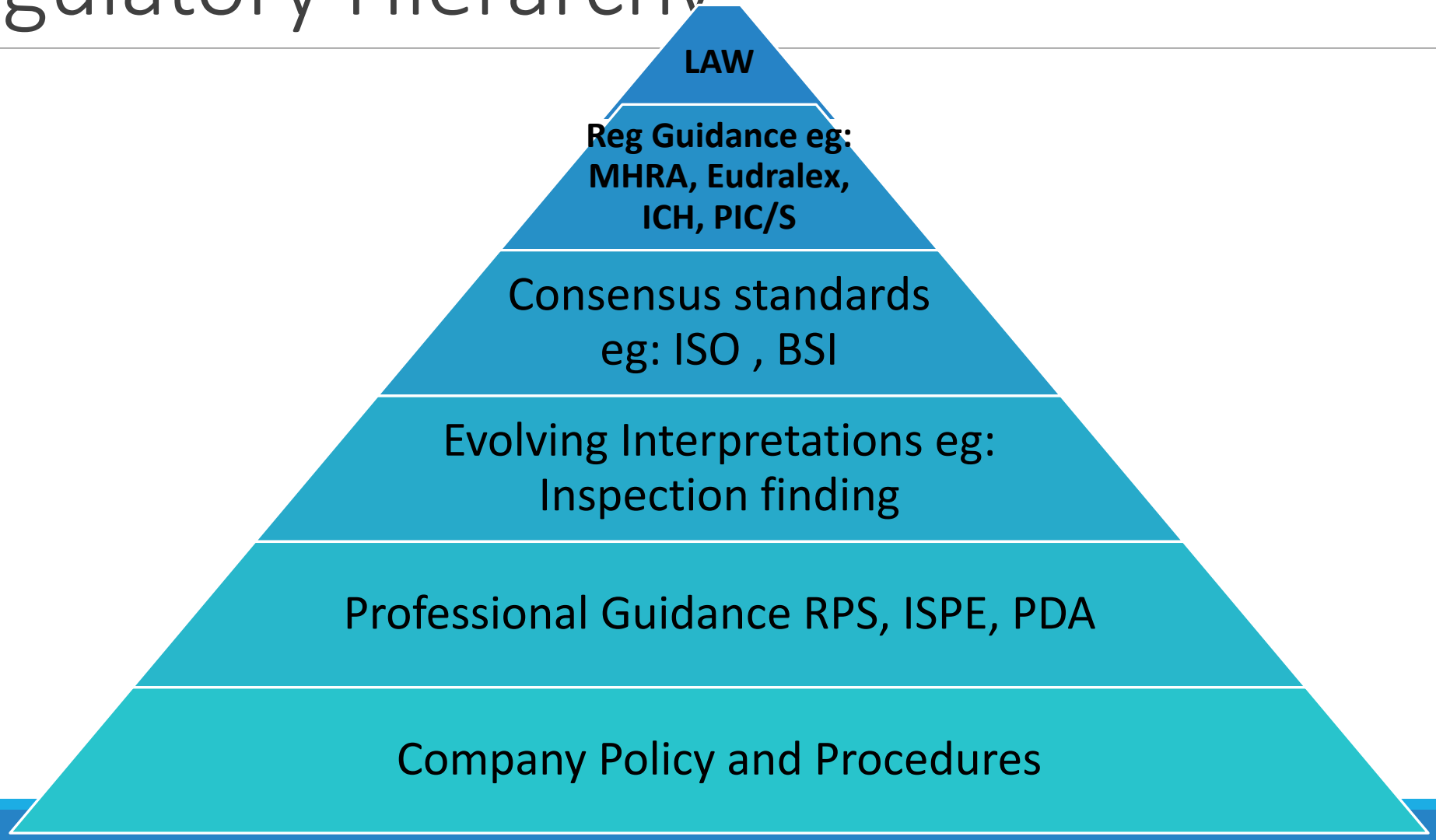
Dependency on Prompts: Output accuracy is heavily influenced by the quality and clarity of given prompts.

Data Exposure: LLMs require relevant data to generate accurate results; insufficient exposure increases error risk.

Bias Amplification: LLMs can inherit and amplify biases from their training data, potentially causing unfair or discriminatory outcomes.

Overfitting: Excessive fitting to training data may result in poor p erformance on new,unseen data.

Regulatory Hierarchy



EU Regulatory Landscape

- EU AI Act – Artificial Intelligence Act 2024/1689

Global First

Risk-based approach

Phased implementation;

1 Aug 2024 → Act entered into force.

Feb 2025 → Prohibited AI practices banned (e.g., social scoring, manipulative AI).

Aug 2025 → General Purpose AI / foundation models rules apply (like GPT-style models).

Aug 2026 → High-risk AI rules apply (covers pharma, healthcare, medical devices, critical infrastructure).

Aug 2027 → All provisions fully applicable.

•Key obligations

Governance
- Risk management and quality management systems
- Transparency, logging, and record-keeping

Data & Technical Standards
- Data governance, traceability, bias controls
- Accuracy, robustness, and cybersecurity

Human Oversight
- Human-in-the-loop where required

Model Scope
- GPAI providers: transparency and risk mitigation
- Systemic-risk models: enhanced obligations for very large LLMs

RoW

AI Regulation — Rest of the World

United States
- No single federal AI law
- Executive Orders + NIST AI Risk Management Framework (voluntary)
- Sector regulators (FDA, FTC) shaping AI oversight

China
- Generative AI rules'(Aug 2023) – binding for providers (registration, transparency, content controls)
- Draft AI Law (2024–25) under discussion – full framework likely coming

Canada
- Artificial Intelligence & Data Act (AIDA) tied to Bill C-27

Japan
- "Soft law' approach
- Principles & guidelines focused on Innovation + international alignment (G7 Hrognapoe)

Australia
- Safe & Responsible AI programme
- Interim government response (2024)
- No singlu Act yet, but risk-based guidance coming

Singapore
- Model AI Governance Framework + AI Verify –practical, non-binding but detailed tools

Japan
- 'Soft law' approach
- Interim govern-ment response (2024)

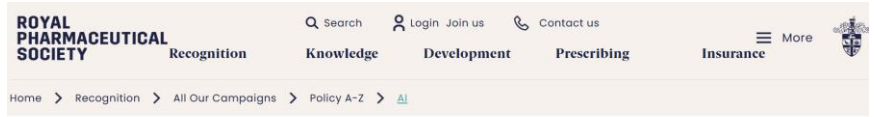
India
- No omnibus AI law
- MeitY advisories (2024–25)

Why does it matter? LLMs

US	Europe	China	Other
OpenAI → GPT-4, GPT-4o (ChatGPT, Copilot)	Mistral (France) → lightweight open LLMs	Baidu → ERNIE Bot	Cohere (Canada) → enterprise LLMs
Anthropic → Claude models	Aleph Alpha (Germany) → Luminous	Alibaba → Tongyi Qianwen	xAI (US) → Grok
Google DeepMind → Gemini		Huawei / iFlyTek / SenseTime → sector models	Stability AI (UK/US) → Stable Diffusion (images)
Meta → LLaMA family (open source)			MidJourney (US) → image generation

UK

AI



2023 AI White Paper

2024 Gov Response 5 principles

2024-25 AI Regulation Bill Draft in Lords

Regulators MHRA AIs as devices

Regulators ICO GDPR, minimisation, explainability

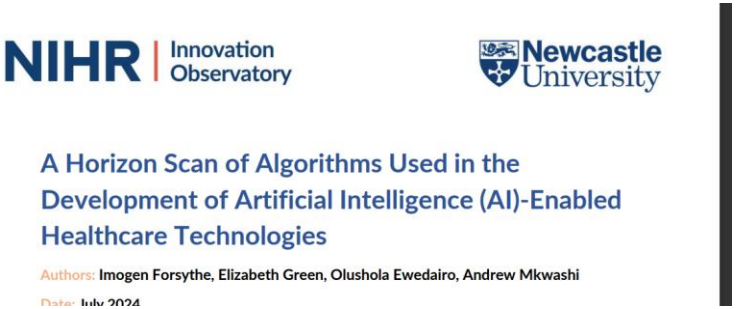
NHS 2025 AI & IG Guidance

NICE AI & Digital Regulations Service

Caldicott Principles apply

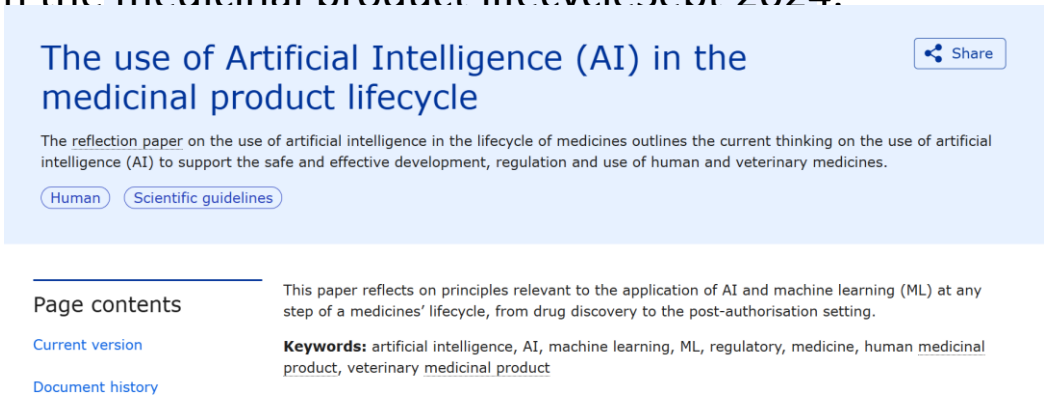
Policy paper
New approach to ensure regulators and regulation support growth (HTML)
Updated 31 March 2025

Consultation outcome
A pro-innovation approach to AI regulation: government response
Updated 6 February 2024



GMP -
EMA Reflection Paper on AI in Drug Lifecycle

Reflection paper issued by EMA on use of Artificial Intelligence (AI) in the medicinal product lifecycleSept 2024.


The use of Artificial Intelligence (AI) in the medicinal product lifecycle

Share

The reflection paper on the use of artificial intelligence in the lifecycle of medicines outlines the current thinking on the use of artificial intelligence (AI) to support the safe and effective development, regulation and use of human and veterinary medicines.

Human | Scientific guidelines

Page contents

Current version

Document history

This paper reflects on principles relevant to the application of AI and machine learning (ML) at any step of a medicines' lifecycle, from drug discovery to the post-authorisation setting.

Keywords: artificial intelligence, AI, machine learning, ML, regulatory, medicine, human medicinal product, veterinary medicinal product

Manufacturing Considerations:
Model Development & Assessment:
Follow quality risk management principles
Consider ICH Q8, Q9, and Q10 principles.
Revisions to current GMPs are anticipated.
Responsibility:
Marketing authorization holders must ensure compliance with GxP standards.
Early regulatory interaction and scientific advice recommended if AI impacts drug benefit-risk balance.
Practical Applications & Regulatory Challenges:
EMA meeting:
Explored AI and digital technology applications in drug manufacturing.
Discussed regulatory challenges and solutions for AI and ML in production settings.
Emphasized aligning AI applications with current and evolving GMP standards.

EU GMP

Document / Annex	What's Changing	Implications (for Pharma / NHS / GMP Teams)
Annex 11 (Computerised Systems – revision)	Tighter requirements for lifecycle management, risk assessment, supplier qualification, audit trails, e-signatures, data integrity.	More rigorous supplier oversight; stronger validation of computerised systems; audit readiness will focus on data integrity and system lifecycle evidence.
Chapter 4 (Documentation – revision)	Documentation expanded beyond paper → must cover hybrid, digital, image, audio, video. Stronger links to risk management and electronic records.	Teams need to manage diverse formats (not just paper/PDF). Expect inspectors to check governance of digital records, metadata, and long-term accessibility.
Annex 22 (NEW – Artificial Intelligence)	Guidance for use of AI/ML in GMP systems. Covers validation, oversight, human review, and risk to product quality/patient safety.	Any AI tool that touches GMP decisions (e.g., batch release support, deviation triage) will need validation and human oversight. Use of "black box" AI will be questioned by regulators.

Part I EU GMP, Annex 15, Annex 16, PIC/S P1011
ICH Guidelines - ICH Q8, ICH Q9, ICH Q10

Example responses to consultation

Annex 22

Comment (only one topic per comment) (max 600 characters)	Rationale (must be included when proposing a change) (max 600 characters)	Proposed wording (must be included when proposing a change) (max 600 characters)
Include validation of data sources and acquisition context in the intended use description.	The Qualified Person must ensure not only data variability but also that data comes from verified and trusted sources to support GMP batch decisions.	*This should include a comprehensive characterisation of the data the model is intended to use as input, i**ncluding its source systems, acquisition method**s and all common and rare variations within the sample space.*
Add requirement to assess potential model bias in test plans.	Bias detection is a core requirement under the EU AI Act and will help identify model risks early in the validation lifecycle.	*Th**e test plan should also include a bias impact assessment where input data includes operator , equipment,process-drift or site-specific attributes.***

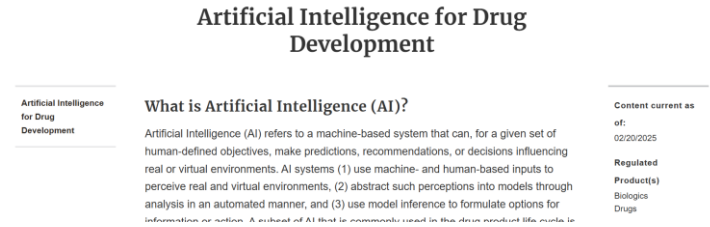
Annex

Comment (only one topic per comment) (max 600 characters)	Rationale (must be included when proposing a change) (max 600 characters)	Proposed wording (must be included when proposing a change) (max 600 characters)
Align wording with Annex 22/EU AI Act principles regarding transparency and human oversight	To future-proof the guidance, references to model transparency, explainability and human-in-the-loop decision-making should be embedded, particularly during lifecycle updates.	'*In systems incorporating AI, organisatiation uld ensure that transparency, human oversight and explainability are maintained throughout the lifecycle, and in accordance with Annex 22 Guidance.*'
Define responsibilities for reviewing AI system updates (e.g., model drift or retraining)	There is no mention of roles responsible for monitoring AI system changes, which is critical for sustained GMP compliance and ensuring proper oversight by qualified personnel.	*Periodic review of system requirements should include inputs from qualified personnel including QP, QA, and AI system owners to assess impact of AI model updates or drifts on GMP compliance.'*

Ch 4

Comment (only one topic per comment) (max 600 characters)	Rationale (must be included when proposing a change) (max 600 characters)	Proposed wording (must be included when proposing a change) (max 600 characters)
Explicitly define how risk-based approaches apply to AI-enabled documentation systems	Risk controls will vary depending on whether AI is involved in decision-making, review or data summarisation.	***Risk-based approaches should also account for whether AI systems are used in data interpretation, generation, or validation processes."***
Lifecycle controls should consider AI model lifecycle, not just data.	AI/ML systems evolve over time, requiring traceability not only for data but also for model training, retraining and deployment steps.	***Controls should ensure traceability and integrity across both data and AI model lifecycles, including training data, model versions and algorithm changes.***

Regulatory Landscape-FDA


Artificial Intelligence for Drug Development

Artificial Intelligence for Drug Development

What is Artificial Intelligence (AI)?

Artificial Intelligence (AI) refers to a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. AI systems (1) use machine- and human-based inputs to perceive real and virtual environments, (2) abstract such perceptions into models through analysis in an automated manner, and (3) use model inference to formulate options for

Content current as of: 02/20/2025

Regulated Product(s)
Biologics
Drugs

FDA's Interaction with AI	Details
Historic Regulation	FDA has a historical track record of regulating AI largely in the context of medical devices, commonly featuring static algorithms.
Submissions	Over 300 submissions for drugs/biological products with AI components have been reviewed by FDA. (Source: Robert M. Califf, M.D., FDA Commissioner)
Approvals	The FDA has granted approval, clearance, or authorization for more than 880 AI/ML-enabled devices. (Source: FDA webpage)
Recognized Benefits	AI is acknowledged by FDA for its potential in improving product quality, reducing manufacturing defects, and mitigating drug shortages by addressing quality issues.
Current Challenges	Regulating generative AI, owing to its relatively recent emergence, poses a modern regulatory challenge for the FDA.

FDA Discussion Papers

Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products

Background and Scope: The FDA's Center for Drug Evaluation and Research (CDER) discusses the use of AI/ML in drug development to enhance safety and innovation.
Current Uses of AI/ML: AI/ML is applied in drug discovery, nonclinical and clinical research, postmarket safety surveillance, and advanced pharmaceutical manufacturing.
Considerations: The document outlines standards and practices for AI/ML use, addressing concerns like bias, data integrity, and transparency1.
Next Steps: FDA seeks feedback and collaboration with stakeholders to refine the regulatory landscape for AI/ML in drug development.

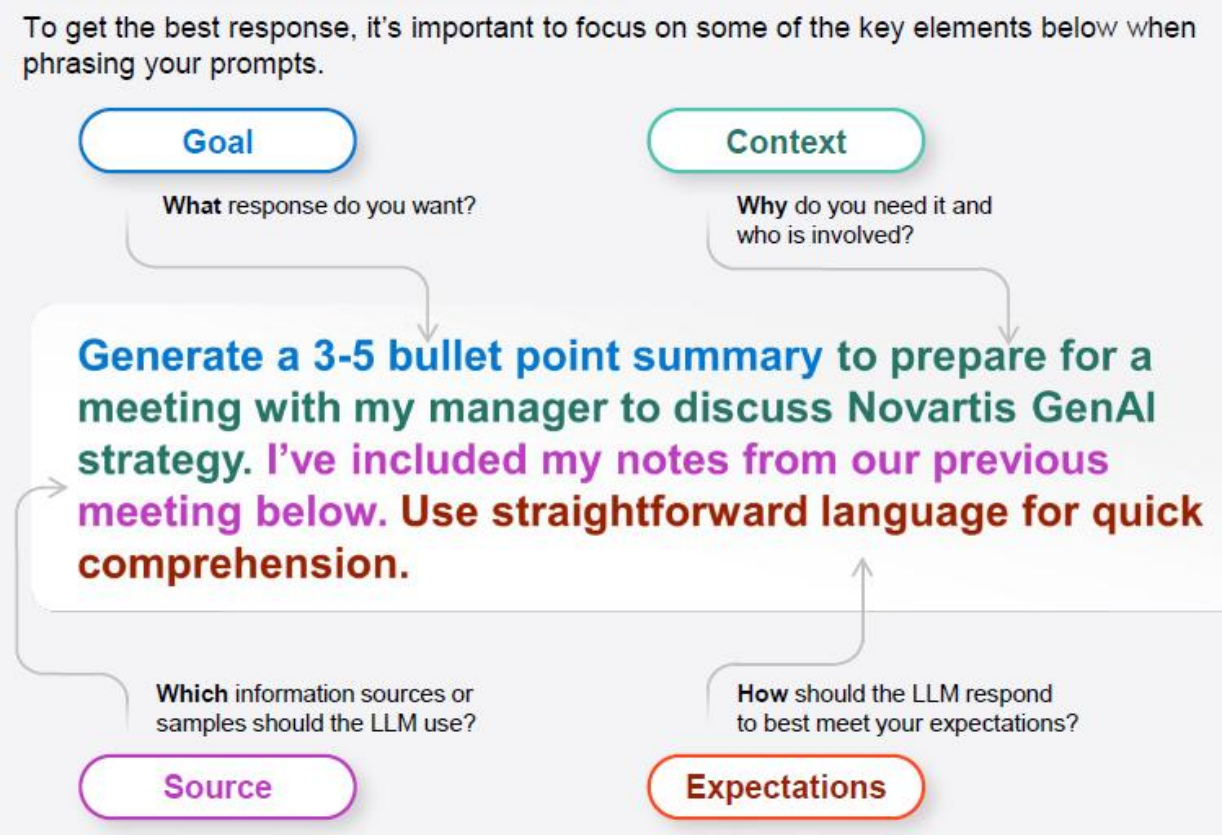
Artificial Intelligence in Drug Manufacturing

- **Purpose:** The paper aims to gather public feedback on the use of AI in drug manufacturing to help develop a future regulatory framework.
- **Mission:** CDER's mission is to ensure that human drugs are safe, effective, and meet quality standards.
- **Advanced Manufacturing:** The paper discusses the potential of advanced manufacturing technologies to improve drug production processes.
- **Public Feedback:** The FDA seeks input on various areas related to AI technologies in drug manufacturing to inform future regulations.

Garbage In= Garbage Out

What is a prompt?

The queries and commands that you can put into an AI to get a generated response.



C Clear and straightforward: Eg: I want to summarise the following report

R Relevant – Include context for what you find most relevant Eg: The focus should be on the investigation action discussed, the audience are Quality Professionals

I Instructive – Set guidelines and instructions for the format of the response Eg: Provide an outline of the issue in 5 bullet points.

S Specific- Define your request precisely, including anything not to be covered
Eg: Do not add any additional information only that which is included in the content

P Persona – Assign a role or characteristic Eg: You are a GXP Quality Professional

Copilot- General

How Copilot Helps in Microsoft 365

Meeting Management

What Copilot Does:

Auto-generates meeting summaries and suggests actions

Key Benefits:

- Quickly catin up on missed meetings
- Clear next steps and owners
- Fewer redundant meetings

Email & Scheduling

What Copilot Does: Summarizes emall threeds, drafts agendas and replies, schedules meetings with click

Key Benefits:

- Saves multiple manual steps
- Faster agenda creation and responses
- Streamlined scheduling

Information Retrieval

What Copilot Does:

Extracts and summarizes key points from long emails and chat conversations

Key Benefits:

- Faster context gathering
- Highlights decisions, risks, and asks

Overcoming Creative Blocks

What Copilot Does:

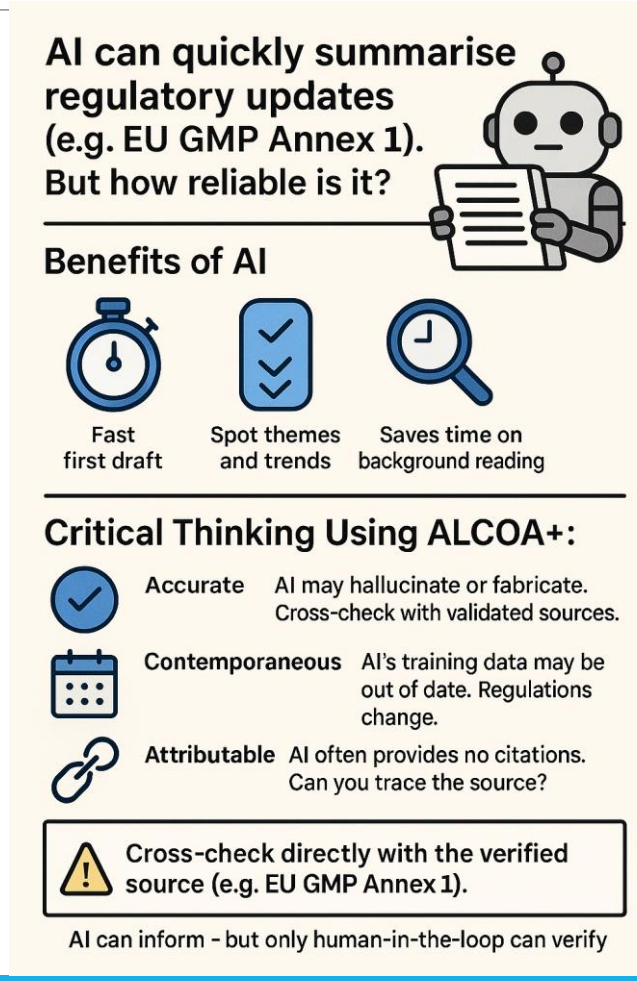
Rephrases and clarifies ideas; suggests alternative tones

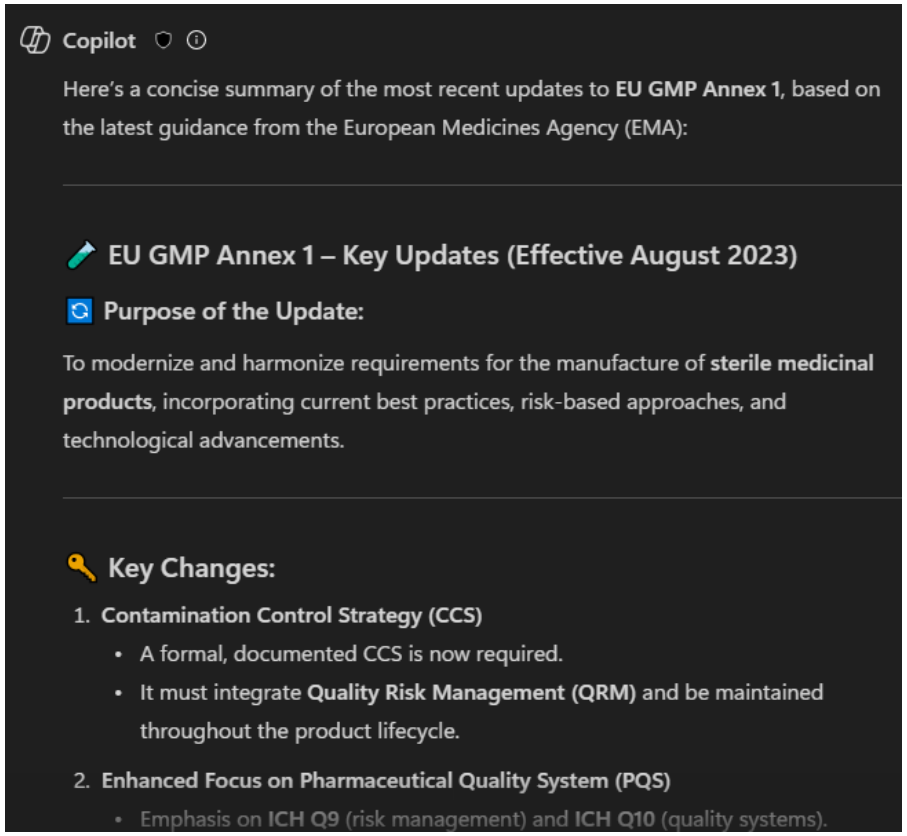
Key Benefits:

- Improves clarity and communication
- Eases drafting and editing

26

CoPilot/GPT for Regulatory Summary





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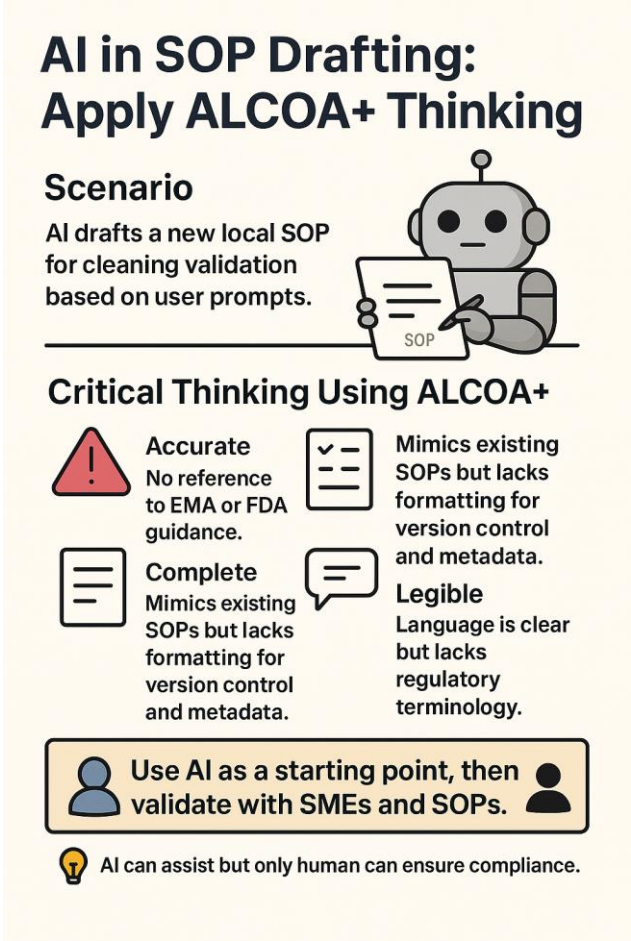
CoPilot/GPT for SOP Drafting



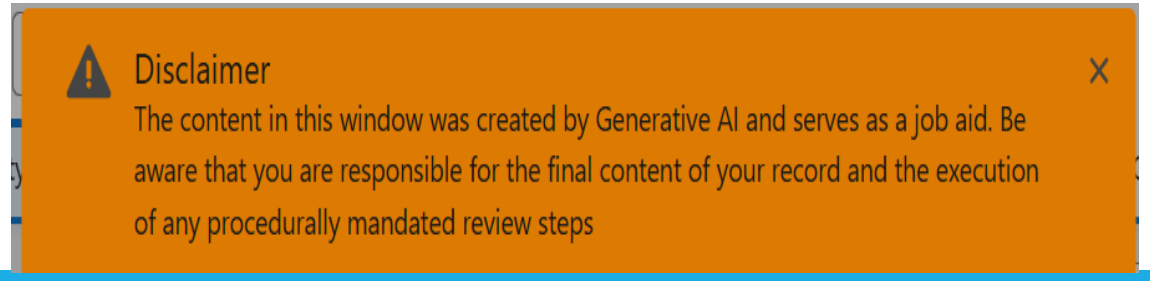
28

Gen AI Examples

Deviations

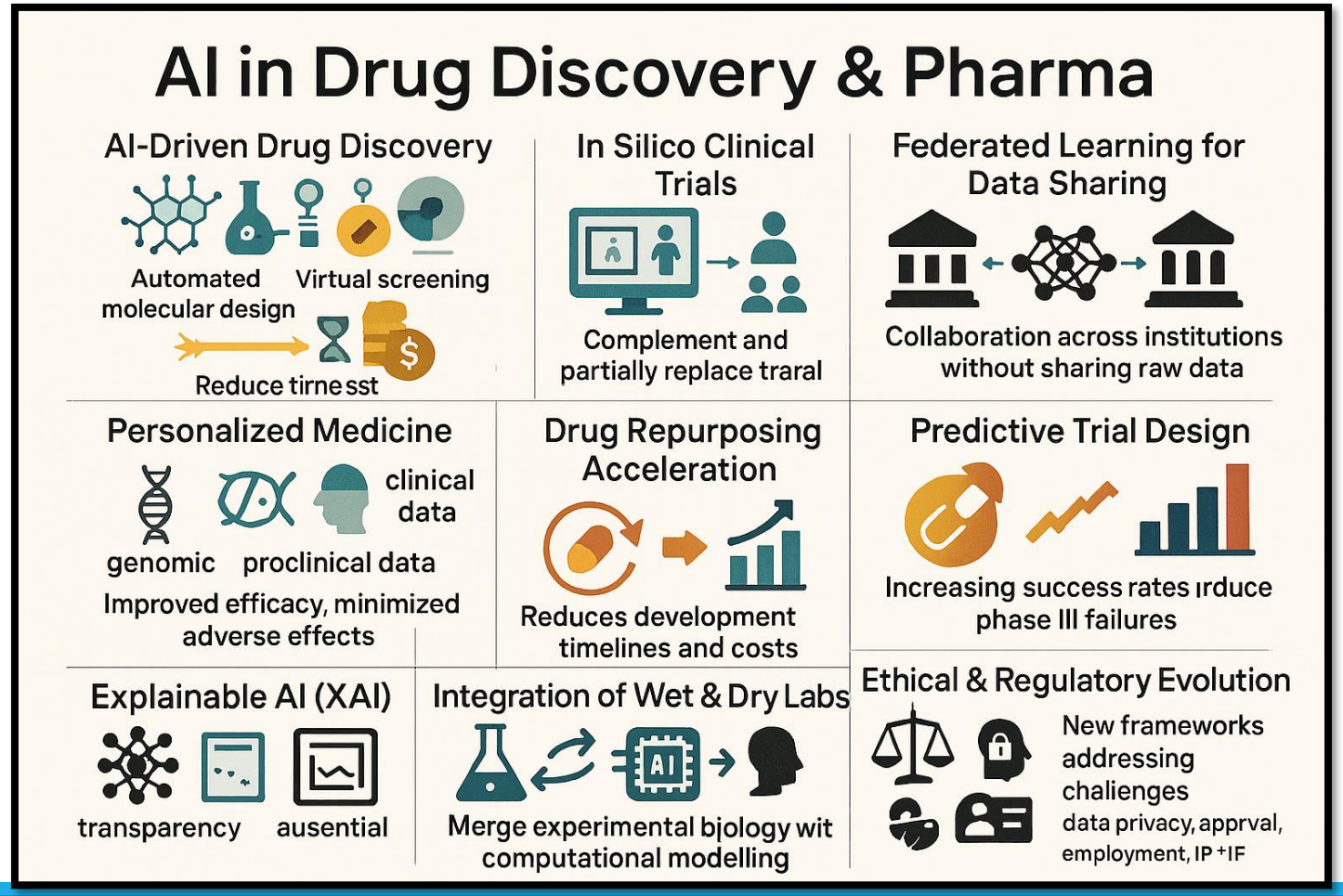
Feature 1 — Proofreading (Deviation Module): Checks compliance to SOP-; highlights missing requirements; enforces data consistency; validates Description (5 Whys + 2 Hs), material/batch, dates, escalations.

Feature 2 — RCA Tools & Summary (Deviation Module): Builds sequence of events; supports 5 Whys & 6Ms analysis; produces deviation and executive summaries for clear decisions.



- SOPie: Chat bot for SOPs
- Complaints close out letter
- Quality Insights Portal

Outside of Quality

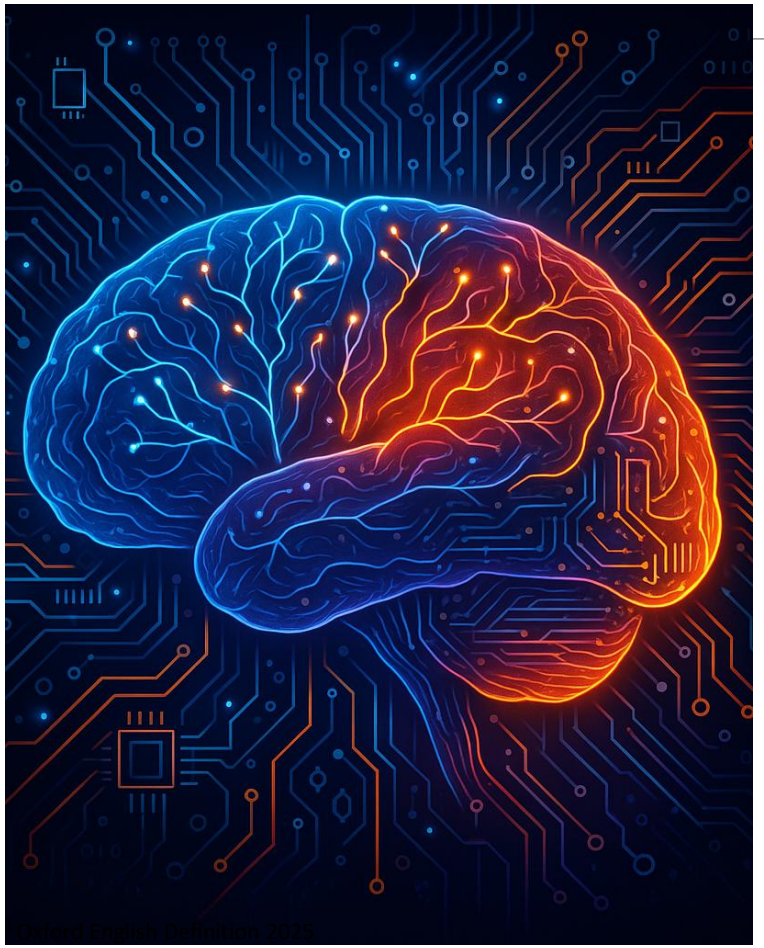


Screening and diagnosis –NHS Cloud

World-first AI system –NHS Patient Safety Concerns

Prescribing Practices

What is Critical Thinking



Oxford English Definition 2025

The objective, systematic, and rational analysis and evaluation of factual evidence in order to form a judgement on a subject, issue, etc...

Critical thinking is our human edge in an AI world

- ❑ Understanding & Evaluating Arguments
- ❑ Awareness of Cognitive Biases

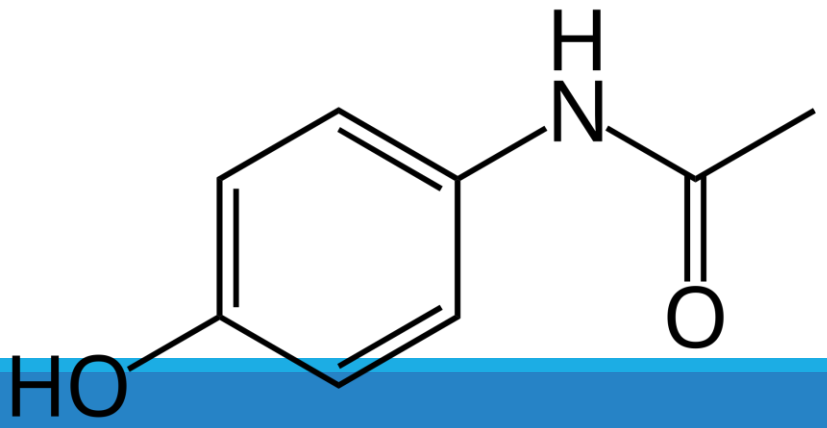
Constant Noise & Speed

Urgent emails. Real-time data. Instant messages
→ **Distraction is the norm**

Decisions Under Pressure
Risk being shaped by bias & emotion
→ **Reflection is often skipped**

Complex Challenges
Unprecedented times go beyond experience or intuition
→ **They demand deeper thinking**

AI: A Double-Edged Tool
Powerful but can be flawed
→ **Unchecked flawed AI data leads to flawed decisions**



The Two Minds of Critical Thinking

Daniel Kahneman's "Thinking, Fast and Slow"

Fast Thinking (System 1)

- Automatic, unconscious, effortless. Rooted in basal ganglia

Examples: Speaking your native language, recognizing faces, reacting instinctively

- Strengths: Speed, efficiency, pattern recognition
- Weaknesses: Prone to biases, errors, and emotional reasoning

🧬 Key Insight:

Automatic thinking is not just simple repetition

It's powerful and capable of learning nuanced, complex patterns-like our spoken language, without our conscious awareness.

The Two Minds of Critical Thinking

Daniel Kahneman's "Thinking, Fast and Slow"

Slow Thinking (System 2)

- Deliberate, conscious, effortful. Tied to the hippocampus/prefrontal cortex

Examples: Used for reasoning, problem-solving, planning, and self-control

- Strengths: Analytical and logical thought
- Weaknesses: Slower, mentally taxing, limited capacity

What thinking habits do you rely on most?"

"Have you ever regretted a fast decision?"

"When was the last time AI helped/hindered your thinking?"

Power lies in observation

But beliefs are hard to change

- ❑ Beliefs resist change due to dopamine rewards from confirming info.
- ❑ Confirmation bias: we seek trust in supportive evidence; contradicting facts feel unrewarding.
- ❑ Changing beliefs requires effort; the brain prefers cognitive ease and consistency.
- ❑ Use AI to challenge assumptions: Devil's Advocate, reflective partner, "rubber duck."

Think Critically

Building Quality Through Mindset + Tools

Mindset

Stay Curious

Practise intellectual humility. Keep an open mind and question assumptions.

Question Assumptions

→ Seek Challenge

→ Be Open to Change

Collaboration

Leverage Team Diversity

Invite different perspectives to strengthen decisions.

Methods & Tools

6W+H
(Who, What, When, Where, Why, How)

ALCOA+
(data integrity check)

Ask thought questions

Evaluate evidence critically

C Challenge assumptions

L Listen to viewpoints

E Evaluate critically

A Ask questions

R Reflect before deciding

Looks can be deceiving: Always verify AI

Utilising AI: Strategies for Success

Evaluate Proficiencies and Constraints

- Analyse the strengths and weaknesses of AI and human capabilities.

Strategic Task Assignment

- Delegate tasks based on whether humans or AI are better suited, optimising efficiency.

Human-AI Collaboration

- Implement AI as a tool to augment human efforts, fostering a synergistic approach.

Take responsibility for your own education

Why this matters

Empathy & compassion

- Judgment & wisdom
- Creativity & imagination
- Ethics & values
- Human connection & dignity

AI can’t replace this — but it can help us protect it.