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Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

“QP In The Loop”

Embracing the ‘C’ in the Age of AI

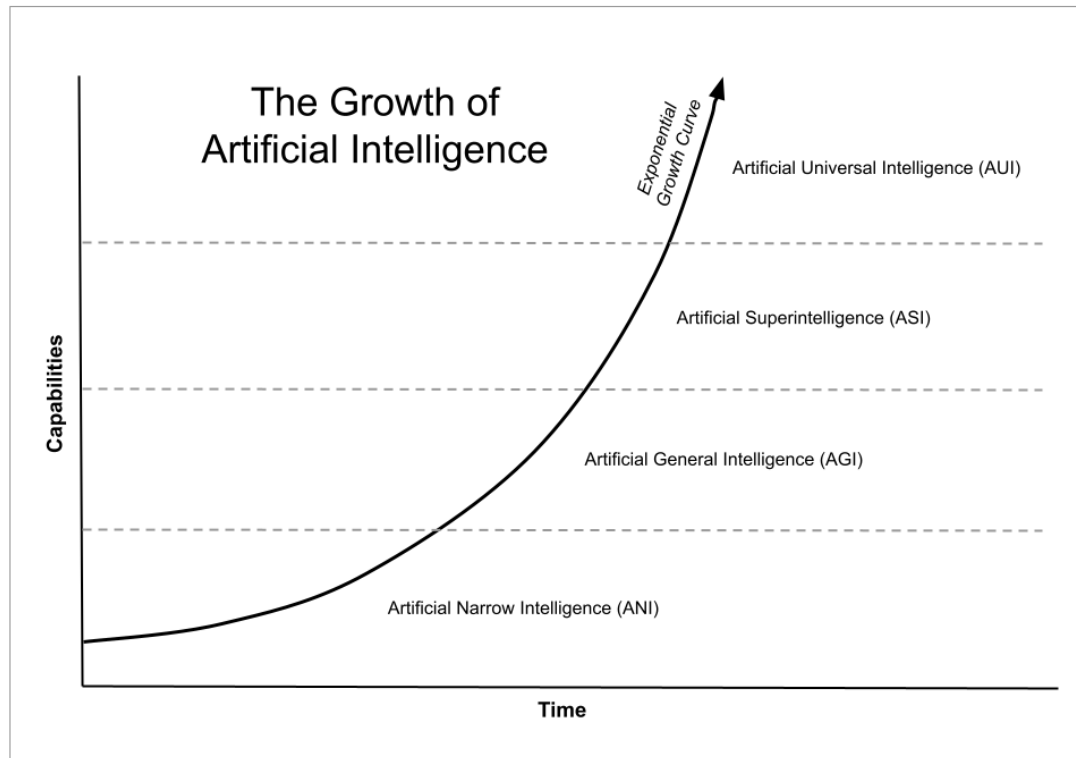
QP Forum: May 12th, 2026

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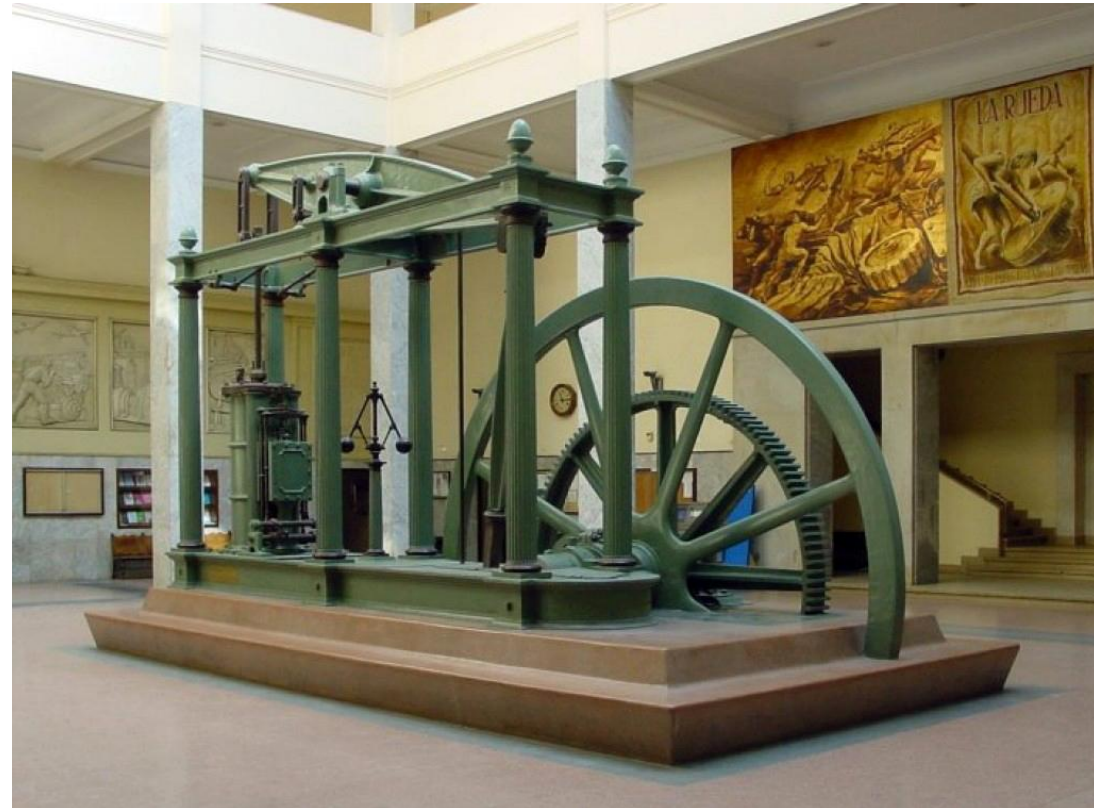
My Plea: Please Listen – Time is Running Out !



Be Prepared - Condenser Moment (James Watt)

It will happen ...

- Computing power doubling every 6-7 months?
- Quantum computing
- AI created algorithms
- AI Agents working in harmony
- Synthetic data
- \$\$\$\$ Investment
- AI – Politicisation (race)



Questions To Think About

- AI computing power **DOUBLES** every **SIX MONTHS** without advancements
 - Quantum Computing
 - Algorithm development (AI training AI)
- A 10-year-old (2025) – 40 to 60% ‘good jobs’ – will be automated on graduation.
- Education systems – challenges memory **NOT** critical thinking
- If we remove ‘junior’ positions – how will people learn to become more senior?



My Experience – Shapes My Opinion

- Please challenge and question
- Your opinions matter
 - Your world – Real World
- Change is Hard
 - Old ways of thinking
 - Old habits
 - Old systems
 - Regulators



Where I'm Coming From

- 44 Years Industry Experience
- QP (Active, Educator, Mentor)
Manufacturing, Operations
- Global VP NSF Health Sciences
- WHO, TBI, EU, FDA
- 'Making Life Easier' (QMS Simplification)
- AI (by accident)
- Experienced *not* Expert



In My Opinion

- AI use will accelerate (unregulated)
- AI = Accelerant (Good & Bad)
- The Tech will fail
- Boom and Bust cycle
- What regulations exist – fit for purpose?
- Regulators – greater interest BUT.
- There will be Bad Players
- Everyone ‘tarnished by the same brush’?
- What we’re experiencing now – is nothing. The Coming Wave – OMG
 - AI
 - Algorithms
 - Quantum Computing
 - Cell & Gene Therapy
 - New Science – New Meds
- ‘VUCA’ is here to stay
- Something BIG will go wrong
Reaction (Governments & Society)
- QPs – Centre Stage (unfairly)
- Future generations unprepared



We EACH Have a Choice

**ACT or BE
ACTED
UPON**

- Your Career
- Your Children's
- Your Grandchildren
- Your Communities

Top Five QP Questions

But I know You Will Have More !

1. What is QP in the Loop. Who is Accountable ?
2. What Questions will HA ask?
3. Where is AI Being Used ...how to spot misuse?
4. How can I use AI to maximum benefit – ASAP?
5. What's questions should I be asking my leadership?

Before we Start:

1. The AI Evangelist
2. The AI Sceptic
3. The AI Sceptic Optimist
4. The AI Ostrich



1. The AI Evangelist: Belief System & Behaviours

- The ‘next’ electricity, the next internet, enthusiasm is mandatory.
- Will solve everything: productivity, ageing, climate, inequality
- Dismiss caution as fear-mongering or “legacy thinking”
- Promotes speed over regulation, disruption over safety, change over consensus. Break things
- “If you’re not using AI, you’re already obsolete.”
- Often companies in crisis (AI = Silver Bullet)
- Senior leadership – Hype Headlines
- ‘Fear of Missing Out’
- AI Literacy 3/10

Upsides: All very simple

Downsides: Very risky



2. The AI Sceptic: Belief System & Behaviours

- Don't believe the hype
- 'Where are the flying cars?'
- This is 'Pharma' (Glacial Pace)
- Bad experience 'It lied to me ...so I don't trust it'
- 'Regulators won't accept it'
- 'My job is unique'
- 'Let's stick with what works'
- 'Status quo is fine'
- AI Literacy 3/10

Upsides:

Doesn't take a lot of thinking

Downsides:

No Plan B



3. The AI Sceptical Optimist: Belief System & Behaviours

- AI – opportunity to transform the world for the better
- Understand Pros and the Cons
- ‘It's not the AI – it's about how we use it!’
- Trust in people to do the right thing
- Accept risk but believe it's solvable through guardrails, regulation, and good leadership
- The future isn't AI vs humans. It's humans who use AI vs those who don't.
- Work on excelling at uniquely human qualities
- Legacy minded: AI and its impact
 - Healthcare
 - Education
 - Society
 - Democracy
 - Future generations
- AI Literacy 8/10

Upside: Human Centric Pragmatist

Downside: None ...provided you remain skeptical



4. The AI Ostrich: Beliefs & Behaviours

- Confused, bewildered, saturated
 - Frightened – switched off (freeze)
 - ‘Company (and peers) don’t seem concerned’
 - No workforce engagement or ‘IT own this’
 - Our systems and incentives won’t allow
 - I will wait and see – status quo is fine
 - I’m too busy!
- I don’t know where to start
 - AI Literacy 3/10

Upside:

Short-term stability.

Downsides:

Strategic blindness. Shadow AI explodes everywhere

This is how Kodak died, slowly, with perfect compliance



Innovation Does Not = Progress

Win Hearts & Minds



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- Biggest group
- Most vulnerable
- Most at risk
- Must be convinced – Education
 - This is the Why
 - This is ‘What’s in It for You’ (personally & professionally)
 - This is what your peers are doing
 - If we don’t ...these are the risks.



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OPPORTUNITY: THE MAGIC FORMULA

DEEP KNOWLEDGE (Products and Processes)

+

CRITICAL THINKING

+

EMOTIONAL INTELLIGENCE

+

AI LITERACY

+

LIFELONG LEARNING

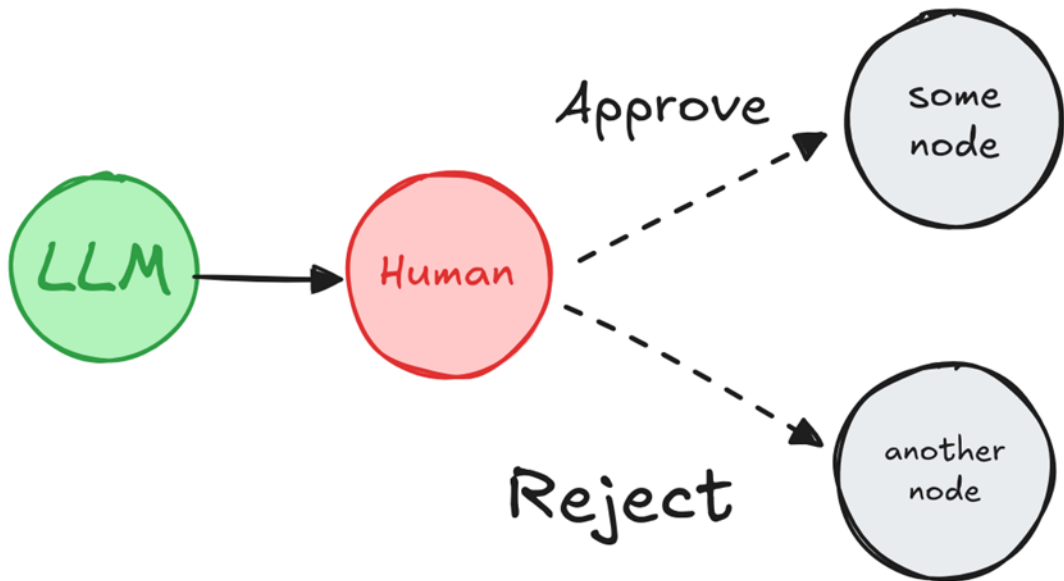
Teach Thinking BEFORE Tools

- Abductive Reasoning
- Socratic Provocation
- Six Hats Thinking
- Red Teaming
- Cynefyn Framework
- Mind Mapping



Q1. Human in The Loop (QP?)

The Theory



My Preference:

Certified Expert in The Loop

- *Proven* DEEP knowledge
- *Proven* critical thinking education and routines
- AI Literacy 8/10
- Authority to override AI
- ‘One Tool at a Time Policy’
 - AI – Intensifies work
 - AI ‘Brain Fry’ (overload)





Health Warning ...*if you don't*

- HITL - Dangerous fantasy
- Asking the wrong questions
- Missing the obvious errors
- Pressure – Stress – Short cuts
 - ‘It looks & sounds OK’
 - Or FAIL SAFE !
- Beware : Don't be scape goated !!



Q2. Questions HA will Ask ? Just MY Opinion

1. Where are you using AI Applications?
2. WHY?
3. How do you know?
4. What AI Applications?
 - Deterministic?
 - Probabilistic?
5. GMP vs Non GMP?
6. AI Education and Training
7. AI Readiness Assessment
 - Data (GIGO)
 - Culture
8. Validation – Change Control – Explainability – DI
9. Third Parties (SaaS)
10. Ethics. Governance and Guardrails (Oversight, HITL)



Q3. WHERE IS AI BEING USED?

My personal involvement

- PPM (40% reduction – down time)
- Human Error Prevention (60% reduction)
- SOP and BMR Simplification (improved compliance and RFT)
- Audit Aide memoires
- Deviation prioritisation
- Pharmacovigilance
- Education and Training
- Remediation – Action Planning
- Deviations
 - Prevention
 - Investigation
 - Reporting
- Change Management Prioritisation (80:20)
- Design and optimisation of audit programs
- Admin (!)



Misuse & Abuse – Signs and Signals

1. Training in the tools – not educated in ‘judgement’
2. Lack of DEEP subject matter expertise (HITL vs EITL)
3. HITL = Rubber stamping
4. Weak Governance ownership & absence of meaningful guardrails.
5. Outputs used for GMP decisions indirectly
6. Prompt engineering = uncontrolled process
Different users, different prompts, different outputs.
7. Cognitive offloading /atrophy
8. Model drift ignored
9. Its ‘just a tool’ mentality (it’s not!!)
10. And Your Experiences ??

Q4. How Can I Use to Maximal Benefit – NOW?

Find me for more examples & demonstrations

SOP Simplification

- 3-4 experienced operators
- Select most hated SOP
- Five key rules for good SOPs
- Prompt – follow the rules

Audits – Aide Memoires

- Identify key regulatory references and published SME's
- Master prompt
 - You are (persona)
 - Task: Top Five CCP's or
 - Task: Top Five problems
 - Task: Top Five Questions
 - Cut and Paste Table of Contents



Risk Based Decision Making & Critical Thinking (LLM = Sounding Board)

ALWAYS DO YOUR OWN THINKING BEFORE HAND

- **Context** : Background. Facts, Assumptions, Don't Know.
- **Persona** :
 - Regulatory auditor?
 - Risk SME (Dylan Evans +)
- **Key references**
 - ICH Q9
 - 'Risk Intelligence TOC)
- **Current Status**: Decision Options 1,2,3
- **Task One**: Top Five pros and cons.
- **Task Two**: Three Socratic Provocations for each one.
- **Task Three**: 4th option from Dylan Evans.

Q5: KEY Questions QPs Must be Asking

1. AI strategy (why, how, where, who)?
2. AI Readiness Health Check ?
3. Unintended Consequences?
- 4. Education?**
5. Governance and Guardrails?
6. Oversight – How?
7. Where is our Sandbox?
8. AI ‘Comfort’ Folder?
9. How will we bring HA with us?
10. Preparing the future workforce

You Must Educate in Thinking *before* Training in Tools

- Deep SME Knowledge (\$\$\$)
- Critical Thinking (\$\$)
 - Socratic Provocation
 - Abductive Reasoning
 - Six Hats Thinking
- AI Tools (\$)
 - ML, DL,LLM
 - Prompting



Once in a Lifetime Opportunity !!



The Coming Wave

- Biotechnology
- Gene Therapy
- AI
- Robotics
- Quantum Computing
- World of ZERO TRUST.

**YOU MUST BE THE ADULT
(HUMAN) IN THE LOOP**



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Adapt - Integrate Or Be Automated.

In last Six Months

- Pharmacovigilance
- Recruitment
- Regulatory
- Annual Product Quality Reviews
- Translation of Global Policies
- SOP creation, simplification and administration
- Product release life cycle
- Regulatory updates
- Remediation – reporting
- Less ‘consultancy’ support.
- QC Testing

Impact

Displacement & Redefinition

- Headcount reduction (repetitive, rules based)
- Role redundancy(doc controllers and checkers)

Transformation & Redirection

- Higher-value work
- Re-skilling & Cross-skilling (acquire hybrid capabilities GMP + data literacy, QP + AI fluency).
- Human-in-the-Loop Models – QA

Growth and Job Creation ...



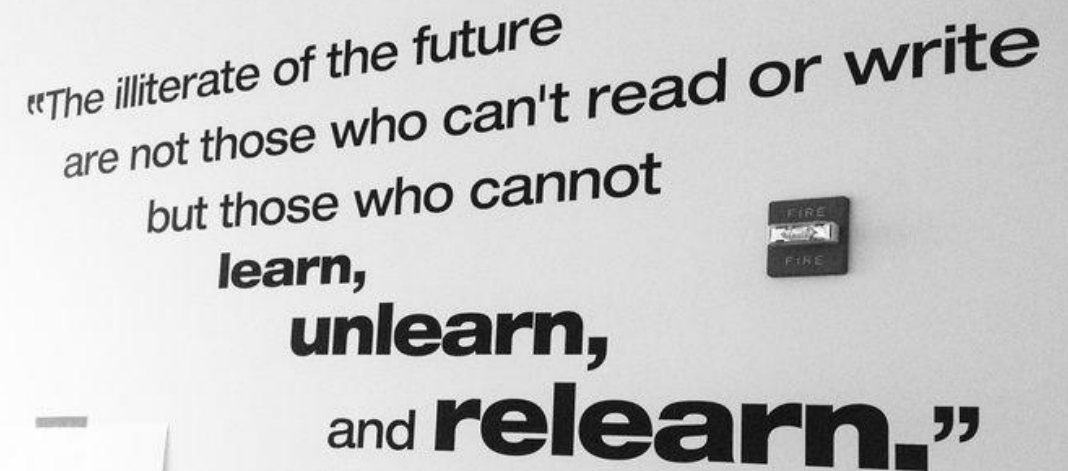
Martin ..we need ..we can't find

New Roles Created

- 'AI Quality Risk Officer'
- 'GxP AI Validation Lead'
- 'Synthetic Data Ethicist'
- 'AI Model Governance Manager'
- 'AI Audit and Oversight'

Remember: *AI-Pharma Translators* will be in BIG demand. Experts who can bridge

- Technical AI knowledge
- Regulatory, clinical, and GxP expectations.



“The illiterate of the future
are not those who can't read or write
but those who cannot
learn,
unlearn,
and **relearn.**”

Alvin Toffler, *Future Shock*

And Finally ...

“The real question is not whether machines think but whether we do”

B.F Skinner

Any Questions:

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Linked Interest Group: AI in Pharma ~ 800 of Your Peers.

PLEASE CONTACT ME IF YOU ANY QUESTIONS

