Workshop Session 2: Latest Learnings from AI as a Tool, Both from the Lens of Industry and Agency

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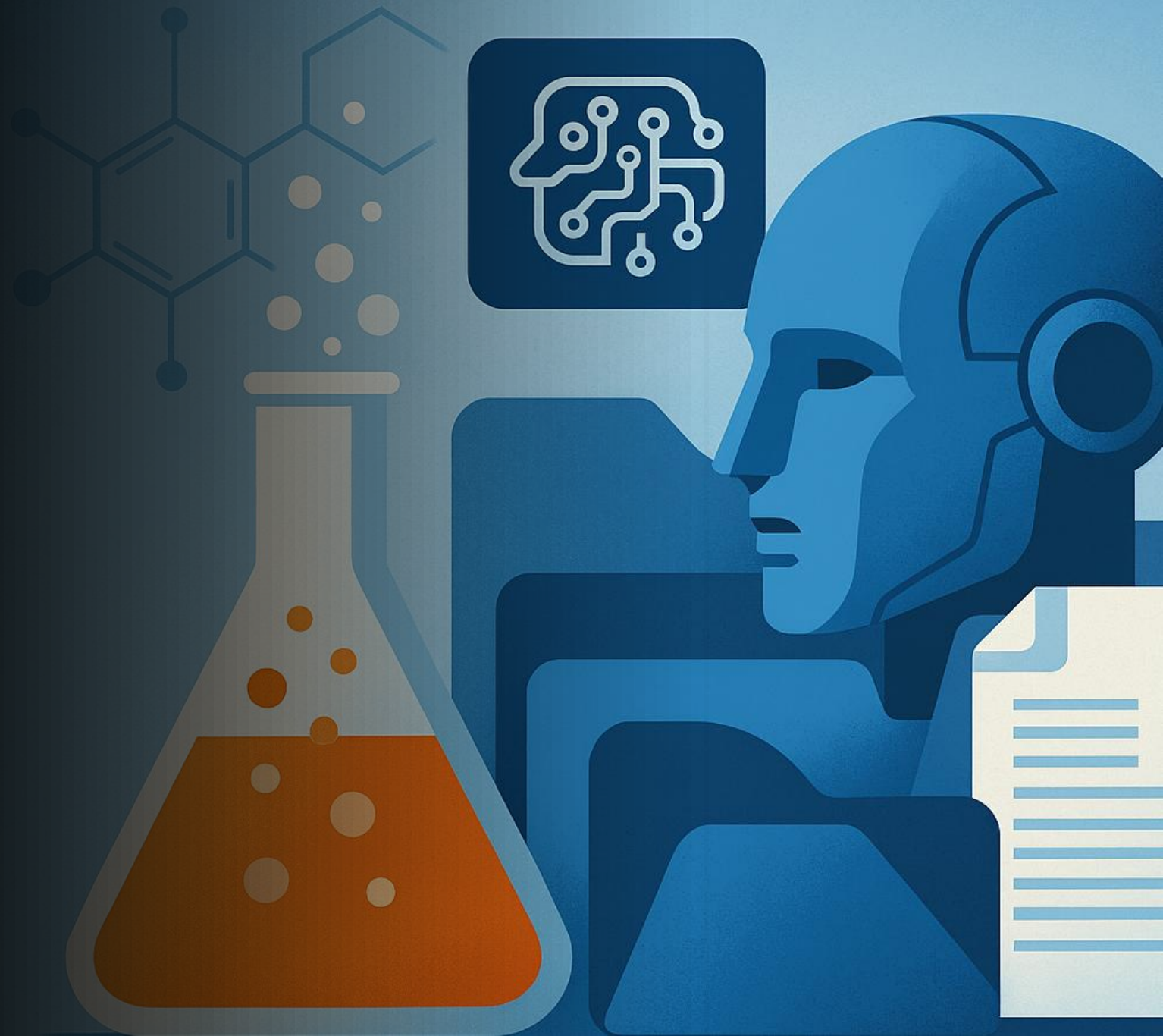

Discussion Questions

1) Use cases and value creation

Where does AI add value **today** in pharma development and manufacturing (e.g., process understanding, monitoring, deviation triage, predictive maintenance, stability, comparability, knowledge management)?

2) Regulatory applications and readiness

What is your experience using AI/ML tools in regulatory contexts (submission preparation, review/inspection support, signal detection, risk triage)? What worked, what failed, and why?

3) Risk, reliability, and global adoption

Where are the biggest risks of widespread AI use by **industry**? By **regulators**? (e.g., automation bias, model drift, data quality, reproducibility, cybersecurity, opaque decisioning)

Discussion Questions

4) Data strategy and governance

How do we handle cross-company learnings (federated approaches, transfer learning, shared ontologies) while protecting IP and patient/competitive confidentiality?

5) Validation, verification, and “continuous AI verification”

What should “validation” mean for AI in GMP-relevant settings—especially for non-deterministic models? What is the practical standard for verification, monitoring, and change control?

6) Ethics, policy, and standards

What are the key ethical considerations for AI use by companies and regulators (fairness, accountability, transparency, explainability, due process, human oversight)?

Discussion Questions

7) The “next platform shift” in submissions

How will revisions to ICH M4Q, increased structured data, and cloud-based submission/review platforms change what’s possible (automation, analytics at scale, reusable evidence packages)?