CONCEPT

AI in Pharma: Drug Discovery, Clinical Trials, Manufacturing and Pharmacovigilance

25 – 29 January 2027
London - Central London four-star



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Introduction:

AI in pharma is moving from discovery labs into clinical operations, production suites and safety databases, yet many companies launch tools without classifying their patient risk, checking training data against data integrity expectations or planning GxP validation. The result is pilots that never reach regulated use. This Core Concept course takes R&D, clinical, manufacturing, quality and pharmacovigilance staff through AI use cases across the drug life cycle without coding, from target discovery to signal detection and validation. Participants produce a Pharma AI Pilot Plan and GxP Risk Assessment for a use case from their own company.

Course Objectives:

- Map AI use cases across discovery, non-clinical, clinical, manufacturing and post-authorisation stages and rank them by patient risk and regulatory impact
- Evaluate AI proposals for target identification, molecule design, trial recruitment and risk-based monitoring using fit-for-purpose data and performance evidence
- Apply AI methods to batch monitoring, equipment maintenance and deviation and CAPA triage within a pharmaceutical quality system
- Assess pharmacovigilance case intake automation and signal detection tools for accuracy, human review and audit trail needs
- Apply ALCOA+ attributes, GAMP 5 life-cycle validation and ICH Q9 risk management to AI-enabled computerised systems
- Produce a Pharma AI Pilot Plan and GxP Risk Assessment with scope, validation approach and go or no-go criteria

Target Audience:

- R&D and discovery data leads responsible for assay, compound and target data used in modelling
- Clinical operations and data management leads responsible for trial feasibility, recruitment and monitoring
- Manufacturing and process engineering leads responsible for batch performance and equipment reliability
- Quality assurance and computerised system validation leads responsible for GxP systems, deviations and CAPA
- Pharmacovigilance and drug safety leads responsible for case processing and signal management
- Digital and data governance leads responsible for AI programmes in pharmaceutical and biotech companies

Course Outline:

Day 1: AI Across the Drug Life Cycle and Readiness Assessment

- Drug Life Cycle Map: Discovery, Non-Clinical, Clinical, Manufacturing and Post-Authorisation AI Use Cases
- Machine Learning, Deep Learning, NLP and Generative AI Concepts for Pharma Staff Without Code
- Pharma Data Inventory: Assay Results, Batch Records, Trial Databases and Adverse Event Reports
- High Patient Risk Versus High Regulatory Impact Classification Grid for AI Use Cases
- Pharma AI Readiness Scorecard for Data, Skills and Quality Systems

Day 2: AI in Drug Discovery, Clinical Trials and Real-World Evidence

- Target Identification and Protein Structure Prediction With AlphaFold at Concept Level
- Molecule Design Concepts: Virtual Screening, Generative Chemistry and ADMET Property Prediction
- Clinical Trial Design Support: Site Feasibility, Eligibility Criteria Modelling and Patient Recruitment Matching
- Risk-Based Monitoring Analytics: Central Data Review, Key Risk Indicators and Site Anomaly Flags
- Real-World Evidence Studies: Registry and Health Record Data Fitness and Representativeness Checks

Day 3: AI in Pharmaceutical Manufacturing, Quality and Pharmacovigilance

- Process Analytical Technology and Multivariate Models for Real-Time Batch Monitoring Under ICH Q8 Principles
- Predictive Maintenance of Tablet Presses, Bioreactors and Aseptic Filling Lines
- Deviation and CAPA Triage With NLP Classification of Quality Event Records
- Pharmacovigilance Case Intake Automation: Adverse Event Extraction From Literature and Safety Reports
- Signal Detection: Disproportionality Analysis and Machine Learning Prioritisation of Drug-Event Pairs

Day 4: Data Integrity, GxP Validation and Regulator Expectations

- ALCOA+ Attributes Applied to Training Data, Model Outputs and Audit Trails
- GAMP 5 Second Edition and ISPE GAMP Guide: Artificial Intelligence Life-Cycle Validation
- ICH Q9 Quality Risk Management and ICH Q10 Change Control for Model Retraining
- Explainability With SHAP and LIME, Bias Screening and Human Oversight Design
- Model Freezing Before Database Lock, Drift Monitoring and Early Regulator Engagement

Day 5: Pharma AI Case Studies and Pilot Plan

- Discovery Case: Critiquing a Vendor Molecule Design Platform Proposal
- Manufacturing Case: Deviation Triage Model Reviewed Against ALCOA+ and Validation Evidence
- Pharmacovigilance Case: Signal Detection Tool Performance and Safety Reviewer Workflow
- Pilot Scope, Success Measures, Validation Deliverables and Go or No-Go Criteria Drafting
- Pharma AI Pilot Plan and GxP Risk Assessment Presentation With Peer Challenge

Skills You Will Gain:

- AI Use Case Risk Classification
- Drug Discovery AI Appraisal
- Clinical Trial Analytics Review
- Pharmaceutical Process Analytics
- Quality Event Triage Design
- Pharmacovigilance Signal Assessment
- AI System GxP Validation
- Data Integrity Assurance

Why Attend This Course:

- Return with a Pharma AI Pilot Plan and GxP Risk Assessment built around a use case from your own company
- Question vendor claims on molecule design, recruitment and safety tools with clear data and performance tests
- Prepare validation and audit evidence early so an AI pilot can move into regulated use
- Compare experience with peers from innovator, generic, biotech and contract manufacturing organisations

Conclusion:

AI adds value in a pharmaceutical company only when use cases are ranked by risk, data meets integrity expectations and systems are validated for their intended use. The course moves from the drug life cycle and data inventory, through discovery, clinical trial and real-world evidence applications, to manufacturing analytics, quality event triage and pharmacovigilance, then ALCOA+, GAMP 5 validation and ICH Q9 risk management. The final day applies these methods to three cases and produces a Pharma AI Pilot Plan and GxP Risk Assessment ready for quality and sponsor review.