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COURSE BROCHURE

# Advanced AI and Machine Learning for Pharma Training Course

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Geneva

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Registered in the United Kingdom and Saudi Arabia

# Advanced AI and Machine Learning for Pharma Training Course

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AI and Machine Learning for Pharma is a 2-week advanced training course for pharmaceutical and biotech R&D scientists, clinical operations specialists and regulatory affairs professionals who will draft a validated ML project plan for a real pharma use case. Machine learning now shortens target selection, molecule design and trial recruitment, yet every model that touches a submission must withstand inspection. Jupiter Prime Training runs this AI and Machine Learning for Pharma course for life-science specialists.

## Why AI and Machine Learning for Pharma Matters Now

Three pressures shape this field: R&D pipelines facing rising attrition and cost per approved medicine, an explosion of omics, imaging and real-world health records that classical statistics struggles to exploit, and inspectors who expect algorithms used in GxP processes to be validated like any other computerised system. Organisations that combine these well move candidates faster and detect safety signals earlier; those that do not risk irreproducible findings and rejected evidence. The course frames model risk with ISO/IEC 42001, the AI management system standard, and the NIST AI Risk Management Framework NIST AI RMF.

## Who Gains Most from AI and Machine Learning for Pharma

- Specialists who select targets and design or optimise candidate molecules
- Specialists who plan trial protocols, site selection and patient recruitment
- Specialists who detect and evaluate adverse event signals after approval
- Specialists who prepare regulatory documentation and validation evidence
- Specialists who manage laboratory, clinical and real-world data assets

A cross-functional drug development group gains most when discovery scientists, clinical operations staff and regulatory specialists attend together, because a model is only usable in a submission when its scientific question, its data provenance and its validation file are agreed by all three.

## AI and Machine Learning for Pharma Capabilities

Participants learn to frame pharmaceutical questions as learnable problems and to produce models that survive scientific peer review and GxP inspection alike.

- Assess which discovery, clinical and safety questions suit supervised, unsupervised or generative methods — R&D portfolio leads
- Build molecular property and activity prediction workflows using descriptors and graph representations — medicinal chemistry teams
- Design trial feasibility and patient recruitment models using real-world data — clinical operations sponsors
- Test pharmacovigilance signal detection approaches on spontaneous reports and literature — drug safety committees
- Specify validation, documentation and change control for models in GxP processes — quality assurance and inspectors
- Communicate model limitations, uncertainty and bias to scientific and regulatory audiences — submission reviewers

## Key AI and Machine Learning for Pharma Terms

- Target identification — finding a biological molecule, often a protein, whose modulation is expected to change the course of a disease.
- QSAR model — a quantitative structure–activity relationship model linking chemical structure features to biological activity or a physicochemical property.
- Graph neural network — a deep learning model that learns directly from molecules represented as atoms and bonds in a graph.
- Real-world data — health information gathered outside controlled trials, such as electronic health records, registries and insurance claims.
- Disproportionality analysis — a pharmacovigilance method comparing how often an adverse event is reported for one drug versus all others.
- Computerised system validation — documented evidence that a system, including a model, consistently performs as intended within a regulated GxP process.

## AI and Machine Learning for Pharma Day by Day

## Day 1: The Pharmaceutical Data Landscape

- R&D Attrition and Cost Drivers — Where Machine Learning Changes Odds
- Omics, Imaging, Assay and Health Record Sources — Data Availability
- Data Reusability Principles for Life Sciences — Reuse Across Research Portfolios
- GxP Expectations for Algorithms — Inspection Readiness From the Start
- Use Case Triage Canvas — Selecting Problems Worth Modelling

## Day 2: Machine Learning Methods for Life Scientists

- Supervised Classification and Regression — Activity and Outcome Prediction
- Unsupervised Clustering and Dimensionality Reduction — Patient and Compound Groups
- Cross-Validation and Scaffold Splits — Honest Performance Estimates
- Class Imbalance and Small-Sample Remedies — Rare Event Modelling
- Uncertainty Quantification — Confidence in Individual Predictions

## Day 3: Target Identification and Biology Models

- Knowledge Graphs of Genes, Pathways and Diseases — Target Hypotheses
- Genetic Association and Multi-Omics Integration — Target Validation Evidence
- Literature Mining With Natural Language Processing — Hidden Mechanism Links
- Protein Structure Prediction Outputs — Druggability Assessment
- Target Prioritisation Scorecards — Go or No-Go Before Screening

## Day 4: Molecular Property Prediction and Design

- Molecular Descriptors and Fingerprints — Feature Choices for QSAR
- Graph Neural Networks for Molecules — Activity and Toxicity Prediction
- ADMET Property Models — Early Attrition Avoidance
- Generative Chemistry and Reinforcement Learning — Novel Candidate Proposals
- Applicability Domain Checks — Trusting Predictions for New Chemotypes

## Day 5: Clinical Trial Design With Machine Learning

- Protocol Complexity Scoring — Amendment and Burden Risk
- Site Performance Prediction — Selecting High-Enrolling Centres
- Synthetic and External Control Arms — Comparator Evidence Options
- Adaptive Design Simulation — Interim Decision Rules
- Endpoint and Biomarker Selection Models — Sensitivity to Treatment Effect

## Day 6: Patient Recruitment and Real-World Evidence

- Eligibility Criteria Matching on Health Records — Recruitment Feasibility
- Patient Population Mapping — Diversity and Representativeness
- Dropout and Adherence Prediction — Retention Interventions
- Real-World Evidence Study Designs — Post-Approval Effectiveness Questions
- Federated Learning Across Hospitals — Privacy-Preserving Collaboration

## Day 7: Pharmacovigilance and Safety Signal Detection

- Disproportionality Analysis on Spontaneous Reports — Signal Prioritisation
- Case Narrative Processing With Natural Language Processing — Triage Speed
- Literature and Social Media Surveillance — Emerging Safety Concerns
- Causality Assessment Support Models — Medical Reviewer Decisions
- Signal Management Workflow Integration — Escalation to Safety Committees

## Day 8: Model Validation in GxP Settings

- Risk-Based Validation Planning — Scaling Effort to Model Impact
- User Requirements and Intended Use Statements — Validation Scope
- Training Data Lineage and Audit Trails — Data Integrity Evidence
- Performance Qualification and Acceptance Criteria — Release Decisions
- Change Control and Retraining Triggers — Keeping Models in a Validated State

## Day 9: Model Risk, Transparency and Submissions

- ISO/IEC 42001 Controls for Life-Science Models — Accountability Records
- NIST AI RMF Measure and Manage Functions — Model Risk Treatment
- Explainability Methods for Scientific Review — Feature Attribution Evidence
- Bias Testing Across Patient Subgroups — Equity of Predictions
- Model Documentation Packs for Regulators — Submission-Ready Evidence

## Day 10: Practising the Validated ML Project Plan

- Use Case Triage Applied to a Participant's Research Area — Problem Selection
- Molecular or Clinical Model Design Applied to Available Data — Method Choice
- Validation Plan Applied to the Chosen Model — Acceptance Criteria
- Subgroup Bias Testing Applied to Pilot Results — Equity Safeguards
- Validated ML Project Plan Assembly — Scope, Data, Validation and Governance Milestones

## Applying AI and Machine Learning for Pharma After the Course

- Run a use case triage session with discovery and clinical colleagues and rank three candidate machine learning problems by data readiness and decision impact.
- Draft a risk-based validation plan and intended use statement for one model already used in a laboratory or safety process and review it with quality assurance.

## AI and Machine Learning for Pharma Questions FAQ

### What is AI and machine learning for pharma, and why does it matter now?

It is the use of learning algorithms to find targets, design molecules, plan trials and detect safety signals. It matters now because data volumes have outgrown traditional methods while inspectors expect every model used in GxP processes to be validated.

### Which roles gain most from AI and machine learning for pharma training?

Experienced life-science specialists gain most: discovery scientists, clinical operations specialists, drug safety staff and regulatory affairs professionals. You benefit if you design studies, prepare submissions or decide which models enter regulated work.

### How does advanced AI and machine learning for pharma differ from a general data science course?

It ties every method to pharmaceutical decisions and GxP validation. A general data science course teaches algorithms on generic datasets, while this course applies them to targets, molecules, trials and pharmacovigilance with inspection-ready documentation.

## What do you bring back from AI and machine learning for pharma training?

You bring back a validated ML project plan for a pharma use case. It defines the scientific question, data sources, modelling approach, validation and acceptance criteria, bias checks and the documentation needed for regulated use.

## AI and Machine Learning for Pharma: The Way Forward

The validated ML project plan first informs whether a chosen use case receives data access and modelling resources. Discovery and clinical leads use it to scope the work, quality assurance to agree validation effort, and regulatory specialists to anticipate submission questions. After the first model release, revisit the retraining triggers, since new assay or patient data can shift performance quickly.