凯莱英医药集团人工智能策略

Asymchem Artificial Intelligence Strategy

本策略将人工智能定位为增强凯莱英药物研发、工艺开发、质量管理、生产运营和供应链韧性的能力工具。凯莱英坚持负责任地开发、采购、部署和使用 AI，以保护患者安全、客户信任、员工权益、数据安全、合规责任和长期可持续价值。

This Strategy positions artificial intelligence as a capability that augments Asymchem's drug development, process development, quality management, manufacturing operations and supply-chain resilience. Asymchem is committed to responsibly developing, procuring, deploying and using AI to protect patient safety, customer trust, employee rights, data security, compliance accountability and long-term sustainable value.

一、宗旨与战略定位

1. Purpose and Strategic Positioning

凯莱英医药集团（英文名称：Asymchem）制定本人工智能策略，旨在建立覆盖集团层面的 AI 战略方向、治理原则、风险边界、生命周期管理和持续改进机制。

Asymchem establishes this Artificial Intelligence Strategy to define the group-level direction, governance principles, risk boundaries, lifecycle management and continuous improvement mechanism for AI.

AI 应当服务于凯莱英"以科学和技术能力支持药物研发与生产"的业务使命，并用于提升研发效率、工艺稳健性、质量合规、运营效率、知识管理和客户交付能力。

AI should serve Asymchem's business mission of supporting drug development and manufacturing through scientific and technological capabilities, and should improve R&D efficiency, process robustness, quality compliance, operational efficiency, knowledge management and customer delivery.

凯莱英将负责任 AI 视为创新能力和信任机制的组成部分，而不仅是合规要求。任何 AI 应用均不得削弱凯莱英对质量、数据、伦理、合规和专业判断的责任。

Asymchem views responsible AI as part of both innovation capability and trust-building, not merely as a compliance requirement. No AI application may diminish Asymchem's accountability for quality, data, ethics, compliance or professional judgment.

二、适用范围与定义

2. Scope and Definitions

本策略适用于凯莱英医药集团及其受控子公司在全球范围内开发、采购、集成、部署、测试、验证、运营或使用的 AI 系统，包括自研系统、第三方模型、SaaS 工具、嵌入式 AI 功能、生成式 AI 工具和自动化决策支持工具。

This Strategy applies globally to AI systems developed, procured, integrated, deployed, tested, validated, operated or used by Asymchem and its controlled subsidiaries, including internally developed systems, third-party models, SaaS tools, embedded AI functions, generative AI tools and automated decision-support tools.

本策略适用于董事、高级管理人员、员工、承包商、顾问、实习人员以及代表凯莱英开展工作的第三方人员。供应商和合作伙伴在向凯莱英提供含 AI 能力的产品或服务时，应遵守与本策略一致的要求。

This Strategy applies to directors, senior management, employees, contractors, consultants, interns and third parties working on behalf of Asymchem. Suppliers and partners providing AI-enabled products or services to Asymchem should comply with requirements consistent with this Strategy.

AI 系统是指基于数据输入生成预测、建议、分类、内容、决策支持或自动化输出的系统。生成式 AI 是指能够生成文本、图像、代码、音频、视频、结构化数据或其他内容的 AI 系统。

An AI system is a system that produces predictions, recommendations, classifications, content, decision support or automated outputs based on data inputs. Generative AI refers to AI systems that can generate text, images, code, audio, video, structured data or other content.

三、负责任 AI 原则

3. Responsible AI Principles

原则 Principle	凯莱英承诺 Asymchem Commitment
以人为本 Human-centered	AI 应增强人的能力，保护患者、客户、员工和其他利益相关方的安全、尊严、权利和自主性。 AI should augment human capability and protect the safety, dignity, rights and autonomy of patients, customers, employees and other stakeholders.
安全可靠 Safe and reliable	AI 系统应在预期用途内保持稳健、可靠、可验证和可追溯，尤其不得损害产品质量、GxP 合规或业务连续性。 AI systems should be robust, reliable, verifiable and traceable within their intended use, and must not compromise product quality, GxP compliance or business continuity.
公平包容 Fair and inclusive	AI 的设计、数据、测试和使用应避免不公平偏见、歧视和排斥，并考虑多样化用户、员工和受影响群体的合理需求。

	AI design, data, testing and use should avoid unfair bias, discrimination and exclusion, and should consider the reasonable needs of diverse users, employees and affected groups.
透明可解释 Transparent and explainable	AI 的能力、局限、使用场景和重要输出应以适当方式说明；重要决策支持应具备可理解的依据和人工复核路径。 AI capabilities, limitations, use cases and material outputs should be communicated appropriately; significant decision support should have understandable rationale and a path for human review.
问责可控 Accountable and controllable	业务负责人、系统负责人、技术负责人和治理职能应对 AI 系统的立项、验证、上线、监控、变更和退役承担明确责任。 Business owners, system owners, technical owners and governance functions should have clear accountability for AI initiation, validation, deployment, monitoring, change and retirement.
可持续创新 Sustainable innovation	凯莱英鼓励以负责任方式探索 AI 价值，并在可行范围内关注算力效率、能源使用、环境足迹和长期社会影响。 Asymchem encourages responsible exploration of AI value and, where feasible, considers compute efficiency, energy use, environmental footprint and long-term societal impact.

四、AI 使用红线与边界

4. AI Red Lines and Boundaries

凯莱英不开发、采购、部署或使用以操纵、欺骗、胁迫或利用个人弱点为目的的 AI 系统。

Asymchem will not develop, procure, deploy or use AI systems intended to manipulate, deceive, coerce or exploit individual vulnerabilities.

凯莱英不使用 AI 进行非法歧视性分类、社会评分、未经授权的生物识别监控、未经授权的敏感个人画像，或其他违反适用法律法规、商业伦理和人权原则的活动。

Asymchem will not use AI for unlawful discriminatory classification, social scoring, unauthorized biometric surveillance, unauthorized sensitive personal profiling or other activities that violate applicable laws, business ethics or human-rights principles.

AI 不得替代受监管场景中的专业判断、质量责任、合规责任或管理责任。在 GxP、质量放行、患者安全、员工重大权益、客户承诺或其他高影响场景中，AI 输出必须接受与风险相称的人工监督。

AI must not replace professional judgment, quality accountability, compliance accountability or management responsibility in regulated contexts. In GxP, quality release, patient safety, material employee-impact, customer commitment or other high-impact contexts, AI outputs must be subject to risk-proportionate human oversight.

五、战略价值领域

5. Strategic Value Domains

价值领域 Value Domain	AI 应用方向 AI Application Direction	治理重点 Governance Focus
研发与工艺开发 R&D and process development	辅助文献洞察、实验设计、工艺参数分析、知识检索和研发效率提升。 Support literature insight, experimental design, process-parameter analysis, knowledge retrieval and R&D efficiency.	确保科学依据、数据质量、专家复核和知识产权保护。 Ensure scientific rationale, data quality, expert review and intellectual-property protection.
质量与合规 Quality and compliance	辅助偏差趋势分析、文件审阅、培训问答、质量风险识别和审计准备。 Support deviation trend analysis, document review, training Q&A, quality risk identification and audit readiness.	保持 GxP 验证、审计追踪、人工批准和受控文件一致性。 Maintain GxP validation, audit trail, human approval and consistency with controlled documents.
生产运营 Manufacturing operations	支持排产优化、设备维护、能耗分析、过程监控和运营韧性提升。 Support scheduling optimization, equipment maintenance, energy analysis, process monitoring and operational resilience.	确保安全、可靠性、变更控制和业务连续性。 Ensure safety, reliability, change control and business continuity.
供应链与客户交付 Supply chain and customer delivery	支持需求预测、供应风险识别、项目知识管理和客户交付效率。 Support demand forecasting, supply-risk identification, project knowledge management and customer delivery efficiency.	保护客户信息、商业秘密、合同边界和第三方依赖风险。 Protect customer information, trade secrets, contractual boundaries and third-party dependency risks.
职能效率与员工赋能 Functional efficiency and workforce enablement	支持办公自动化、代码辅助、数据分析、知识问答和内容初稿生成。 Support office automation, code assistance, data analysis, knowledge Q&A and draft content generation.	落实保密、核验、可接受使用、版权和员工 AI 素养要求。 Implement confidentiality, verification, acceptable use, copyright and AI literacy requirements.

六、治理架构与责任

6. Governance Structure and Accountability

凯莱英应建立跨职能 AI 治理机制，由信息技术、质量、法务合规、数据隐私、信息安全、业务部门、采购、人力资源及必要时的高级管理层共同参与。

Asymchem should establish a cross-functional AI governance mechanism involving information technology, quality, legal and compliance, data privacy, information security, business functions, procurement, human resources and, where necessary, senior management.

AI 系统应指定业务负责人和系统负责人。业务负责人负责用途合理性、业务价值、流程嵌入和人工监督；系统负责人负责技术控制、运行监控、变更管理和退役管理。

Each AI system should have a business owner and a system owner. The business owner is responsible for use-case justification, business value, process integration and human oversight; the system owner is responsible for technical controls, operational monitoring, change management and retirement management.

董事会或其授权管理机构应定期了解 AI 治理成熟度、重大 AI 风险、高风险 AI 系统、AI 事件、培训完成情况和外部监管趋势。

The Board or its delegated management body should periodically review AI governance maturity, material AI risks, high-risk AI systems, AI incidents, training completion and external regulatory trends.

七、AI 生命周期管理

7. AI Lifecycle Management

AI 系统应按照生命周期进行管理，包括需求提出、用途定义、数据准备、模型或工具选择、风险评估、验证或测试、上线批准、运行监控、变更控制、定期复审和退役。

AI systems should be managed across their lifecycle, including request initiation, use-case definition, data preparation, model or tool selection, risk assessment, validation or testing, deployment approval, operational monitoring, change control, periodic review and retirement.

AI 系统不得在未经授权的情况下持续学习或自动改变影响受控流程的关键行为。对模型、数据、提示词模板、接口、供应商能力或使用场景的重大变更，应按风险重新评估。

AI systems must not continuously learn or automatically change key behavior affecting controlled processes without authorization. Material changes to models, data, prompt templates, interfaces, supplier capabilities or use cases should trigger risk-based reassessment.

八、数据、隐私与网络安全

8. Data, Privacy and Cybersecurity

AI 使用应遵循数据最小化、目的限定、合法合规、访问控制、保密和数据质量原则。未经授权，不得向公共 AI 工具或未获批准的第三方模型输入客户保密信息、个人信息、商业秘密、受控文件、GxP 数据或其他受限数据。

AI use should follow the principles of data minimization, purpose limitation, legality and compliance, access control, confidentiality and data quality. Without authorization, customer confidential information, personal information, trade secrets, controlled documents, GxP data or other restricted data must not be entered into public AI tools or unapproved third-party models.

涉及个人信息、敏感个人信息、员工数据、客户数据或跨境数据处理的 AI 场景，应在上线前完成适用的数据隐私评估、告知或授权、数据处理协议和安全控制。

AI use cases involving personal information, sensitive personal information, employee data, customer data or cross-border data processing should complete applicable privacy assessments, notices or authorizations, data-processing agreements and security controls before deployment.

AI 相关代码、脚本、模型接口和自动化流程应遵守信息安全要求，不得硬编码密钥，不得绕过身份认证、日志、审计、漏洞扫描或软件批准要求。

AI-related code, scripts, model interfaces and automation workflows should comply with information-security requirements, and must not hard-code secrets or bypass authentication, logging, audit, vulnerability scanning or software approval requirements.

九、透明、解释、人类监督与申诉

9. Transparency, Explanation, Human Oversight and Appeal

在员工、客户、合作伙伴或其他相关方与 AI 系统交互，或 AI 输出可能实质影响其权益、服务、交付或判断时，凯莱英应以适当方式披露 AI 的使用、目的、局限和人工支持渠道。

When employees, customers, partners or other stakeholders interact with an AI system, or when AI outputs may materially affect their rights, services, delivery or judgment, Asymchem should appropriately disclose AI use, purpose, limitations and human-support channels.

对重要 AI 输出，使用者应进行人工核验，不得将 AI 输出作为唯一事实来源或唯一决策依据。高影响场景应保留人工干预、纠错、升级和申诉机制。申诉渠道详见《凯莱英举报政策》

Users should verify material AI outputs and must not treat AI outputs as the sole source of fact or the sole basis for decisions. High-impact contexts should retain mechanisms for human intervention, correction, escalation and appeal. For details of the reporting channels, please refer to the <Asymchem Whistleblowing Policy>.

凯莱英应在可行范围内使用可解释性方法，帮助业务负责人、用户和治理职能理解 AI 系统的主要输入、输出逻辑、限制、适用条件和风险。

Asymchem should use explainability methods where feasible to help business owners, users and governance functions understand key inputs, output logic, limitations, applicable conditions and risks of AI systems.

十、公平、包容与偏见治理

10. Fairness, Inclusion and Bias Management

凯莱英应在 AI 系统设计、数据选择、训练或配置、测试、部署和监控过程中识别并降低不公平偏见，避免基于受保护特征、敏感信息或不合理代理变量产生歧视性结果。

Asymchem should identify and reduce unfair bias during AI system design, data selection, training or configuration, testing, deployment and monitoring, and avoid discriminatory outcomes based on protected characteristics, sensitive information or unreasonable proxy variables.

涉及招聘、员工管理、绩效、培训机会、供应商评价、客户服务或其他可能影响个人或组织权益的 AI 系统，应开展与风险相称的公平性评估和人工复核。

AI systems involving recruitment, employee management, performance, training opportunities, supplier evaluation, customer service or other contexts that may affect individual or organizational interests should undergo risk-proportionate fairness assessment and human review.

凯莱英鼓励 AI 应用兼顾可及性和包容性，避免因语言、地域、身体条件、数字能力或岗位差异导致不合理排斥。

Asymchem encourages AI applications to consider accessibility and inclusion and to avoid unreasonable exclusion due to language, geography, physical condition, digital capability or job differences.

十一、GxP 与业务关键流程要求

11. Requirements for GxP and Business-Critical Processes

在 GxP、质量、生产、实验室、药物研发关键数据、客户交付和其他业务关键流程中使用 AI 时，应遵循适用法规、质量体系、计算机化系统验证、数据完整性和变更控制要求。

When AI is used in GxP, quality, manufacturing, laboratory, critical drug-development data, customer delivery and other business-critical processes, applicable regulations, quality systems, computerized-system validation, data integrity and change-control requirements should be followed.

生成式 AI 和聊天机器人在 GxP 或业务关键流程中原则上仅可作为受控的效率辅助工具，不得自主执行受监管活动、替代批准人、改变受控记录或绕过质量流程。

Generative AI and chatbots should generally be used in GxP or business-critical processes only as controlled productivity assistants, and must not autonomously perform regulated activities, replace approvers, alter controlled records or bypass quality processes.

所有受监管或高影响输出应保留来源、版本、提示词或输入、人工复核、批准和必要的审计追踪，以支持偏差调查、CAPA、审计和客户问询。

All regulated or high-impact outputs should retain sources, versions, prompts or inputs, human review, approvals and necessary audit trails to support deviation investigation, CAPA, audits and customer inquiries.

十二、第三方与供应商 AI 治理

12. Third-Party and Supplier AI Governance

采购、订阅或集成第三方 AI 系统前，应开展与风险相称的尽职调查，内容包括供应商资质、数据处理、模型更新、信息安全、隐私、可用性、可解释性、审计支持、退出机制和合同责任。

Before procuring, subscribing to or integrating third-party AI systems, risk-proportionate due diligence should be conducted, covering supplier qualifications, data processing, model updates, information security, privacy, availability, explainability, audit support, exit mechanisms and contractual accountability.

供应商不得将凯莱英数据用于未经授权的训练、再训练、产品改进或第三方共享。涉及客户数据、个人信息、GxP 数据或商业秘密的，应签署适当的数据处理、安全和保密条款。

Suppliers must not use Asymchem data for unauthorized training, retraining, product improvement or third-party sharing. Where customer data, personal information, GxP data or trade secrets are involved, appropriate data-processing, security and confidentiality terms should be executed.

第三方 AI 能力发生重大变化、模型版本变更、服务中断、安全事件、合规变化或数据处理变化时，应触发重新评估和必要的变更控制。

Material changes to third-party AI capabilities, model versions, service availability, security incidents, compliance status or data processing should trigger reassessment and necessary change control.

十三、员工 AI 素养与可接受使用

13. AI Literacy and Acceptable Use

凯莱英应按角色建立 AI 素养培训机制，使员工理解 AI 能力与局限、数据保密、提示词安全、输出核验、偏见风险、版权风险、GxP 限制和违规后果。

Asymchem should establish role-based AI literacy training so employees understand AI capabilities and limitations, data confidentiality, prompt safety, output verification, bias risk, copyright risk, GxP restrictions and consequences of misuse.

员工使用 AI 生成文本、代码、分析结果、会议纪要、培训材料、客户材料或其他工作成果时，应对最终内容承担责任，并标识 AI 辅助生成或经过 AI 处理。

Employees using AI to generate text, code, analytical results, meeting minutes, training materials, customer materials or other work products remain responsible for the final content and should label AI assistance or AI processing.

员工不得使用 AI 规避审批、伪造记录、生成误导性信息、侵犯知识产权、处理未经授权的数据，或将 AI 输出直接作为受控文件、监管提交、客户承诺或质量结论。

Employees must not use AI to bypass approvals, falsify records, generate misleading information, infringe intellectual property, process unauthorized data or treat AI outputs directly as controlled documents, regulatory submissions, customer commitments or quality conclusions.

十四、监控、事件响应与持续改进

14. Monitoring, Incident Response and Continuous Improvement

凯莱英应根据风险等级监控 AI 系统表现，包括准确性、稳定性、模型漂移、性能退化、异常输出、安全漏洞、偏见迹象、用户反馈、供应商变更和业务影响。

Asymchem should monitor AI system performance based on risk level, including accuracy, stability, model drift, performance degradation, abnormal outputs, security vulnerabilities, bias indicators, user feedback, supplier changes and business impact.

AI 事件可包括由模型偏移或性能下降导致的错误或误导性输出、数据泄露、未经授权使用、偏见或歧视、网络安全问题、质量或合规偏差、业务连续性影响以及违反本策略的行为。事件应按严重性分级、记录、调查、纠正并在必要时升级。

AI incidents may include erroneous or misleading outputs caused by model drift or performance degradation, data leakage, unauthorized use, bias or discrimination, cybersecurity issues, quality or compliance deviations, business-continuity impact and violations of this Strategy. Incidents should be severity-classified, recorded, investigated, corrected and escalated where necessary.

与质量体系相关的 AI 事件，应按照适用流程连接偏差、CAPA、变更控制、客户通知或监管报告要求。

AI incidents related to the quality system should be connected to applicable deviation, CAPA, change control, customer notification or regulatory reporting requirements.

十五、环境足迹与可持续发展

15. Environmental Footprint and Sustainability

凯莱英在规划 AI 应用时，应综合考虑业务价值、风险、算力需求、能源使用、环境足迹和替代方案，优先选择与实际用途相匹配、资源效率更高的 AI 方案。

When planning AI applications, Asymchem should consider business value, risk, compute requirements, energy use, environmental footprint and alternatives, and should prefer AI solutions that match the actual use case and use resources more efficiently.

凯莱英鼓励利用 AI 支持节能、减排、工艺优化、供应链韧性和资源效率提升，同时避免为低价值场景引入不成比例的算力消耗。

Asymchem encourages the use of AI to support energy savings, emission reduction, process optimization, supply-chain resilience and resource efficiency, while avoiding disproportionate compute consumption for low-value use cases.

十六、政策维护、批准与生效

16. Maintenance, Approval and Effective Date

本策略由凯莱英指定的 AI 治理牵头部门会同质量、法务合规、信息安全、数据隐私、人力资源、采购及相关业务部门维护，并根据法律法规、监管要求、业务变化、技术发展和重大事件进行更新。

This Strategy is maintained by Asymchem's designated AI governance lead function together with quality, legal and compliance, information security, data privacy, human resources, procurement and relevant business functions, and should be updated based on laws, regulations, regulatory requirements, business changes, technology developments and material incidents.

本策略建议至少每年评审一次，并在重大法规变化、重大 AI 事件、重大业务流程变化或高风险 AI 应用扩展时及时修订。

This Strategy should be reviewed at least annually and revised promptly in the event of major regulatory changes, material AI incidents, major business-process changes or expansion of high-risk AI applications.

本策略经董事会战略委员会审议通过后生效。

This Strategy shall come into effect upon approval by Strategy Committee of the Board.