

Guiding Principles of Good AI Practice in Drug Development

10 Principles

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AI here means **system-level technologies used to generate or analyze evidence** across the drug product life cycle — nonclinical, clinical, post-marketing, and manufacturing. These principles lay the foundation for good practice, helping ensure AI outputs are **accurate, reliable, and reinforce the quality, efficacy, and safety** that drug authorization depends on.

USE THIS CHECKLIST TO EVALUATE ANY AI TECHNOLOGY ACROSS THE DRUG LIFE CYCLE 10 CHECKS

01

Human-centric by design

Development and use align with ethical and human-centric values.



02

Risk-based approach

Apply validation, risk mitigation, and oversight proportionate to the context of use and determined model risk.



03

Adherence to standards

Meet relevant legal, ethical, technical, scientific, cybersecurity, and regulatory standards, including Good Practices (GxP).



04

Clear context of use

Define a well-scoped role and reason for why the AI is being used.



05

Multidisciplinary expertise

Integrate expertise in both the AI technology and its context of use throughout the life cycle.



06

Data governance & documentation

Document data provenance, processing, and analytical decisions traceably; maintain governance, privacy, and protection of sensitive data.



07

Model design & development practices

Follow best practices in design and software engineering with fit-for-use data, weighing interpretability, explainability, and performance.



08

Risk-based performance assessment

Evaluate the complete system, including human–AI interactions, using fit-for-use data and context-appropriate metrics and testing.



09

Life cycle management

Run risk-based quality management with scheduled monitoring and periodic re-evaluation (e.g., to address data drift).



10

Clear, essential information

Use plain language to convey context of use, performance, limitations, data, updates, and explainability to users and patients.