



Building Quality into GxP AI

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Building Quality into GxP AI.

- Where is GxP AI emerging?
- We already have what we need to control GxP AI quality. Well, almost....
- Novel areas of GxP AI quality control.
- The roles Quality and IT teams need to play.
- Where to start.



Where is GxP AI emerging?

AI will emerge *everywhere*, but not all “AI” presents the same risks

Type of AI	GenAI <i>Generative AI</i>	RAG <i>Retrieval Augmented Generation</i>	ML <i>Machine Learning</i>	DL <i>Deep Learning</i>
What it does	Takes existing processes and improves productivity.	Feeds information into a model that can be then queried	AI systems that learn from data, recognize patterns, make predictions with human help.	AI systems that learn from data, recognize patterns, make predictions with on their own.
Example Use Cases	<ul style="list-style-type: none"> • Document/content authoring • Gene/Protein/Molecule Design • Data augmentation for model training (virtual patients, sample data, 	<ul style="list-style-type: none"> • Equipment/system manuals • Medical diagnosis • Clinical trial optimization • Literature summaries • Chatbots / Support 	<ul style="list-style-type: none"> • Drug candidate identification • Supply chain optimization • Image Analysis • Supporting GenAI/RAG models 	<ul style="list-style-type: none"> • Scientific research • Image Analysis • Data Integratoin
Humans in the Loop	Yes	Yes	Yes	No
AI Risk Level	Low	Low	Low-High	High



We have what we need to control GxP AI quality.

Well, almost...

We have managed major technology transitions before.

The cloud was scary and impossible. Now it's the norm.

GxP AI can be managed with risk-based Computer Systems Lifecycle Management.

GAMP5 Edition 2 provides guidance.

“Human in the Loop” AI models have natural points of control.

ISPE has recommended an AI Maturity Model and RAMM model in alignment with ICH Q9.

Establishes risk profile of an AI system/capability.

RAMM model focuses test methods on areas risk.

But..., GxP AI has some unique areas where risk needs to be controlled.



Novel areas of GxP AI quality control.

Data Quality

Good data is essential to AI performance. Initial data sets, data splits and the quality of data in operation need control.

Model Design

Ensuring the model design is accurate and supports quality objectives. Inferior models can create risk.

Model Training

How we manage the process of fine-tuning the model to generate the best performance.

Model Evaluation

The methods we use to measure and accept model performance before we release it to production. This defines the risk the organization is willing to accept.

Release Management

Updates to technology, data, and model design need effective and efficient risk-based change control with human interaction.

Data Privacy

Ensuring data privacy is rigorously understood, managed, and monitored. Essential when using LLMs.



The roles Quality and IT teams need to play.

- **GxP AI is a change management challenge.**
 - Cultural shifts can be large and need to be managed.
 - The human change is larger than the technology change.
 - Quality organizations will be worried about the validation load up front and over time.
- **How do we need to partner to bring AI into GxP?**
 - Like any other modern technology change, IT, Quality and the Business need to be on the same page.
 - Clear boundaries for acceptable use and for ROI measurement need to be set and monitored.
 - Vendors have a necessary role in providing education, support, and compliance management.
- **Embracing a risk-based approach is essential.**
 - It's all about how we put our trust in a machine vs. a human.
 - We need to build trust in the skills of GxP AI tools.
 - This is analogous to how we control for human skills (e.g. job evaluations, resume screening).





Where to start.

- **An Acceptable Use Policy is a valid starting point.**
 - Understanding and articulating the risks of GxP AI up front
- **Find your Use Case.**
 - Early adopters are going to want more and more tools but you can't rush going beyond what is approved as acceptable for use.
- **Crawl. Walk. Run.**
 - Update (or add) SOPs to apply quality control to AI systems.
 - Make the effort visible to the organization to get buy-in and identify early adopters.
- **Start investing in your People.**
 - **Education and skills.** Upskilling and re-skilling is required.
 - **Attract talent.** AI is attractive to the future workforce.



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