TECHNOLOGY · IT AND QUALITY

Set Up a Working Partnership with IT and Quality on AI

An OmniTek Consulting implementation guide for VPs and Directors in pharma, biotech, and medical device companies.

READING TIME
About 5 minutes

WHO IT'S FOR
VPs and Directors

GOES WITH
The AI Maturity Quick Check

> Most department-level AI work needs IT to set it up and, in regulated work, Quality to sign it off. Departments that treat IT and Quality as partners from the start move in weeks; departments that send them requests one at a time wait months.

SCOPE This guide covers AI used in how your company works, such as drafting, analysis, and operations. It doesn't cover AI that is part of a product you sell, such as AI-enabled device software or software as a medical device. That has its own regulatory path; check it with your Regulatory team.

Why it matters

- **Requests queue up.** One-off tickets compete with everything else IT and Quality are doing.
- **Late involvement means rework.** A pilot designed without Quality often has to be redesigned before it can touch regulated work.
- **Shared priorities get funded.** When IT, Quality, and the department agree on a short list, it's much easier to get budget and time.

Who does what

Decision or task	Department	IT	Quality	Privacy or Legal
Which AI ideas to pursue	Decides	Advises on feasibility	Advises on risk	Consulted for personal data
Tool evaluation and approval	Requests and tests	Leads security review	Signs if approved for any GxP use; otherwise informed (non-GxP use only)	Reviews contracts and privacy

Decision or task	Department	IT	Quality	Privacy or Legal
GxP classification of a use	Completes the worksheet	Informed	Signs off	Consulted if personal data
Data access for a use	Data owner approves	Provides the access route	Confirms integrity controls	Confirms consent and contract limits
Validation of GxP direct uses	Owns the use	Supports technical testing	Approves the approach	Not usually involved
Monitoring after go-live	Watches results and issues	Watches performance and access	Reviews changes	Informed of incidents

A monthly AI working group

Sixty minutes a month with the AI owner, an IT partner, a Quality partner, and Privacy when needed.

Minutes	Item
0–10	Results from live AI uses, against their baselines
10–30	New ideas: quick triage, classification, and data needs
30–45	Tool requests and access issues
45–55	Risks, incidents, and regulatory changes
55–60	Decisions and owners, recorded in the AI use register

A fast path for new ideas

Agree a simple route so people know what to expect:

1. **Submit.** One short form: the task, the tool, the data, and who will use the output.
2. **Triage within one week.** The working group classifies the use and confirms the data class. Triage gives a first view; the classification is final only when Quality signs it.
3. **Non-GxP uses start once the tool is approved for the data. GxP supporting uses start once Quality has signed the classification and the tool is approved for GxP use**, with documented review.
4. **GxP direct uses go to a risk assessment and validation plan**, with Quality approving the approach.
5. **Try new ideas in a test environment** kept separate from validated systems, so experiments never touch GxP records. Don't load patient or personal data, or copies of GxP records, into the test environment unless Privacy and Quality approve it; use synthetic or de-identified data where you can, and handle any copies as your data integrity SOP requires.

A shared roadmap

Keep one page that all three groups agree on, and review it every quarter.

TEMPLATE · COPY AND ADAPT

[Department] AI Roadmap: [quarter]

Initiative	Class	Owner	IT support	Quality support	Target	Status
[Approve general-purpose AI tool]	n/a	[ ]	[security review]	[informed, non-GxP only; signs if GxP use]	[date]	[ ]
[Draft monthly quality report with AI]	GxP supporting	[ ]	[access to trending data]	[review step agreed]	[date]	[ ]
[ ]	[ ]	[ ]	[ ]	[ ]	[ ]	[ ]

Your first 30 days

1. **Week 1: Name your partners.** Ask the heads of IT and Quality for one named person each who can spend time on your department's AI work.
2. **Week 1: Agree who does what.** Walk through the table above together and adjust it to your organization.
3. **Week 2: Hold the first working group.** Bring your current AI ideas and tool requests.
4. **Week 3: Agree the fast path.** Publish how to submit an idea and what happens next, including the one-week triage target.
5. **Week 4: Draft the shared roadmap.** Fill in the template with your first few initiatives, and set the quarterly review date.

By day 30 your department has named IT and Quality partners, a regular forum, and a clear route for new ideas. That covers the partnership question in the Quick Check at the Operationalizing level; a shared roadmap with dedicated support moves you toward Scaling.

Common mistakes

- **Treating IT and Quality as approvers only.** Invite them to shape ideas, not just sign them off at the end.
- **Bringing every request to every meeting.** Use the fast path for routine items; save the working group for decisions.
- **No test environment.** Without a safe place to experiment, people either don't experiment or do it somewhere risky.
- **Skipping Privacy until late.** Personal data questions are much easier to solve before a pilot starts.
- **A roadmap only one group owns.** If IT and Quality didn't help write it, they won't prioritize it.

How OmniTek can help

The full AI Maturity Report Card measures your partnership with IT and Quality, how fast new ideas can start, and GxP maturity, and shows where to build the partnership first.

To talk through working with IT and Quality on AI, or your Quick Check results, book time with OmniTek.

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