PEOPLE · ROLES

Write AI Responsibilities into Roles

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

READING TIME
About 4 minutes

WHO IT'S FOR
VPs and Directors

GOES WITH
The AI Maturity Quick Check

> Work that belongs to no one's job gets done last. Writing AI responsibilities into a handful of roles, with time set aside and recognition attached, turns AI from a side project into part of how the department operates.

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

- **Volunteers burn out.** Early adopters carry AI work on top of their day jobs until they can't.
- **Regulated work needs named people.** Regulated work depends on documented responsibilities: EU GMP Chapter 2 expects people in responsible positions to have their duties recorded in written job descriptions, and Annex 11 names process owners and system owners. Expect Quality and inspectors to ask who reviews AI output, who owns a use, and who approved it.
- **What gets recognized gets repeated.** If AI improvements never show up in goals or reviews, people stop investing in them.

Five roles to define

One person can hold more than one role in a small department. What matters is that each is named.

Role	Responsible for	Typical holder
AI owner	Direction, priorities, results, and reporting for the department	A senior leader in the department
AI champion	Helping colleagues use approved tools well and sharing what works	One per team, a respected practitioner

Role	Responsible for	Typical holder
Use owner (process owner)	Running one AI use day to day: performance, issues, and changes	The lead for the process the AI supports
Quality reviewer for AI	Classifying AI uses and reviewing GxP uses with the department	A named Quality partner
Data owner	Approving use of a data source and answering for its quality	The business lead for each key system

Where a role matches a quality-system term, use that term. In Annex 11 terms, the use owner is usually the process owner, and whoever is responsible for an AI tool's availability, maintenance, and data security is its system owner. Use your own quality system's terms.

A role description addendum

Add a short section to each person's existing role description rather than creating new jobs.

TEMPLATE · COPY AND ADAPT

AI Responsibilities: [Name, current title]

Role: [AI champion / Use owner / Quality reviewer for AI / Data owner] Effective: [date] | Agreed with: [manager] | Reviewed: [at annual goal setting]

Responsibilities

- [e.g. Help the Clinical Operations team use the approved AI tool well]
- [e.g. Run a monthly 30-minute tips session and collect AI ideas for the AI owner]
- [e.g. Flag issues with AI output or tool access to the AI owner within one week]

Time

[Share of the week or hours per month] set aside, reflected in workload planning.

Goal for this year

[One measurable goal, e.g. "Every team member has used the approved tool on real work by June"]

Support

Training: [ ] | Reports to on AI matters: [AI owner]

Recognize the work

- **Put it in goals.** Each role gets one AI-related goal in the annual review, measured on results, not on how much AI was used.
- **Say it out loud.** Share AI improvements in team meetings and name the people behind them.

- **Make it a development step.** Being an AI champion or use owner is good experience; treat it that way in career conversations.

Check any change to role descriptions or goals with HR first. In the EU, changes to roles or work organisation may require informing and consulting employee representatives or works councils first (Directive 2002/14/EC); check with HR and legal before announcing changes. Many GMP organisations treat job descriptions and training records as controlled documents. That's common company practice rather than a regulatory requirement; if yours does, route the addendum and any updated job descriptions through document control.

Your first 30 days

1. **Week 1: Map the roles to people.** Use the table above. Note which roles are filled informally today and which are empty.
2. **Week 2: Talk to each person.** Ask rather than assign, agree the time, and agree one goal.
3. **Week 3: Write the addenda.** One per person, reviewed with their manager and HR.
4. **Week 4: Announce the roles.** Tell the team who the AI owner, champions, and use owners are, and who in Quality reviews AI uses.

By day 30 AI work has named owners with time and goals. That covers the roles questions in the Quick Check at the Operationalizing level; adding AI results to performance reviews moves you toward Scaling.

Common mistakes

- **Adding the work without the time.** A role with no time set aside is a wish, not a role.
- **Rewarding usage instead of results.** Counting prompts encourages careless use. Reward better outcomes.
- **Forgetting Quality.** A named Quality reviewer for AI is what lets GxP uses move at a sensible pace.
- **Creating a separate AI team too early.** In most departments, AI work belongs with the people who do the work, supported by a few named roles.
- **Never revisiting.** Review the roles each year as AI use grows.

How OmniTek can help

The full AI Maturity Report Card measures roles and incentives alongside the other maturity dimensions, and shows which roles to formalize first for your department.

To talk through AI roles for your team, or your Quick Check results, book time with OmniTek.

Book time with OmniTek

This guide is general information for leaders in regulated life sciences functions, not legal or regulatory advice. Confirm requirements with your Quality, Regulatory, and Legal teams. © 2026 OmniTek Consulting.