Syner·G Frequently Asked Questions

The CMC Project Manager: Frequently Asked Questions

By Ray Forslund, PhD, MBA
EVP, Head of Product Development

A veteran practitioner's answers to the toughest objections to how the CMC PM role should be structured, positioned, and measured

A CMC PM with two decades in the seat has watched most of the arguments for a dedicated, well-positioned CMC PM role collide with reality and knows where the theory does — and does not — translate into practice. Below are the objections a seasoned practitioner is most likely to raise, and how those recommendations hold up against them.

Isn't dotted-line reporting usually decorative?

This is correct more often than it should be, and it is the single most common reason the hybrid model underdelivers. A dotted line only functions if it comes with a written charter: the CMC PM sits in program governance as a voting participant, owns and presents the integrated CMC schedule at that forum, and the program lead has a real voice in that person's performance review, not just a courtesy CC. Without those three things in writing, call the structure what it is — a solid line with a mailing list — and stop presenting it to leadership as shared accountability.

Isn't visibility different from authority? Can't a CMC PM see a problem coming and still be unable to get anyone to act on it?

Also correct, and worth saying plainly rather than glossing over. Line of sight buys time to escalate, not the power to compel a decision. The organizational value only converts into a business outcome if functional leaders act on early warning and executives do not punish the person who surfaces bad news before it is a crisis. A CMC PM function without that cultural support produces excellent early warnings that get ignored, which is worse for morale than never having the visibility in the first place — because the PM now owns the paper trail of a call nobody made.

Isn't the stability-slip example too clean? In the real world, doesn't the CMC PM find out about problems at the same meeting as everyone else?

This is the actual failure mode most veteran CMC PMs have lived, not the neat version most examples describe. Line of sight is not an entitlement that comes with the title, it is built by being embedded enough to hear about a problem while it is still being characterized, sitting in on deviation huddles and analytical troubleshooting discussions before they generate a formal report, and having enough technical credibility that a bench scientist will mention a worrying result informally instead of waiting for the data package. A CMC PM who is only a downstream consumer of finished status updates will always be structurally late to the one piece of information that mattered.

Doesn't routing sponsor-CDMO communication through a single point of contact break down once you need subject-matter-expert-to-subject-matter-expert conversation?

Direct analytical-to-analytical or engineer-to-engineer conversation with the CDMO is necessary and should be encouraged, not routed through the PM. The CMC PM's job is narrower and still essential: make sure those direct technical conversations get reflected back into the integrated plan before scope, cost, or timeline quietly shifts. The PM is the person who closes the loop and ensures information is disseminated, not the switchboard operator who has to be on every call.

Isn't the hybrid matrix really a mid-size-and-up structure being sold as a universal best practice?

Agreed — the hybrid model is something organizations should grow into as program count and portfolio complexity increase, not a structure to impose on day one. Below roughly two to three active programs, a formal matrix adds governance overhead the organization cannot yet justify. A ten-person virtual biotech with one asset does not need two reporting lines; it needs one adult in the room who owns the CMC plan. Project management requirements evolve with the number, scale, and complexity of an organization's programs, and should be reassessed continually as the company and its projects develop — there is no one-size-fits-all approach.

Isn't this just advocacy for more headcount and organizational complexity?

That is a legitimate limitation of any case made from inside the function it defends, and it should be acknowledged rather than argued away. An argument like this works best paired with a specific internal retrospective — a real delay, rush fee, or filing slip the organization already absorbed, quantified in dollars and months, and traced back to a coordination gap this role would have caught. What lands with a skeptical CFO or board is rarely the theoretical case; it is the specific near-miss with a number attached to it.

> **Taken together, these answers don't undercut the case for a dedicated CMC PM — they sharpen it, by naming exactly what has to be true for the role to deliver on its promise: a written charter behind the dotted line, cultural support for early warning, structural access to information rather than downstream status updates, concrete performance metrics, and a reporting model sized to the portfolio rather than borrowed from a bigger organization.**