How to Talk About RA/QA in a Way Your CEO Actually Hears

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One dynamic I hear about often, from RA/QA leaders and from CEOs separately, is the disconnect between a Regulatory or Quality leader and a CEO who genuinely wants the same outcome, but aren't speaking the same language. The Regulatory leader is talking about submission requirements, design controls, changing regulations, audit readiness, or documentation. The CEO is thinking about product launches, investors, revenue, cash runway, customer commitments, and whether the company can hit the milestones everyone is counting on. Neither person is wrong. They're just looking at the same challenge from different angles.

The strongest RA and QA leaders I've met understand this. Their job is more than explaining the regulations. It's applying them in a way that keeps the business moving toward what it's actually trying to accomplish. For example, instead of saying, "We need another validation before we can move forward," they explain what skipping that step could mean six months from now. Maybe it delays a submission. Maybe it creates questions during an inspection. Maybe it forces the team to revisit work they thought was already finished. Now the conversation isn't about validation. It's about protecting the timeline.

Good CEOs aren't expecting their Regulatory or Quality leaders to simplify complex requirements. They are looking for help understanding what those requirements mean for the company's objectives. Can we launch when we said we would? Can we manufacture consistently? Can we expand into another market? Can we support commercial growth without creating problems we'll have to fix later? Those are business conversations. Regulatory and Quality happen to be a big part of the answer.

The leaders who earn a seat in those conversations tend to be less focused on knowing the most regulations, and more focused on how their recommendations show up in the company's bottom line, timeline, or next milestone. Leaders who've made that shift tell me it changes the entire dynamic of leadership meetings. Instead of being viewed as the group that says, "Here's what we can't do," Regulatory and Quality become the people explaining, "Here's how we get where we want to go without creating bigger problems down the road."

There's a longer-term effect too. When a CEO can clearly see how a misstep in Regulatory or Quality could hold the company back, something shifts in how they think about timing. RA/QA leadership stops looking like something to add later, once the company is bigger, and starts looking like something worth bringing in earlier, because the cost of getting it wrong becomes obvious well before it actually happens.

Where that connection isn't made, the opposite tends to play out. Companies delay bringing on dedicated leadership, or lean on outside consultants well past the point where a permanent hire would have produced a better outcome, simply because nobody made the business case clear enough, early enough.

Most CEOs aren't asking Regulatory or Quality to think less like technical experts. They're asking them to help the rest of the organization understand how good decisions today protect the business tomorrow. When that connection is made, the conversation changes, and so does the influence those leaders have across the organization, and often, how early that leadership gets brought on board in the first place.