

Leading Well When Everything Feels High Stakes



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One thing that's true about this industry is that there are very few weeks when everything feels calm. There's always something that can't slip. The submission deadline is getting closer. An audit is on the calendar. A product launch is approaching. A customer issue needs attention. Investors are waiting for the next milestone. The leadership team is asking for updates.

When you're leading a Regulatory or Quality organization, it's easy to feel like every decision carries enormous weight. Because many of them do. The challenge is that if everything is treated as equally urgent, eventually nothing gets the attention it deserves.

I've watched leaders spend their days moving from one fire to the next, answering questions, joining meetings, solving problems, and making hundreds of decisions along the way. They're working incredibly hard. But they're also making it harder for their teams to know what really matters. The leaders who seem to navigate these periods the best don't pretend the pressure isn't there. They simply create clarity in the middle of it.

They make sure everyone understands the one or two outcomes that matter most right now. That doesn't mean the other work disappears. It means people know where to focus when competing priorities inevitably collide. I've seen this make a remarkable difference during submission preparation and inspection readiness.

In one organization, every request felt urgent, and the team was constantly shifting directions. Work kept starting, but very little was being completed. In

another, the leadership team made a conscious decision to protect the priorities that would have the biggest impact on the company's next milestone. Other work continued, but it didn't distract from what absolutely had to be finished. The teams were equally talented. The difference was focus.

Pressure has a way of making leaders feel like they need to be involved in everything. Sometimes that's necessary. Just as often, giving the right people the information, authority, and confidence to make decisions without waiting for approval at every step keeps things moving faster. That creates something every organization needs during high-pressure periods.

Momentum.

When decisions slow down, everything else slows down with them. The strongest leaders I've worked with focus less on carrying every challenge themselves, and more on creating an environment where the team can keep moving, even when the stakes are high. People take their cues from leadership. If every conversation feels like a crisis, the organization starts operating like it's in one.

If leaders stay focused, communicate clearly, and keep everyone's attention on what matters most, that approach spreads just as quickly. The pressure doesn't disappear. But the team handles it differently. There will always be moments in this industry when the stakes feel high. That's part of bringing safe, effective products to patients and supporting the companies working to get there. The leaders who make the biggest difference help their teams do their best work in the middle of pressure, rather than trying to eliminate it, which usually isn't possible anyway.

This topic reflects something I've seen repeatedly in medical device and life sciences organizations. High-pressure periods are inevitable. The leaders who consistently move their companies forward are usually the ones who create clarity and focus when everyone else is feeling pulled in every direction.