Why Good Hires Sometimes Still Struggle

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I’ve watched companies bring in genuinely strong RA or QA talent, people with the right background, the right experience, the right instincts, and still watch that person struggle for the first several months. It’s tempting to assume the hire was wrong. Often, the real issue started before the person ever walked in the door.

Most job descriptions describe the work. Very few describe what success actually looks like. “Manage the submission process” tells someone what they’ll be doing. It doesn’t tell them what “doing it well” means to the people they’ll be reporting to. Is success hitting a specific date? Reducing back-and-forth with reviewers? Building a process the team didn’t have before? Those are three different jobs wearing the same title.

I’ve sat in enough hiring conversations to notice a pattern. When I ask a hiring manager what the new person needs to accomplish in the first six months, I often get a pause before the answer. They can describe the work in detail, task by task. What’s usually missing is a clear sense of what “this is going well” actually looks like from where they sit.

That gap doesn’t disappear once someone’s hired, it just moves. The new person spends their first few months guessing at what matters most, prioritizing based on assumptions instead of agreement. Sometimes they guess right. Often, they focus on the wrong thing, working hard on something the hiring manager considers secondary, while something that actually matters sits untouched. Three months in, the hiring manager starts wondering why this “great hire” isn’t clicking. The new person, meanwhile, thinks they’ve been doing exactly what was asked.

Nobody had agreed on the definition of right.

The leaders I've seen avoid this problem take a few extra minutes early in the process to answer three questions out loud, before the first candidate is ever interviewed. What will this person own, specifically, that no one else is currently responsible for? What decision-making authority comes with the role? And what would need to be true in six months for both of us to agree this was a good hire?

Those questions are uncomfortable in a useful way. They often expose disagreement within the leadership team itself about what the role is really for, a disagreement that is much cheaper to resolve before a candidate is involved than after someone's already three months into a job they were never fully briefed on.

Once that clarity exists, everything downstream gets easier. Interview questions get sharper, because you're testing for the actual outcome rather than a general sense of experience. Onboarding gets faster, because the new hire isn't spending their first quarter reverse-engineering what actually matters. And when performance conversations happen later, they're grounded in something both sides agreed to at the start, not something that got decided after the fact, by whoever was more frustrated.

This comes up often in growing RA and QA organizations, where roles evolve quickly and job descriptions rarely keep pace. The strongest hiring outcomes I've seen don't come from finding a more impressive résumé. They come from leaders who take the time to define success before they ever start looking for someone to deliver it.

Building a Team Around Your Next

Milestone, Not Your Org Chart

Building a Team Around Your Next Milestone, Not Your Org Chart

One thing I've noticed is that growing companies often start asking the same question.

"What should our organization look like?"

It's a fair question. But I think there's a more useful one to ask first.

"What are we trying to accomplish over the next twelve to twenty-four months?"

Those lead to very different conversations. I've seen companies spend weeks debating reporting lines, titles, and organizational charts before they've agreed on the milestone that's actually driving all of those decisions.

Is the goal to get a submission out the door? Prepare for a first FDA inspection? Move from development into commercial manufacturing? Expand into a new market? Support a product launch? Each of those milestones places different demands on the organization. The team that gets a company through product development isn't always the team that's needed for commercialization. The structure that worked when there were twenty people may not work when there are one hundred, and that's normal.

The mistake is assuming the organization should grow in a straight line, when in reality most companies grow in stages, and each new milestone exposes a different constraint. One year, the challenge is getting enough technical expertise around the table to solve complex problems. The next, it's creating enough structure that work moves consistently without depending on a handful of people who know everything. Then the focus shifts again.

I’ve seen this play out at more than one small company that decided to have Quality report into Operations or Engineering rather than stand as its own function. On paper, it can look like a reasonable way to streamline headcount and reporting lines. In practice, Quality and Operations often have different agendas, and the arrangement can create something closer to a conflict of interest than a clean reporting structure. Operations is usually measured on speed and output. Quality is measured on catching problems before they become bigger ones, sometimes by slowing things down on purpose. When one reports into the other, it’s not hard to guess which priority tends to win when the two disagree.

In the cases I’ve seen, that tension showed up as real turnover on the Quality team, roles that stayed open for months, and delays the company hadn’t planned for. Some strong candidates learned about the structure during the interview process and chose not to move forward at all. The org chart had been drawn to simplify things on paper. It just wasn’t built around what the company actually needed to accomplish next.

That’s why I think the best leadership teams spend less time asking, “Who should report to whom?” and more time asking, “What’s going to help us reach the next milestone without creating problems down the road?” That question forces the conversation away from titles and toward outcomes, and it encourages leaders to think about where decisions need to be made, where work is slowing down, and where people are stretched too thin to keep the business moving at the pace it needs.

An organization chart is a snapshot. A milestone is a destination. The strongest leaders I know build their teams with the destination in mind. They understand that the right structure today may not be the right structure a year or two from now, and that’s okay. As the business changes, the team should evolve with it.

This is a conversation I hear more often as companies move from one stage of growth to the next. The leaders who navigate those transitions well tend to keep their attention on what the team needs to achieve next, rather than on what the organization is supposed to look like.

What the Interview Didn't Tell You

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Every hiring manager has had this experience. Someone gets hired, and within a few months, something that seemed settled during the interview turns out not to be.

Maybe the travel requirements were fine on paper, but three trips in, it’s clear they’re not willing to keep that pace. Maybe the role requires being onsite several days a week, and the commute that seemed manageable in theory becomes something they’re no longer willing to do. Or sometimes it’s not about willingness at all. The skills discussed in the interview don’t quite show up in the work, and it becomes clear the fit wasn’t as strong as it sounded.

When that happens, the instinct is usually to look at the interview process. Did we ask the right questions? Did we miss something? Most of the time, the process wasn’t the problem. The candidate was answering honestly, based on what they believed about themselves and the role, in the moment they were being asked.

Here’s what I mean. Once someone is excited about a specific opportunity, it’s natural to downplay the things that don’t quite fit, or to genuinely believe they can handle something they haven’t actually tested yet. None of that is dishonest. It’s just what happens when a real opportunity is in front of someone and they want to make it work.

The problem is that those things don’t disappear once someone accepts the job. They resurface. Sometimes it’s the travel or the commute. Sometimes it’s a skill gap that only shows up under real conditions. Either way, the company ends up back where it started, except now with a hire, a ramp-up period, and a re-opened search all behind it.

I’ve learned that the most reliable way to see this coming is to have the conversation before a specific role is ever on the table, and to ask more specific questions than most interviews allow for. When someone is talking about their career in general, not about whether they’re a fit for the job in front of them, the answers change. There’s nothing to perform for. That’s usually when you get to the root of what someone actually wants and what they can genuinely deliver, not what they think will get them the next offer.

It works the other way too. Most job postings describe responsibilities. They rarely describe what someone will actually be judged on six months into the role, or what the real day-to-day pressure looks like underneath the listed duties. Asking specific enough questions on the company side often reveals that what they think they need and what they actually need aren’t quite the same thing either.

That’s the real value of getting the full picture on both sides before a role is discussed. It protects the company from discovering a mismatch after the hire is already made. It protects the candidate from accepting a role that was never going to ask what they thought it would. Neither side finds out the hard way, after the offer’s been made and accepted.

Good hiring decisions rarely fail because someone was underqualified in an obvious way. They fail because nobody asked specific enough questions, on either side, until it was too late to do anything about it.

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.

When You Don't Need a Senior Hire (Yet)

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One of the assumptions I see companies make is that the next challenge automatically requires a more senior person. Sometimes it does. But not always.

I’ve had conversations with leaders who are convinced they need a VP, a Director, or someone with twenty years of experience because the business is growing. When we start talking through what they’re actually trying to accomplish over the next six to twelve months, the picture often changes.

Often, the real need is getting specific work done, not adding another executive. Maybe it’s preparing a 510(k). Maybe it’s building out parts of the quality system. Maybe it’s closing out design history files, supporting verification activities, or getting ready for an inspection. Those are important priorities, but they don’t always require the most senior person available.

In fact, bringing in someone who’s significantly more experienced than the role demands can create a different set of problems. Senior leaders are at their best when they’re setting direction, making difficult decisions, mentoring others, and helping the company navigate what’s coming next.

If most of their day is spent executing work that someone else could own, neither the individual nor the business gets the full value of that experience. I’ve seen companies hire a seasoned executive only to discover six months later that there wasn’t enough strategic work to keep them engaged.

Meanwhile, the execution work that was creating the bottleneck still wasn’t moving any faster because there simply weren’t enough people doing it. That’s usually a sign that the organization solved the wrong problem. Before deciding what level of experience to add, I think it’s worth asking a different question.

What’s keeping the business from moving forward today?

Is it that no one knows what to do?

Or is it that the people who know exactly what to do simply don’t have enough time to do it?

Those are very different situations. One calls for experience and leadership. The other calls for capacity. The strongest leaders I’ve worked with spend time understanding where the real constraint is before making a decision.

Sometimes the answer is a senior hire who can build the function, establish priorities, and guide the company through the next stage of growth. Other times, the organization already has that leadership. What it needs is someone who can take ownership of the work that’s piling up so the senior team can focus only on the decisions they can make.

That’s often what keeps submissions on track, quality systems improving, and commercialization moving forward. Every company reaches a point where it needs additional leadership.

Recognizing which one you’re facing changes everything about the hire you make.

The organizations that seem to grow the smoothest are usually the ones that understand the difference.

This is something I hear leaders wrestle with frequently. This conversation usually comes down to understanding the problem the business is trying to solve before deciding what kind of support will move it forward, not the job title attached to it.

Leading Well When Everything

Feels High Stakes

Leading Well When Everything Feels High Stakes

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.

The Hidden Cost of Trying to Do More With the Same Team

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One conversation I've had with leadership teams more times than I can count starts with a simple question.

"Can you get through this without adding anyone?"

It's a reasonable question. Every company wants to make the most of the people they already have. Budgets are tight. Priorities keep changing. Every new hire has to be justified. The problem is that adding more work to the same team doesn't always create more output.

Sometimes it just creates more pressure.

I see this most often in Regulatory and Quality teams. The same people are supporting new product development, managing submissions, preparing for audits, handling supplier issues, responding to customer complaints, implementing regulatory changes, and answering questions from every other part of the business.

Then leadership decides to accelerate a product launch. Or enter a new market. Or prepare for an acquisition. Or remediate findings from an audit. None of the existing work disappears. It simply gets added to the list.

At first, good people make it work. They stay a little later. They skip holidays. They push paperwork into the evenings. They protect deadlines by sacrificing their own time. From the outside, it looks like the team is coping. Inside the business, it can even feel like the right decision because nothing has broken.

What often goes unnoticed is the work that slows down or stops. Continuous improvement projects get delayed. Training gets pushed back. Documentation reviews become rushed. Process improvements stay on someone's to-do list. The team spends all of its time reacting instead of improving.

That's usually where the hidden cost begins. The business hasn't actually become more efficient. It's borrowed time from the people holding everything together, and that time eventually has to be paid back.

Eventually, that time runs out. Projects start slipping. Mistakes become more common. Experienced people become frustrated. And leaders find themselves dealing with problems that could have been avoided months earlier.

The strongest organizations I've worked with don't wait for that moment. They regularly ask whether the workload still matches the capacity of the team.

Sometimes the answer is hiring. Sometimes it's bringing in specialist support. Sometimes it's removing work that no longer creates value. The solution is different every time. The principle isn't.

There comes a point where asking the same people to do more stops being efficient. It simply becomes expensive in ways that don't show up on a spreadsheet until much later.

Why Some Roles Sound Great on Paper but Fail in Reality

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Every now and then, I'll hear a leader describe a role they're planning to add, and on paper it sounds perfect. It checks every box. The person will lead key projects, improve processes, support product development, strengthen the quality system, help prepare for inspections, work cross-functionally, mentor the team, and somehow still have time to tackle everything that's been sitting on the "when we get a chance" list.

It's an impressive job description. It's also a role that probably doesn't exist in the real world.

This usually isn't about leaders having unrealistic expectations. Most of the time, a company is running lean and can only justify hiring one person when the work really calls for two or three. So instead of stepping back and deciding what the role actually needs to accomplish over the next year, everything gets combined into a single description.

It also tends to backfire before anyone even gets hired. A role written that broadly is a good way to overwhelm a strong prospective candidate. They read through the list, see the two or three things they're genuinely not strong in, and self-select out before ever applying. The company loses good candidates without ever realizing why.

Beyond the hiring funnel, not all of those priorities naturally fit together anyway. The person who's exceptional at building long-term systems may not be the same person who thrives in a fast-moving execution role. Someone who enjoys coaching and developing a team may not be the best fit for spending months buried in documentation to meet a critical deadline.

Neither approach is better. They're just different.

I’ve seen organizations spend months trying to define the “perfect” role, when what they really needed was clarity about the business problem they were trying to solve.

Was the biggest priority getting a submission out the door?

Preparing the company for commercialization?

Improving a quality system that has grown faster than the business?

Each of those requires a different focus. When everything gets bundled into one position, priorities become blurred. Then something predictable happens. The person joins the company and immediately has to choose what gets attention first. Before long, people start asking why other areas aren’t moving as quickly as expected.

More often, one role was simply expected to accomplish the work of several. Performance rarely has much to do with it.

The strongest leaders I’ve worked with tend to ask a different question before defining a position.

Instead of asking, “What would our ideal person look like?”

They ask, “What’s the most important outcome we need over the next year?”

That changes the conversation. The role becomes focused. Expectations become clearer. Decisions become easier because everyone understands what success actually looks like.

Can one person still contribute in other areas? Of course. But they aren’t measured against a list that was never realistic in the first place.

As companies grow, it’s natural for responsibilities to evolve. The important part is recognizing that growth doesn’t happen by creating bigger job descriptions. It happens by making sure every role has a clear purpose and enough room for someone to do it well.

The better move is usually deciding what matters most over the next year, and building the role around that, rather than asking one person to do everything.

This topic comes up often in growing medical device and life sciences companies. Most role-related challenges aren't caused by the people in the roles, they start much earlier, when expectations become broader than what any one person can realistically deliver.

Who You Involve in a Hiring Decision Matters More Than You Think

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I was working on a search for a smaller, growing company that needed to add an RA Sr Specialist to their team. I found a few strong candidates, and the team decided to bring two of them in to meet everyone.

The interview team was eight people. Most of them would work closely with this person day to day. One of them was the VP of R&D, who wouldn't interact with the role much at all.

The first candidate went through all eight interviews. Seven people came back enthusiastic and ready to move to the final stage. The VP of R&D said no. He didn't have specific feedback, no particular concern he could point to, just a feeling that this wasn't the right fit.

One no outweighed seven yeses. Not because his objection carried more insight into the role. Because he was the highest ranking person in the room.

I asked the hiring manager why that one vote decided the outcome. The answer was simple. He was the VP. Nobody wanted to overrule him, even though he was arguably the person least qualified to judge fit for a role he'd barely interact with.

The position stayed open for several more months. The workload didn't stay open with it. The existing team kept absorbing the gap while the search started over.

Nothing about that process was designed to fail. Eight smart people gave their honest input. But nobody had asked, ahead of time, whose input should actually carry the most weight for this particular role, and whose shouldn't.

The strongest hiring processes I've seen don't start with the interview list. They start with a few questions, asked before anyone gets scheduled.

"What problem is this role actually solving?"

"Who will this person work with closely enough to judge fit?"

"What does success in this role look like six months in?"

Those questions would have changed the outcome here. If the hiring manager had asked who this Sr Specialist would actually work with closely, the answer wouldn't have included an R&D VP who rarely crossed paths with RA at that level. And if the interview team had agreed up front on what success looked like for this specific role, a vague feeling wouldn't have been enough to override seven people who'd actually be doing the work alongside this person.

The strongest hiring processes I've seen aren't the ones with the most people in the room. They're the ones where someone decided, before the interviews started, who belonged there and what they were actually being asked to evaluate.

How Strong Leaders Decide What Not to Take On

How Strong Leaders Decide What Not to Take On

One thing I've noticed over the years is that the best Regulatory and Quality leaders don't necessarily have fewer priorities than everyone else. If anything, they usually have more.

A submission is moving toward a deadline. An inspection is on the horizon. Commercial teams need answers. Product development keeps moving. Someone wants to launch a new system. Someone else thinks it's the right time to rewrite procedures or reorganize responsibilities.

Most of it makes sense. The problem is that it all arrives at the same time.

I was talking with a VP of Quality not long ago who walked me through everything on his team's plate. By the end of the conversation, I counted eight major initiatives. I asked him which one mattered most.

He laughed. "That's the problem," he said. "They're all important."

A week later we spoke again. He'd met with his leadership team and made a different decision. Instead of trying to move eight projects forward, they agreed to focus on three. The others weren't cancelled. They were simply pushed back until the work in front of them was finished.

His comment stuck with me. "I finally realized we weren't short on ideas. We were short on capacity."

I think that's a realization a lot of leaders eventually come to. I've seen organizations spend months trying to improve everything at once, only to find themselves making very little progress anywhere. Every project gets a little attention, but nothing actually crosses the finish line.

Then I see other companies make a different choice. They protect the work that's tied to the company's next milestone. Maybe that's getting a submission out the door. Maybe it's preparing for an inspection. Maybe it's supporting a product launch without creating unnecessary risk. Everything else waits. Not because it isn't valuable. Because right now it isn't the most important thing.

That isn't always an easy conversation. It sometimes means telling another department they'll have to wait. It sometimes means explaining to executive leadership why a worthwhile project needs to start next quarter instead of next week. Those conversations can be uncomfortable. But they're often what allows the team to deliver on the commitments that matter most.

One pattern I keep seeing is that organizations don't usually struggle because they have too few good ideas. They struggle because every good idea becomes an immediate priority. The leaders who consistently move their companies forward know the difference.

They aren't saying "no."

They're saying, "Not yet."

And in many cases, that's one of the most important leadership decisions they make.