

The 90-Day Performance Illusion.

THE CONSULTING ROOM

Why your team looks fine until it doesn't.

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Does your organization put personalities over process? The answer may already be in your 483.

Ali Khan, field CISO at Reversing Labs, offers one of the most useful diagnostic questions in organizational governance: “Does my organization put personalities over process?” His test is simple. When something goes wrong at your facility, do people call a specific person, or do they follow a defined escalation path? When a quality issue surfaces on a Friday night, does the right action depend on whose cell number is in whose possession?

If the honest answer is the first option in either case, you are not running a process-driven organization. You are running a personality-dependent one. And in regulated manufacturing and MedTech, that distinction has a measurable cost, one that is increasingly showing up in FDA enforcement data.

Source: Ali Khan, Field CISO, Reversing Labs, quoted in ISACA, “Examining the Risks of IT Hero Culture” (Jul. 2024)

What personality dependency looks like when it fails at scale

The clearest modern case study in organizational fragility caused by process dependency is not from MedTech. It is from British Airways in May 2017. An IT contractor, a single individual, improperly disconnected a power supply while performing routine maintenance. The system had no documented failover protocol for this scenario. There was no backup process, no escalation map, and no tested recovery procedure that did not depend on that specific person's knowledge of the system.

The result: over 75,000 passengers stranded across 170 destinations. Flights grounded for days. A public apology from the CEO. An estimated £80 million in compensation and remediation costs. And a subsequent investigation revealed that the root cause was not the contractor's mistake; it was a quality

system that had allowed a single point of failure to exist, undocumented, at the center of a mission-critical operation.

“Fragility doesn’t show up until stress is applied. By then, the cost of finding it is much higher than the cost of designing around it.”

ISACA’s research on hero culture names this pattern precisely: when organizations rely more on a person than on a solid, documented process, the risk is not hypothetical. It is latent — invisible during normal operations, catastrophic when the single point of failure is removed. In IT, the failure mode is a system outage. In regulated manufacturing, it is a quality escape, a missed delivery, a CAPA that surfaces a training gap, or an FDA inspection that finds undocumented procedures where there should be systems.

Sources: ISACA, “Examining the Risks of IT Hero Culture” (Jul. 2024); Reuters, British Airways outage investigation (2017)

The regulatory cost of personality-dependent operations

For MedTech and regulated device manufacturers, this is not an abstract risk. The FDA’s enforcement posture has shifted significantly in the past two years, and the data is unambiguous about what it is finding.

In fiscal year 2024, the FDA issued 47 warning letters to medical device companies, a 96% increase from the 24 issued the prior year. In 2025, QSR-related warning letters rose a further 58%, from 12 to 19 as of September, already surpassing the full-year total for 2024. The agency has explicitly moved away from the “integrative approach,” under which companies could resolve issues through informal responses. It is now issuing follow-up inspection commitments inside warning letters and providing critical feedback via untitled letters even when 483 responses are deemed adequate.

What is the FDA finding at the root of these escalating actions? The pattern is consistent and revealing. CAPA violations appear in over 60% of enforcement actions, as companies fail to investigate complaints, identify root causes, or implement corrections that actually hold. Document control failures are a close second: procedures that are not written, not followed, not specific enough for a trained new hire to execute to standard, or not updated when processes change. And complaint handling failures are the third most common finding: no systematic process for trending, no defined escalation, no documented path from signal to action.

FDA SIGNAL

A 2024 warning letter to a surgical instrument manufacturer cited the company for having no systematic process for trending customer complaints or implementing corrective actions. The finding was not about the complaints themselves; it was about the absence of a system for managing them. The institutional knowledge of how to handle them existed. It just lived in people, not in processes.

Sources: Complizen, “FDA Warning Letters for Medical Devices: Complete Guide 2025” (Sep. 2025); MedDeviceGuide, “FDA Form 483 and Warning Letter Guide” (Apr. 2026); Hogan Lovells, “FDA Medical Device Inspections in 2025” (Sep. 2025); Emergo by UL, “US FDA CDRH Warning Letters: A Review of 2024” (Jan. 2025)

The newest form of the same problem: AI dependency

In April 2026, the FDA issued what Morgan Lewis reported as its first warning letter explicitly related to a manufacturer's overreliance on an AI tool as a compliance mechanism. The company had used AI to generate drug product specifications, procedures, and master production and control records. When the FDA investigation found compliance gaps, company representatives attributed their lack of awareness of certain process validation requirements to the failure of their AI system to flag those requirements.

The FDA's response was direct: the responsibility for compliance cannot be outsourced to technology. AI-generated documents require adequate review and validation by the quality unit. The human oversight function cannot be replaced by an automated one.

The connection to the hero culture argument is precise: personality dependency says, "We relied on John to know how this works." AI dependency says, "We relied on the system to tell us what mattered." In both cases, the organization has substituted a person or a tool for a documented, reviewed, and accountable process. The FDA treats both as the same class of failure. So should your leadership team.

Source: Morgan Lewis, "FDA's Warning Letter Suggests Growing Scrutiny of AI Overreliance" (Apr. 2026)

The three-part diagnostic for your organization

When I work with executive teams in regulated manufacturing and MedTech, one of the first things I map is where organizational performance depends on institutional memory rather than documented systems. In most organizations, the gap is significant and invisible until someone leaves, a regulator asks, or a customer escalates. McKinsey's organizational resilience research consistently identifies the gap: failure is almost never at the technology or strategy level. It is at the operations level — in the hand-off points, the escalation paths, and the documentation infrastructure that should allow the system to function without any single individual.

Here is a three-part diagnostic I use with leadership teams in the first 30 days of an engagement:

Part 1: The coverage test. For each critical function, can a qualified backup execute core responsibilities within 48 hours without calling the primary? If the answer is no for more than two functions, you have a coverage design problem.

Part 2: The documentation audit. Pull five SOPs governing your highest-risk processes. Are they written at a level of specificity that a trained new hire could follow to standard? Or do they assume the reader already knows what they're doing? Remember: an FDA investigator will make the same assessment during an inspection, and they will not give credit for institutional knowledge that lives only in someone's head.

Part 3: The escalation map. When something goes wrong at 11 pm on a Friday, is there a defined path for who gets called, in what order, with what authority to act? Or does it depend on who has the right person's cell number? This is Ali Khan's question made operational. The answer tells you everything.

Most teams pass Part 1 on paper and fail Parts 2 and 3 in practice. The performance they have achieved is real, but it is held together by the same people in the same roles executing the same informal playbook. That is not a system. That is a team that has figured out how to make it work. Those are not the same thing. And the FDA, as the enforcement data shows, is increasingly able to tell the difference.

Source: McKinsey, "Building Organizational Resilience" (Oct. 2022)

The design question underneath the diagnostic

The goal of this diagnostic is not a corrective action list. It is to surface the leadership question that sits underneath every operational risk conversation: Are we building an organization that performs because of how it is designed, or despite how it is designed?

The British Airways case, the FDA's escalating enforcement posture, the ISACA research on hero culture, and the new AI overreliance warning letter all point to the same structural conclusion: organizations that depend on a person, a hero, or a system rather than on a documented and governed process are not running a risk they can manage. They are carrying a risk they cannot see until the moment they can no longer ignore it.

The organizations that pass inspections when the quality director is traveling, that deliver on time when the operations VP is unavailable, that close audits without heroics are not the ones with the best people or the best tools. They are the ones who built systems good enough that their best people are freed to lead, rather than required to hold everything together.

One question to carry this week:

If an FDA investigator walked into your facility tomorrow and Ali Khan's question appeared on their clipboard — 'Does this organization put personalities over process?' — what would they find?

The organizations that perform well under pressure did not get lucky. They designed it.



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