LEAP

Pre-work Case Study 2

Strategic and Big Picture Thinking

Module 4.1

Faster, Cheaper, Riskier?

The Automation Acceleration Decision in a Global Pharma Services Firm

By 2024, the global pharmacovigilance and regulatory services industry was under pressure like never before. Drug approvals were increasing, post-marketing surveillance requirements were tightening, and regulatory bodies across the world were demanding faster reporting with zero tolerance for errors.

For companies providing outsourced safety and compliance services to pharmaceutical clients, the expectations were clear: do more work, faster, at lower cost, without compromising quality.

One such organization, a rapidly growing global life sciences services firm, had built its reputation on reliability and compliance excellence. Over the past decade, it had expanded from a regional provider into a multi-country operation, supporting dozens of large pharmaceutical clients with safety case processing, medical review, regulatory submissions, and quality oversight.

The company's growth had been impressive. Revenues were rising year after year. New clients were signing multi-year contracts. However, behind the scenes, operational stress was mounting.

Case volumes had increased by nearly forty percent in two years. Hiring skilled medical reviewers was becoming difficult and expensive. Attrition among trained staff was creeping up. Margins were shrinking as clients demanded price reductions during contract renewals. At the same time, regulators were conducting more frequent audits and inspections, leaving little room for error.

Every week, leadership meetings revolved around the same themes: capacity, cost, and risk.

Operations leaders complained that teams were overloaded. Quality teams warned about near-misses and rising rework. Finance highlighted declining profitability. HR flagged burnout and retention issues. Despite everyone working harder, the organization constantly felt one step behind.

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During one quarterly review, the Chief Operating Officer presented what seemed like a breakthrough solution. Advances in artificial intelligence and automation tools, he argued, could dramatically change the game. New systems were capable of auto-triaging safety cases, extracting data from reports, and routing tasks without human intervention. Several competitors had begun experimenting with similar technologies. If implemented correctly, the company could reduce manual effort significantly.

The proposal was ambitious.

Within six months, the firm would deploy automation across all major accounts. The system would handle first-level screening and data entry. Manual reviewers would only focus on complex cases. Headcount requirements could drop by twenty-five percent. Turnaround time could improve by thirty percent. Costs would decrease immediately. On paper, the benefits looked compelling. Faster delivery. Lower costs. Higher scalability. Improved margins. Finance strongly supported the plan. Operations leaders were enthusiastic about reducing workload. Clients had repeatedly asked for faster processing times. The proposal appeared to solve multiple problems at once.

Yet not everyone was convinced.

The Head of Quality raised concerns. What if automated triage missed critical signals? What if regulators questioned the validity of algorithm-based decisions? Who would be accountable for errors that slipped through? The organization had built its reputation on careful human review. Would over-reliance on automation weaken that strength?

The Medical Affairs team worried about capability erosion. If junior reviewers stopped doing foundational work, would they develop the expertise needed to handle complex cases later? Would the organization slowly lose its knowledge base?

HR voiced another risk. Reducing headcount could damage morale and create anxiety. High performers might leave, fearing instability. Recruitment could become harder if the company was perceived as replacing people with machines.

Meanwhile, the Client Relationship team cautioned that some pharmaceutical clients valued the "human touch" and might resist rapid changes. Any dip in quality or trust could threaten long-standing partnerships.

For the first time, what looked like a simple productivity improvement began to feel like a strategic crossroads.

The leadership team realized that this was not just a technology decision. It was an enterprise decision that could reshape the organization's capabilities, culture, risk profile, and client relationships for years to come.

They had sixty days to decide.

As discussions continued, the proposal revealed layers of complexity that had not been obvious at first. If automation reduced processing time, clients might send even more volume, increasing dependency on the system. If the system failed or produced errors, recovery could be difficult. If experienced reviewers were released to cut costs, rebuilding that expertise later might be expensive or impossible. If regulators scrutinized automated workflows more closely, compliance overhead could actually increase.

Some leaders argued that delaying automation would leave the company behind competitors. Others believed rushing could expose the firm to unacceptable risks. A few proposed a gradual rollout, but worried that partial implementation would dilute the financial benefits.

The debate increasingly centered around trade-offs rather than solutions. Was the company optimizing for short-term margin improvement or long-term capability? Was speed more important than trust? Could technology enhance quality, or would it quietly erode it? How much risk was acceptable in a safety - critical environment?

Different stakeholders saw the situation differently.

Finance saw *cost savings.*
Operations saw *efficiency.*
Quality saw *risk.*
HR saw *morale issues.*
Clients saw *service reliability.*
Regulators would likely see *accountability and compliance.*

Each perspective was valid, yet incomplete on its own.

The Chief Executive Officer summarized the challenge in one sentence: "If we make this decision only from a cost lens, we may win the quarter and lose the company."

The leadership team realized that the impact of automation would not be limited to immediate outcomes like cost and speed. It would create ripple effects across the entire organization. Small changes in workflow could alter skills, behaviors, trust levels, and regulatory exposure. What appeared beneficial at first glance might generate hidden consequences months or years later.

The question was no longer simply "Should we automate?" but "How will this decision reshape the entire system?" They now faced several possible paths. They could accelerate full deployment and capture quick savings. They could pilot the solution slowly with limited clients. They could redesign roles and training before automation. Or they could postpone until risks were better understood.

Each option carried both opportunity and danger. The clock was ticking. Clients expected answers. Competitors were moving fast. Employees were watching closely.

The decision the leaders made would determine not just operational performance, but the organization's future identity. Would it become a technology-driven efficiency machine, or a high-touch expert services partner? Could it be both? And what unintended consequences might follow whichever path they chose?

For an organization operating in a highly regulated, trust-dependent industry, the stakes could not have been higher.