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PARTNERING FOR EXCELLENCE

WHY ARTWORK & LABELLING MODELS FAIL AT SCALE

AND WHY IT'S
NOT A PEOPLE PROBLEM

SCALE, IS WHERE CONTROL IS WON OR LOST

Most Artwork and Labelling models do not fail because people fall short. They fail because **scale outpaces governance**.

As organisations grow, complexity increases, change accelerates, and volume expands across markets, products, and stakeholders. What once worked through experience, informal coordination, and individual judgement begins to strain. In response, teams compensate - absorbing variation, resolving ambiguity, and keeping work moving through effort and ingenuity.

For a time, this looks like resilience.

In reality, it is fragility. Risk quietly shifts from systems into people. Informal workarounds become embedded. Quality and compliance come to depend on who is involved, how busy they are, and how much pressure they are under. Failures rarely appear suddenly; they surface later, often under scrutiny, as delayed consequences of decisions made when scale was smaller and complexity lower.

This paper argues that most Artwork and Labelling issues are not execution failures. They are **governance failures** - not in intent, but in design. Adding checks, escalations, or heroics may mask the problem, but they do not resolve it. At scale, effort does not equal control.

True resilience comes from operating models that are deliberately designed for growth: where accountability is clear, decisions are traceable, and systems - not individuals - carry the burden of risk. Governance, often dismissed as bureaucracy, is in fact what enables scale, calm delivery, and confidence under inspection.

The question is no longer whether teams are capable. It is whether the model they are working within can sustain them.

WHY WE BLAME EXECUTION INSTEAD OF DESIGN

When quality issues arise, organisations tend to respond in predictable ways.

- Additional review steps are introduced
- Escalations happen earlier
- Senior reviewers are pulled in more frequently
- Teams are asked to work harder and faster

In the short term, these interventions appear effective.

Control is restored, the immediate issue is resolved, and confidence returns.

But these responses all rest on the same assumption:

that the problem is execution.

What if it isn't?

What if the operating model itself - designed for a very different level of complexity - is now stretched beyond what it can reliably support?

“ WHEN CAPABLE TEAMS KEEP FAILING, EFFORT IS RARELY THE ISSUE.”

“ WHAT IF THE PROBLEM ISN'T EXECUTION?”

WHAT SCALE REALLY CHANGES

Most Artwork and Labelling models begin life in relatively calm conditions.

- Product portfolios are smaller
- Markets are fewer
- Change cycles are predictable
- Teams are stable and familiar with the unwritten rules

Under these conditions, even loosely defined processes can appear robust.

*“ VARIATION
INCREASES
FASTER THAN
GOVERNANCE.”*

Then scale arrives.

- Portfolios expand
- Language variants multiply
- Change activity overlaps
- Regulatory variation increases
- Dependencies between teams and systems grow

At this point, something subtle but decisive occurs.

Variation increases faster than governance.

Initially, the system absorbs the strain. Over time . . . **people do.**

WHEN **CONTROL** QUIETLY SHIFTS INTO **PEOPLE**

As complexity grows, experienced individuals begin compensating for system gaps.

- They remember rules that were never formally documented.
- They catch inconsistencies others do not see.
- They bridge processes & systems that were never designed to connect cleanly.

Quality is preserved - but quietly.

From the outside, the operation still appears to function.

Deadlines are met. Inspections pass. Launches proceed.

But risk has shifted!

Quality no longer resides *in* the process.

It resides in individual experience.

This is often mistaken for resilience.

It is not.

It is **heroics** - and heroics **do not scale.**

*“ QUALITY NO
LONGER
LIVES IN THE
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IT LIVES IN
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WHY FAILURE FEELS **SUDDEN BUT RARELY IS**

Artwork and Labelling failures rarely appear without warning. They feel sudden only because the conditions that made them inevitable were already in place.

As complexity grows, small compromises accumulate. Temporary workarounds become accepted practice. Decisions made to “get through this one” are quietly repeated. None of these moments feel critical in isolation - in fact, they are often framed as sensible, pragmatic responses to pressure.

For long periods, the system appears stable. Delivery continues. Issues are absorbed by experience, effort, and goodwill. This creates the illusion of control.

When failure finally surfaces - during an inspection, an audit, or a high-pressure release - it appears abrupt. In reality, it is the delayed consequence of risk that has been building unnoticed over time. What breaks is not a single process, but the assumption that informal resilience can indefinitely compensate for structural weakness.

WHY COMPLEXITY EXPOSES **WEAK GOVERNANCE**

Complexity itself is not the problem. It is an unavoidable feature of modern pharmaceutical operations.

Multiple markets, frequent change, evolving regulations, and interconnected systems are now the norm. Attempting to simplify this reality away - or to treat complexity as an anomaly - is both unrealistic and counterproductive.

The real issue arises when operating models fail to adapt as complexity increases. When governance remains static while the environment evolves, risk begins to migrate. Decisions become harder to trace. Ownership becomes blurred. Control depends less on design and more on experience.

High-performing organisations do not eliminate complexity. They design for it. They recognise that as complexity increases, governance must become more explicit, not heavier - clearer, not more restrictive. The goal is not to reduce work, but to make control visible and defensible.

GOVERNANCE IS WHAT **SCALE MAKES POSSIBLE**

Governance is often misunderstood as bureaucracy: a layer of oversight that slows delivery and adds friction. In practice, the opposite is true.

Effective governance is what allows work to proceed at speed without sacrificing control. It provides clarity on who decides, how decisions are made, and where accountability sits. It ensures that when questions are asked - internally or by regulators - answers are consistent, traceable, and calm.

At scale, governance is not about adding more checks or approvals. It is about designing systems that make the right actions the default, rather than the exception. Where governance is weak, people compensate. Where governance is strong, people are supported.

The measure of good governance is not how restrictive it feels in steady state, but how well it holds when pressure increases.

A DIAGNOSTIC PEOPLE **CAN'T IGNORE**

The health of an Artwork and Labelling model can often be assessed with a small number of questions.

Can you explain how decisions remain controlled as volume and complexity increase?

Is accountability clear when something goes wrong - without relying on personal knowledge?

Can work be transferred, scaled, or inspected without loss of confidence?

If these questions are difficult to answer, the issue is not capability or commitment. It is design.

Diagnostics like these are uncomfortable precisely because they surface systemic risk that day-to-day delivery may be masking. But they are also powerful: they shift the conversation away from individuals and towards the operating model itself.

FROM RESILIENCE BY EFFORT TO **RESILIENCE BY DESIGN**

Most Artwork and Labelling challenges are not the result of poor execution. They are the predictable outcome of operating models that have not evolved at the same pace as the environment around them.

When scale increases, relying on effort, experience, and informal coordination becomes progressively riskier. What once enabled progress becomes the source of fragility. Adding more checks, more escalation, or more pressure may delay failure - but it does not prevent it.

Sustainable performance at scale requires a deliberate shift: from resilience based on people to resilience based on design.

WHAT **HOLDS** WHEN **PRESSURE IS APPLIED**

At scale, calm delivery is not accidental. It is engineered.

The organisations that perform best under scrutiny are not those with the most capable individuals - they are those with operating models that make capability repeatable, transferable, and defensible. In these environments, governance is not a brake on progress, but the structure that allows progress to continue without drama.

Turning INSIGHT into OPERATING REALITY

For more than two decades, Vakils has worked alongside pharmaceutical organisations operating at scale, supporting Artwork and Labelling activities at the point where regulatory scrutiny, operational pressure, and patient impact converge.

What we see consistently is not a lack of intent or expertise. Quality and compliance are most often challenged when operating models evolve faster than governance - when resilience is assumed rather than deliberately designed.

Vakils' role is therefore not simply to deliver Artwork and Labelling services, but to help organisations translate insight into operating models that hold under pressure. This means making governance explicit, scalable, and inspection-ready, so that quality is embedded in the system itself rather than relying on individual experience.

As portfolios expand and change accelerates, the organisations that succeed are those that act early - strengthening governance before scale forces the issue. Vakils partners with teams at that point of transition, helping them modernise responsibly and move forward with confidence, without losing control.

The question for leaders is not whether their teams can cope today. It is whether the model they are operating within will still hold tomorrow.

Because in regulated environments, resilience is not proven when things go well - *it is proven when pressure is applied.*