Whitepaper

Flexibility in drug development: From tactical response to strategic imperative

Sustaining momentum as complexity, scale, and change increase

Executive summary

Drug development programs rarely unfold as planned. Scope shifts, timelines compress, and requirements evolve as data emerges and decisions are revisited. Today, change is a defining condition of how programs move forward.

For much of the industry's history, drug development has been built around fixed plans and stable assumptions. Processes, timelines, and execution pathways were designed to hold when conditions were relatively predictable. When change occurred, it was often managed through workarounds or late adjustments rather than anticipated as part of normal execution.

The ability to adapt now has a direct effect on whether programs continue moving or stall under pressure. Decisions about where work is performed, how programs scale, how transitions are handled, and how expertise is applied as new information emerges increasingly shape outcomes. When those elements are rigid, change introduces friction. When they are designed to absorb change, progress is more likely to hold.

Flexibility has therefore taken on a different role. It influences whether programs can expand without resetting work, maintain continuity as requirements evolve, and adjust technical and operational approaches without introducing delay or loss of control. In this environment, flexibility is no longer situational; it shapes execution across the lifecycle.

This report examines how flexibility in drug development shows up in practice, drawing on execution and experience across Thermo Fisher Scientific Pharma Services, with a focus on three critical dimensions:

1. Reach and scalability
2. Continuity and reliability
3. Partnership and adaptability

Together, these dimensions help determine whether change becomes a source of disruption or whether programs are able to sustain momentum from early development through commercialization.

Reach and scalability

Most drug development programs begin with limited scope. Early work is often concentrated in a small number of sites, regions, or functions, with execution shaped by near-term needs rather than long-term trajectory. As data emerges and programs progress, that scope rarely holds. Volumes increase, geographic reach expands, and expectations shift from development readiness to sustained supply.

Scaling itself is not the primary challenge. The difficulty lies in scaling without disruption. When programs grow beyond their initial assumptions, rigid execution pathways often force work to be transferred, systems to be requalified, or supply strategies to be reconfigured. These transitions introduce delay and risk at moments when timelines are already under pressure.

For example, as clinical programs expand into additional countries, new regulatory, labeling, and packaging requirements must be absorbed. In many cases, adding regions mid-study triggers last-minute changes to packaging configurations or distribution plans, interrupting supply or delaying site activation. Where execution is already aligned across regions, geographic expansion can be accommodated without resetting packaging, labeling, or release processes.

> *Related reading: Clinical trial logistics is becoming a strategic discipline*

Reach becomes meaningful when it supports continuity across growth. Development, manufacturing, and supply activities that operate across multiple regions using consistent standards reduce the need for handoffs as scope expands. This continuity is particularly important when programs move from early clinical supply into later-stage or commercial preparation, where changes in volume and geography often occur at the same time.

A similar test occurs as programs transition from early to later phases. Modest initial volumes give way to higher throughput, different dosage strengths, or expanded packaging configurations, including transitions from vials to more complex delivery formats such as auto-injectors or pens.

Disruption at this stage rarely reflects a lack of capacity. More often, it results from execution models that require work to be transferred between sites or processes to be requalified before scale can increase. Where development and manufacturing activities are connected within a single network, scale becomes a continuation of existing execution rather than a reset. When validated execution can be carried forward into commercial scale, transition becomes an extension of prior work rather than a new starting point.

> *Related reading: What's the real challenge in biologic manufacturing scale-up?, How to achieve late-phase success in complex oral solid dose development*

Reach and scalability are particularly critical for programs with uncertain trajectories. Many early-stage assets progress without fixed assumptions about volume, cadence, or market scope. Initial runs may be small, followed by rapid expansion as data emerges or development priorities shift.

Technical flexibility plays a similar role in early-stage development. Assets with solubility challenges or evolving formulation requirements often require iteration across multiple enabling approaches. Access to a broad range of capabilities, including solubility enhancement strategies and lipid-based formulation expertise, allows development pathways to adjust without forcing work into new environments or fragmenting execution. When technical depth is available within the same network, formulation complexity can be managed without introducing delay.

In these cases, infrastructure that supports variable batch sizes and evolving supply strategies allows programs to adjust incrementally. Small initial runs can be followed by larger campaigns without reconfiguring execution or introducing new constraints, preserving optionality as decisions are made.

> *Related reading: Streamlining preclinical pathways for a fast transition to First-in-Human trials*

As programs mature, the same principles apply. Late-stage and commercial execution require consistency across regions, sustained output at higher volumes, and the ability to respond to changes in demand without compromising reliability. In biologics manufacturing, for example, the use of single-use technologies and modular bioprocessing infrastructure can support more flexible scaling, allowing capacity to be adjusted without the extended downtime or reconfiguration associated with traditional stainless-steel systems.

Commercial programs supplying multiple markets may need to adjust production levels or distribution patterns in response to demand variability. When reach and scalable infrastructure have been established earlier across development and supply, these adjustments can be made within existing execution pathways rather than through new site transfers or last-minute requalification.

When reach and scalability are aligned with execution, growth does not force disruption. Programs are able to expand across regions, volumes, and phases while maintaining continuity, reducing the risk that scale itself becomes a source of delay.

Continuity and reliability

As drug development programs progress, change rarely occurs in isolation. Shifts in scope, geography, or volume are often accompanied by changes in packaging, labeling, regulatory requirements, or supply strategy. Each transition introduces risk—not because the work is unfamiliar, but because continuity is difficult to maintain when execution pathways change.

Reliability is tested at these transition points. Recent industry data show that drug shortages remain elevated—with 323 active shortages reported in the U.S. in early 2024, the highest level on record — and that many shortages now persist for years rather than resolve quickly, reflecting systemic strain on continuity as programs and supply networks evolve[1,2].

As development programs expand across regions, modalities, and supply configurations, execution models with fragmented systems or loosely connected handoffs have less capacity to absorb change without interruption.

As complexity increases, programs that rely on fragmented systems or loosely connected handoffs are more vulnerable to disruption as requirements evolve. Changes that occur late or unexpectedly—whether driven by regulatory updates, protocol amendments, or supply constraints—can trigger rework, delay release, or interrupt supply.

For example, clinical programs moving into later phases or additional regions often encounter new labeling and regulatory requirements. When packaging and release processes are not aligned across regions, these changes can require last-minute adjustments that delay site activation or shipment. Where labeling, packaging, and quality oversight are coordinated across regions, regulatory changes can be absorbed without disrupting ongoing studies.

> *Related reading: Unlocking significant IGST savings and accelerating clinical supply timelines*

Continuity becomes increasingly important as programs move from development into late-stage and commercial supply. Transitions between development and commercial configurations often involve changes in batch size, packaging formats, and distribution models. When these transitions require new execution pathways or requalification late in the process, reliability is compromised. When development and commercial supply are supported within aligned systems, programs are better positioned to move forward without interruption.

Can your program withstand real-world pressures?

Few development programs fail because a single plan was wrong. More often, progress is compromised when real-world conditions test assumptions the program was not designed to accommodate.

In practice, the difference between programs that absorb pressure and those that stall is not the presence of disruption, but whether adaptability has been designed into execution.

Across development, manufacturing, and supply, several questions tend to reveal whether a program is built to adjust without losing control.

- When scope expands or shifts geographically, can materials be manufactured, packaged, released, and distributed through an existing network without introducing new vendors, new quality systems, or new handoffs?
- When timelines or volumes change, is there capacity available within the current supply chain to adjust production cadence or batch size incrementally, or does scale require structural change?
- When regulatory requirements must be applied in new contexts, are quality systems, labeling, and release processes already harmonized across regions, or must compliance pathways be rebuilt as programs advance?
- When pressure emerges unexpectedly, is there shared visibility across development, manufacturing, quality, and supply to identify constraints early, or do issues surface only once execution is underway?

Taken together, these questions point to a clear conclusion: adaptability is not a trait a program discovers under pressure, but a consequence of how execution has been designed. Programs supported by resilient supply chains, globally aligned networks, and coordinated decision-making can adjust scope, timing, and geography without resetting execution. Where these conditions are absent, even routine changes introduce friction, forcing reactive trade-offs that erode control and predictability.

1. ASHP (2024). Drug Shortages Statistics and Trends.
American Society of Health-System Pharmacists Drug Shortages Resource Center.
2. Pharmacy Times (2024). Survey: 50% of active drug shortages persist for two or more years.

A similar dynamic appears when supply strategies must adapt in response to external pressures. Changes in demand forecasts, component availability, or regional trade conditions can require adjustments to sourcing or distribution. Programs with limited visibility or fragmented quality oversight often struggle to respond quickly, increasing the risk of delay or non-compliance. Where quality systems and supply planning are integrated, adjustments can be made while maintaining control.

In these situations, manufacturing capacity embedded within a coordinated global network adds an additional layer of resilience. The ability to shift production, adjust sourcing, or rebalance distribution within aligned regional infrastructures reduces exposure to localized constraints while preserving consistent standards and oversight. Geographic flexibility, in this context, becomes a structural advantage rather than a reactive measure.

Continuity is also shaped by how information flows across teams and stages. When development, manufacturing, quality, and supply functions operate with separate data and decision frameworks, even small changes can cascade into larger disruptions. Shared visibility and aligned decision-making help ensure that changes are managed deliberately rather than reactively.

As programs mature, reliability depends less on avoiding change and more on managing it predictably. Late-stage and commercial supply require consistent execution across regions, sustained quality oversight, and the ability to respond to evolving requirements without introducing new sources of risk. Continuity built earlier in development supports this stability, allowing programs to adapt while maintaining confidence in supply.

When continuity and reliability are embedded into execution, programs are able to move through transitions across phases, regions, and supply strategies, while maintaining control and predictability.

Partnership and adaptability

Maintaining control and predictability across transitions requires execution systems that can adjust as conditions change. In practice, this means planning for variability rather than exception. Even when timelines, volumes, and geographic scope are well defined, development rarely unfolds exactly as planned. The ability to absorb change depends on how capabilities, capacity, and networks have been designed to flex as programs expand.

Adaptability at this level is rarely achieved through infrastructure alone. It is shaped by how decisions are made once programs are in motion and how quickly constraints are surfaced as conditions evolve. When responsibilities are narrowly defined or execution is segmented across disconnected teams, change tends to introduce friction. Adjustments that could be managed early instead surface late, increasing the risk of rework or delay.

Partnership becomes critical when it enables decisions to be made in context rather than in sequence. Programs benefit when development, manufacturing, quality, and supply teams operate with shared visibility and a clear understanding of priorities. This alignment allows potential impacts to be assessed earlier and trade-offs to be made deliberately, reducing the likelihood that adaptation introduces new disruption.

For example, shifts in clinical timelines or enrollment patterns often require changes to production cadence, packaging configurations, or distribution plans. When these adjustments are addressed through coordinated planning rather than downstream escalation, programs are better able to respond without compromising compliance or continuity. Adaptability in this context reflects preparedness, not reaction.

> *Related reading: Optimizing clinical supply management with a one-team approach*

The same principle applies in later stages, where change must be managed with greater discipline. Late-phase and commercial programs often face evolving demand forecasts, regional requirements, or supply constraints. Effective partnerships support adaptability by combining flexibility with accountability, ensuring that changes are evaluated systematically and absorbed without undermining reliability.

Across phases, adaptability is ultimately a function of design. When capabilities, capacity, and decision-making frameworks are aligned from the outset, programs retain the ability to adjust without losing momentum. Partnership, in this sense, is not an abstract attribute but a practical mechanism for maintaining control as conditions evolve.

From tactical response to strategic discipline

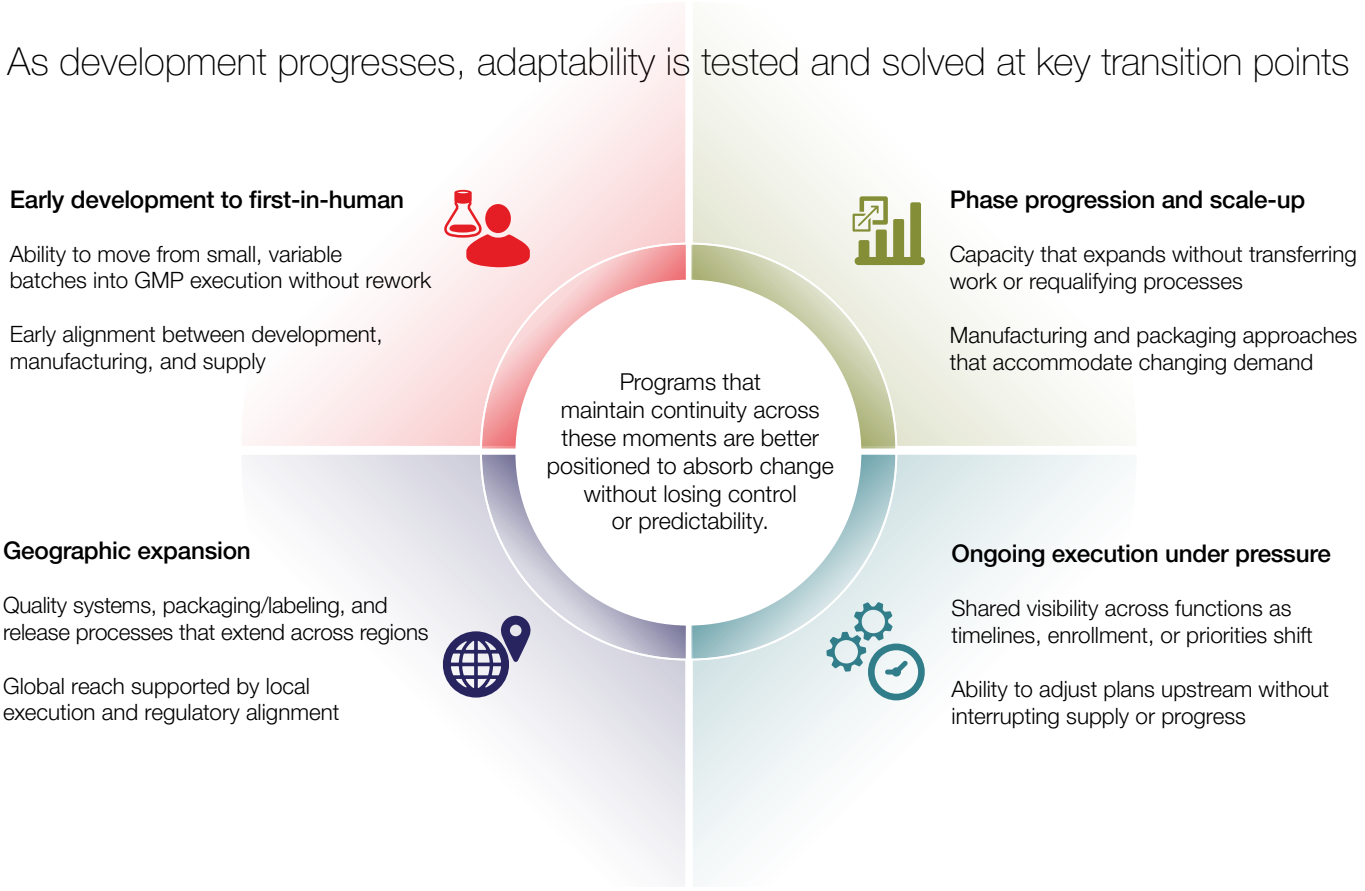
Flexibility in drug development is often discussed as a response to uncertainty. In practice, programs that perform most consistently treat adaptability as a design principle rather than a contingency plan. Control and predictability are not preserved by resisting change, but by anticipating where it is likely to occur and building systems capable of absorbing it.

Across development, manufacturing, and supply, flexibility becomes meaningful when it is embedded into execution. Reach that allows programs to expand without reset. Continuity that holds as scope and complexity increase. Partnerships that support coordinated decision-making when assumptions are tested. Together, these elements shape whether change introduces disruption or can be managed deliberately.

This distinction matters because the conditions facing development teams are unlikely to become simpler. Programs now span more regions, modalities, and supply configurations, often simultaneously. Timelines are tighter, and tolerance for disruption is lower. In this environment, flexibility is no longer a tactical lever used when plans break down. It is a strategic capability that influences how reliably programs move forward.

Organizations that approach flexibility in this way are better positioned to maintain momentum through inflection points, by absorbing variability without losing control and adjusting course without sacrificing predictability. That distinction defines flexibility as a strategic discipline, rather than a reactive response.

As development progresses, adaptability is tested and solved at key transition points



Learn more at thermofisher.com/patheon