White paper

Thermo Fisher SCIENTIFIC

Quality as a strategic differentiator in drug development

The systems, innovations, and culture required to sustain performance at scale

Executive summary

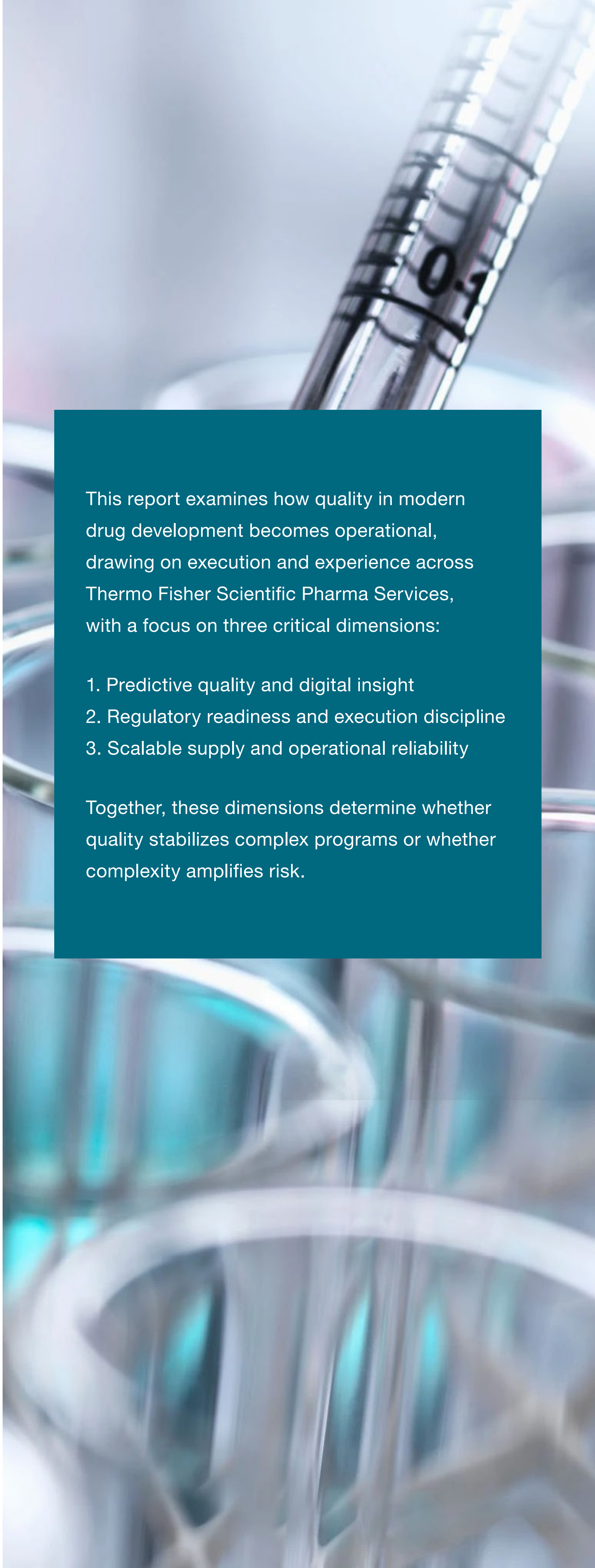
Drug development has become more complex, more distributed, and more compressed. Programs span modalities, regions, and regulatory environments, increasing the consequences of variability at every stage.

Under these conditions, quality can no longer function solely as a downstream control. It must operate as a stabilizing force that preserves rigor as programs evolve.

Operationalized quality becomes visible in how risk is anticipated, how regulatory expectations are embedded into execution, and how discipline holds as volume, complexity, and interdependence increase across the development lifecycle.

Across development and manufacturing, decisions about how variability is detected, how regulatory readiness is maintained, and how operational discipline is sustained increasingly determine whether programs maintain momentum or accumulate risk.

When these elements are fragmented, complexity amplifies variability. When they are designed to function together, quality stabilizes execution as programs scale.



This report examines how quality in modern drug development becomes operational, drawing on execution and experience across Thermo Fisher Scientific Pharma Services, with a focus on three critical dimensions:

1. Predictive quality and digital insight
2. Regulatory readiness and execution discipline
3. Scalable supply and operational reliability

Together, these dimensions determine whether quality stabilizes complex programs or whether complexity amplifies risk.

Introduction

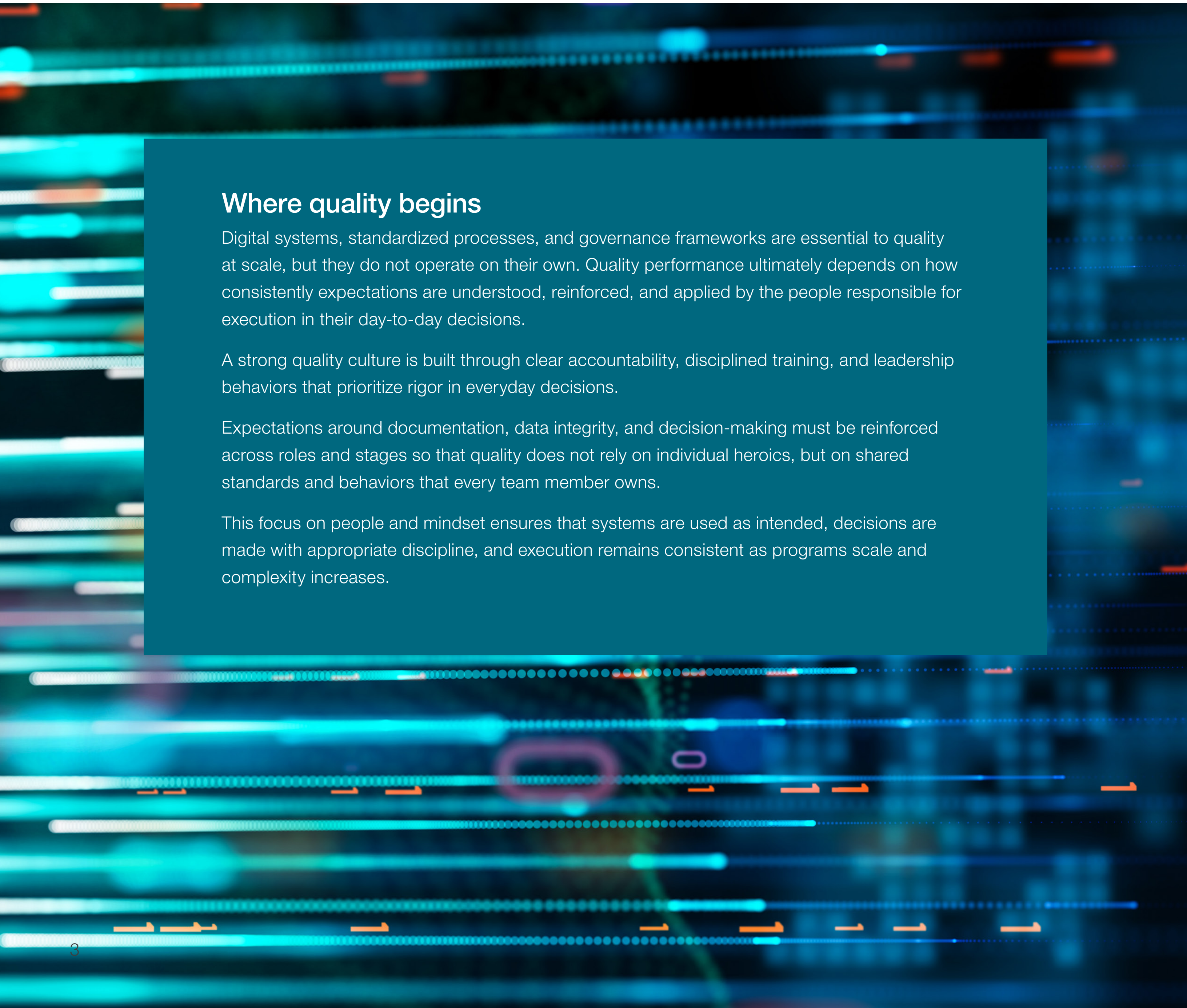
Drug development now operates at a level of scientific and operational complexity that did not exist even a decade ago. Programs span advanced modalities, global networks, and compressed timelines, increasing the consequences of variability at every handoff and transition.

Quality has always been foundational. What has changed is its role. Beyond meeting requirements, quality now determines whether execution remains disciplined as programs scale. When operationalized effectively, quality reduces variability across decisions, documentation, and transitions—preserving momentum from development through commercial supply.

The ability to sustain that discipline becomes visible in three areas: how risk is identified and managed, how regulatory expectations are embedded into routine work, and how rigor holds as volume and interdependence increase.

Across Thermo Fisher Scientific's Pharma Services, these signals are reflected in digital systems that surface variability early, regulatory practices embedded into execution, and operating models designed to preserve intent through scale and transition.

The sections that follow examine what enables quality to remain coherent under pressure, and what differentiates organizations that sustain performance as complexity grows.



Where quality begins

Digital systems, standardized processes, and governance frameworks are essential to quality at scale, but they do not operate on their own. Quality performance ultimately depends on how consistently expectations are understood, reinforced, and applied by the people responsible for execution in their day-to-day decisions.

A strong quality culture is built through clear accountability, disciplined training, and leadership behaviors that prioritize rigor in everyday decisions.

Expectations around documentation, data integrity, and decision-making must be reinforced across roles and stages so that quality does not rely on individual heroics, but on shared standards and behaviors that every team member owns.

This focus on people and mindset ensures that systems are used as intended, decisions are made with appropriate discipline, and execution remains consistent as programs scale and complexity increases.

Digital insight and predictive control

As variability increases across development, manufacturing, and clinical supply, the ability to identify risk early and act on it consistently becomes a defining element of quality performance. Digital insight shifts how risk is identified and addressed, enabling earlier intervention rather than late-stage correction.

Digital quality systems are used across Thermo Fisher to create shared visibility across the drug development lifecycle, from early phases through commercialization and supply. These systems support earlier identification of variability, more consistent interpretation of data, and informed decision-making before issues propagate downstream. The examples below illustrate how digital insight is applied in practice.

In oral solid dose (OSD) development, for example, the OSDPredict™ platform and digital subject matter expert (dSME) framework support early formulation decisions and decision discipline. The OSDPredict platform enables systematic assessment of formulation risk and solubility behavior across large molecule sets, helping surface variability earlier in the lifecycle. The dSME framework applies consistent, data-informed expert review across programs, ensuring insights are interpreted and acted upon in a standardized way.

Together, these capabilities influence how risk is evaluated and decisions are made early in development—establishing the same discipline around data interpretation and action that must hold as programs advance.

> *Related reading: Redefining OSD development through foresight and innovation*

In biologics manufacturing, digital process analytics platforms such as Discoverant support core quality activities across the network, including Continued Process Verification (CPV), Annual Product Review (APR), and process investigations and deviations. Through consistent data aggregation, trend analysis, and automated alerting for out-of-trend and out-of-specification conditions, these systems help identify emerging risk earlier and strengthen process robustness. Discoverant also supports secure data sharing and standardized interpretation of data, reinforcing transparency and alignment as programs move from development into commercial manufacturing.

In settings where timelines are compressed and materials are highly temperature sensitive—such as sterile fill-finish and clinical supply—digital systems play a critical role in inspection readiness, labeling accuracy, and supply-chain visibility.

Capabilities such as ATLAS translation, digitally managed label design and manufacturing, and integrated logistics monitoring help preserve quality as products move through execution. Recent innovations—including labeling solutions engineered to maintain adhesion across refrigerated, frozen, and cryogenic conditions, as well as enhanced cold-chain data capture—support right-first-time execution across clinical supply and temperature-sensitive sterile commercial manufacturing.

These efforts are guided by shared quality principles that shape how digital insight is applied—emphasizing data integrity, predictive control, and consistency across handoffs. Those principles ensure insights are interpreted consistently, acted on early, and carried forward as programs move between teams and stages.

Across development and manufacturing, digital insight reinforces a consistent approach to risk identification and decision-making, allowing variability to be addressed before it becomes operational or regulatory risk.

Regulatory readiness and transparency

Regulatory readiness is often associated with inspection preparation. In practice, it is shaped much earlier by how consistently quality expectations are built into day-to-day execution, long before regulatory engagement occurs.

This rigor becomes especially critical in high-potency environments, where containment, cleaning validation, and data integrity expectations leave little room for reinterpretation once execution is underway.

At Thermo Fisher, regulatory readiness is approached as an operational discipline. Harmonized quality standards, disciplined documentation practices, and experienced oversight are applied as part of routine work across development, manufacturing, and supply, rather than activated only in response to inspections.

A key enabler of this approach is quality transparency: the ability to demonstrate control, traceability, and intent across processes, sites, and lifecycle stages. Integrated quality systems support data integrity, lifecycle documentation, and deviation management, allowing potential issues to be identified and addressed early—before they escalate into regulatory findings.

Qualified Person (QP) readiness and release provide a concrete example of how regulatory expectations are addressed upstream, as a form of applied regulatory expertise rather than a downstream compliance checkpoint. Quality systems are designed so that development decisions, documentation, and control strategies align with QP requirements as work progresses.

In oral solid dose development, regulatory readiness is shaped upstream by how development decisions, documentation practices, and process understanding are aligned with eventual release expectations. Applying Quality by Design (QbD) principles early, through structured risk assessment, defined control strategies, and clear decision rationale, helps ensure data integrity and regulatory alignment are built in from the start, reducing the need for retrospective remediation as programs move toward scale and market authorization.

For example, when formulation and process decisions are aligned early with EU QP release expectations, documentation and data packages can be built to support future certification, reducing the risk of late-stage remediation or delayed release.

Questions that reveal whether quality will hold

As programs scale, quality is tested less by intent and more by execution under pressure. Useful questions to ask include:

- **How early are Quality by Design (QbD) expectations embedded into decisions?**
  Are regulatory and release considerations reflected in development choices, or deferred until later stages?
- **How is variability surfaced and addressed as complexity increases?**
  When data is incomplete or conditions change, are risks identified early or managed reactively?
- **How consistent is execution across transitions?**
  As work moves between teams, sites, or phases, what ensures decisions and rationale are preserved?
- **What does accountability look like under constraint?**
  When timelines compress or exceptions arise, who has visibility and authority to act?

These indicators often matter more than formal structures in determining whether quality holds as programs evolve.

Regulatory readiness is further reinforced through sustained operating experience under continuous regulatory oversight. Rather than preparing for inspections as discrete events, quality systems are designed to support repeatable inspection outcomes across authorities and regions. Experience gained through inspections and day-to-day operations is systematically shared across sites, allowing teams to anticipate common issues, apply proven controls, and reinforce consistent expectations over time. This includes consistent approaches to documentation, deviation handling, change management, and data traceability that hold across sites and over time.

As a result, regulatory engagement becomes more predictable—not because issues are absent, but because they are surfaced, documented, and resolved within established systems before they escalate. In practice, this helps to enable:

- Fewer late-stage surprises during inspection or review
- Reduced remediation during development-to-commercial transitions, including preparation for major regulatory submissions
- Greater confidence when programs move between sites, phases, or regions

When regulatory readiness is embedded into execution, it functions less as a compliance checkpoint and more as a stabilizing mechanism, preserving momentum, reducing friction, and supporting trust as programs progress.

These same regulatory principles apply across dosage forms, where QP judgment is informed by experience certifying products with different risk profiles, manufacturing models, and regulatory considerations.

In clinical trial supply, regulatory readiness is tested under particularly high stakes. QP release for investigational medicinal products requires comprehensive documentation review, real-time visibility into manufacturing and supply records, and confident judgment under strict regulatory accountability.

Within Thermo Fisher's clinical trial services, QP readiness is treated as an execution discipline grounded in region-specific regulatory expertise rather than a final sign-off step. Documentation practices, audit evidence, and batch records are aligned early to support timely certification, reducing friction when products move into patient-facing use. This is especially critical for trials spanning the EU and UK, where QP certification requirements differ and recertification can introduce delays if not planned for upfront. By embedding QP considerations into routine execution and drawing on regional regulatory expertise rather than treating QP review as a downstream checkpoint, clinical supply teams are better positioned to support predictable release timelines, maintain compliance across markets, and preserve patient safety as trials evolve.

> *Related reading: Understanding the essential role of Qualified Persons in clinical trials*

Scalable execution and supply reliability

As programs progress toward late-stage development and commercialization, quality is tested less by design intent and more by execution under pressure. Volume increases, timelines compress, and dependencies across sites and supply chains multiply, amplifying the impact of variability.

Across Thermo Fisher, scalable execution is enabled by quality systems designed to preserve rigor as programs grow. This includes standardized operating models, disciplined technology transfer practices, and integrated oversight applied consistently across development, manufacturing, and supply.

Technology transfer represents a critical inflection point for quality at scale. It is the moment when process understanding, control strategies, and documented decision rationale must carry forward intact despite changes in people, equipment, and operating context.

A right-first-time transfer approach focuses on preserving intent at the point of handoff. Prior decisions, assumptions, and control strategies are documented clearly, remain traceable, and are executable in the receiving environment. Harmonized transfer frameworks and shared documentation standards reduce ambiguity at the point of handoff, limiting variability introduced during scale-up and minimizing downstream remediation. By reducing reinterpretation and rework during transfer, this approach limits variability introduced at scale and minimizes downstream remediation.

> *Related reading: The critical role of tech transfer in pharma manufacturing*

As manufacturing scales, execution discipline depends on reducing sources of manual variability and maintaining control as volume and complexity increase. Automation, digital inspection, and environmental controls reinforce consistency under these conditions.

In sterile fill-finish, automated processes and digitally supported inspection practices help stabilize performance at higher volumes. In oral solid dose and biologics manufacturing, standardized process controls and monitoring practices support consistent execution as batch sizes grow and processes intensify.

Beyond the manufacturing suite, quality is tested in how product integrity is preserved across labeling, packaging, cold-chain handling, biorepository storage, and logistics under real-world conditions. Chain of custody, environmental monitoring, and data traceability become especially critical when managing temperature-sensitive products and long-term sample storage.

Integrated oversight across labeling, packaging, and distribution helps maintain continuity as products move from production into clinical and commercial supply. In clinical labeling, cycle time discipline and inspection readiness depend not only on translation accuracy through platforms such as ATLAS, but also on tightly controlled label manufacturing and printing processes that reduce rework and variability under compressed timelines. Capabilities such as ultra-low-temperature labeling and digitally supported label management reinforce accuracy when handling requirements are exacting.

> *Related reading: Packaging and labeling support for a global cell therapy program*

Transportation and ancillary supply introduce another layer of operational risk as programs scale. Total transportation management services provide centralized oversight of route selection, carrier performance, and depot coordination, strengthening visibility and control across clinical and commercial shipments. Global clinical ancillary supply solutions extend the same quality discipline to the sourcing, qualification, and distribution of trial materials, helping ensure standards hold beyond core drug product handling.

Together, these practices support:

- Right-first-time execution during scale-up and technology transfer
- Consistent manufacturing performance as complexity increases
- Reliable clinical and commercial supply under compressed timelines

How quality shows up at scale

At scale, quality becomes visible in outcomes. In 2025, Thermo Fisher's quality systems supported 44 inspections by 20 regulatory agencies and 517 commercial drug products. Since 2017, those same systems have supported more than 1,700 commercial drugs, with approvals and supply spanning over 100 countries.

This level of activity reflects repeatable execution under sustained regulatory and commercial pressure, not isolated success. Quality practices are applied consistently as programs move from development into manufacturing and supply, reducing the friction that often appears late as complexity increases.

In practical terms, this supports:

- Fewer late-stage disruptions
- Smoother transitions from development to commercialization
- More predictable regulatory engagement
- Continuity of supply across regions and markets

Aligning rigor, execution, and accountability

In an industry defined by competitive timelines and regulatory scrutiny, quality becomes a differentiator when rigor and reliability are built into how work is done and reinforced through accountability at every level.

As scientific and operational complexity increase, variability becomes the central risk. Managing that risk depends on disciplined decisions about data, regulatory expectations, and execution, and on whether those decisions hold as programs move across teams, sites, and regions. That alignment depends on quality being personal to the people making those decisions, not abstracted into systems alone.

When digital insight supports earlier identification of risk and regulatory readiness is sustained through day-to-day work, operating models are better able to hold as volume and complexity increase. In this environment, quality stabilizes programs rather than slowing them down.

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