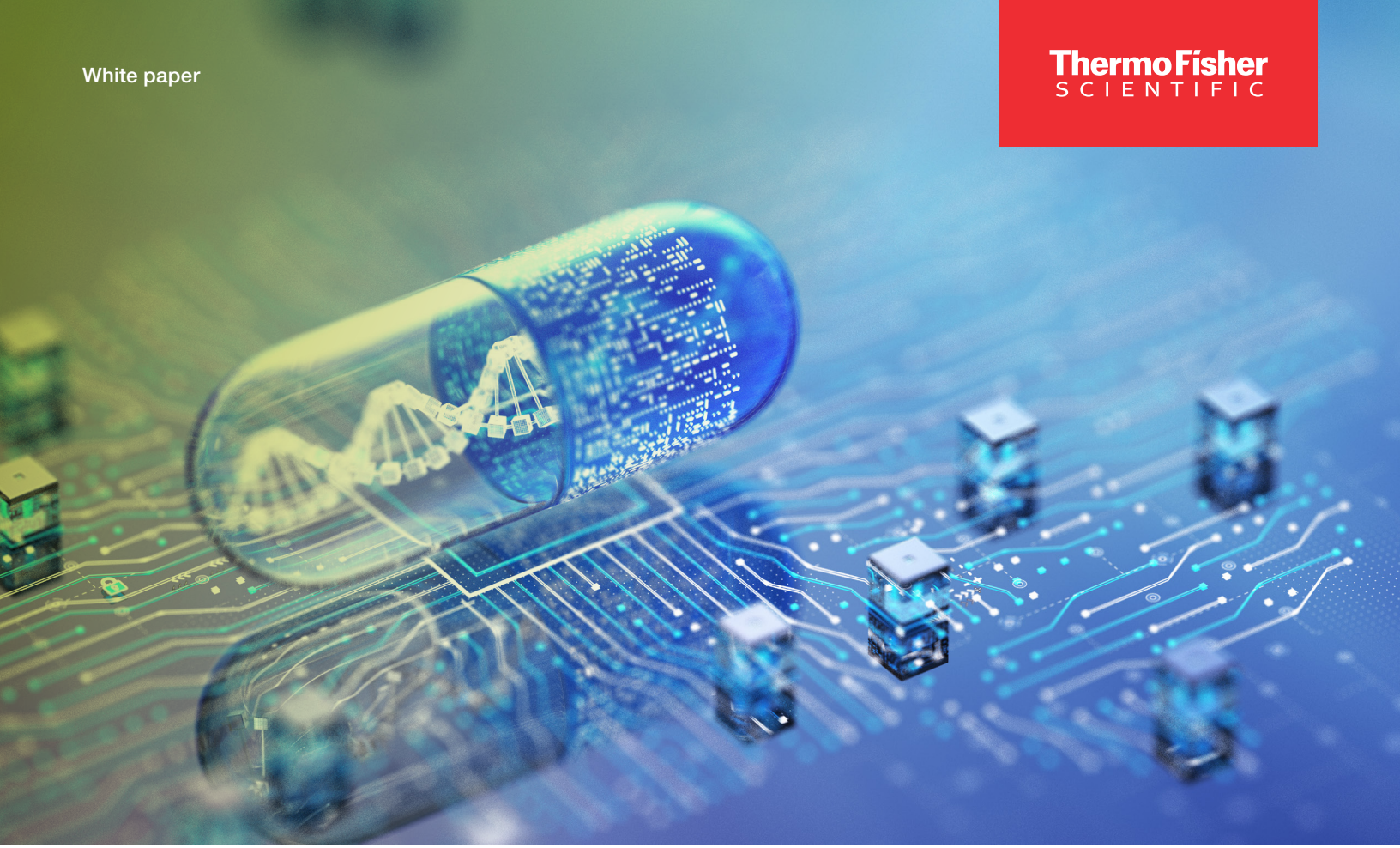
White paper



Building the advantage

Where innovation and investment reduce drug development risk

Executive summary

The pharmaceutical manufacturing ecosystem is operating under a different set of expectations than it did even a few years ago. Scientific complexity continues to expand across modalities. Development timelines are compressed. Device integration is moving earlier in lifecycle planning. Regional diversification and supply continuity are now baseline operating requirements.

These shifts increase the consequences of misalignment across phases and regions. Decisions made during early development shape validation and commercial execution. Infrastructure must perform reliably under regulatory scrutiny and sustained throughput. Geographic distribution must support continuity without introducing new variability.

In this environment, risk accumulates across the lifecycle. Reducing that accumulation requires coordinated investment in the stages where variability intensifies.

In this paper, we examine how investment across Thermo Fisher Scientific Pharma Services has been directed toward four structural priorities:

1. Reinforcing early technical alignment to reduce downstream adjustment
2. Building infrastructure capable of sustained performance under commercial scale
3. Expanding and balancing global capacity to support geographic continuity
4. Integrating digital visibility to strengthen cross-site execution discipline

Together, these priorities reflect an enterprise approach to lifecycle risk management in a more demanding manufacturing ecosystem.

Risk expands as programs progress

The operating environment for drug development now requires programs to move faster while maintaining readiness for inspection, transfer, and supply continuity. As programs advance from feasibility into validation and scale, the room for adjustment decreases.

Early technical assumptions shape downstream performance. Regional differences that are manageable in small batches become more consequential at commercial volumes. Individually, these factors are navigable. Cumulatively, as programs mature, exposure increases.

When variability remains unresolved in early phases, correction becomes more disruptive later. For that reason, investment has been directed toward stages where earlier clarity strengthens lifecycle stability.

Strengthening alignment in early development

Earlier technical clarity has become essential in an environment where material availability is constrained and timelines compress quickly. Investment in early development has focused on increasing predictive insight and maintaining continuity between feasibility and scale.

Within oral solid dose development, the OSDPredict™ digital toolbox expands predictive modeling across solubility and formulation pathways. More than 400 solubility challenges have been analyzed using this framework, achieving 90% accuracy in selecting appropriate solubility enhancement technologies and 80% accuracy in excipient selection without consuming active pharmaceutical ingredient. Modeling can be performed without consuming active pharmaceutical ingredient, allowing development teams to evaluate solubility enhancement strategies before material is allocated.

Structured risk evaluation is reinforced through the FirsTab self-risk assessment tool, which enables development teams to assess technical risk prior to formal subject matter engagement and supports more informed progression decisions.

Early-stage alignment is also supported through investments in development infrastructure. Several new sterile drug product development lines are being introduced across the network to support liquid fill, lyophilized presentations, and pre-filled syringe development. These lines expand sterile process development capacity and support early clinical manufacturing, strengthening continuity between formulation development, process characterization, and later-stage manufacturing readiness.

Continuity between early work and later-stage execution is supported through network-level research and development extensions. The addition of an R&D suite in Toronto, new equipment investments in Cincinnati, and continued capability enhancements in Bend and Bourgoin align development and scale-up on compatible equipment platforms, reducing adjustment during transfer.

In biologics, the Path to First-in-Human integration model reflects the same lifecycle discipline. By combining high-concentration formulation, cell line intensification, and integrated media and resin induction capabilities, this pathway supports DNA-to-ready-for-first-in-human and regulatory submission timelines in as few as nine months for immunoglobulin G molecules and thirteen months for more complex biologics. The emphasis is on aligning early development with manufacturing readiness and regulatory preparation.

Across modalities, these investments reinforce technical alignment before scale amplifies uncertainty.

> *Related reading:*
> • *Reducing uncertainty in early oral drug development*
> • *First-in-Human: Reach milestones sooner with a technology-driven approach to early-stage biologic development*

Building infrastructure that performs at scale

As programs enter Phase II, commercial readiness, and long-term supply, infrastructure performance becomes central. The ecosystem expects commercial-scale environments to operate with inspection readiness, device integration, and throughput stability embedded from the outset.

Within sterile fill-finish operations, infrastructure investment spans both development and commercial manufacturing environments. Gloveless isolator systems reinforce contamination control and inspection readiness across sterile operations, supporting performance during process development, clinical manufacturing, and sustained commercial production.

Capacity expansion across the sterile network supports both development and commercial demand in oncology, neurology, and immunology. Across several sites, new sterile vial, pre-filled syringe, lyophilization, and antibody drug conjugate lines are being introduced. As these lines come online through 2026 and 2027, they expand sterile development capacity while also strengthening commercial-scale manufacturing across high-growth therapeutic areas.

As sterile infrastructure expands, device integration capabilities are evolving in parallel. Pre-filled syringe growth reflects increased adoption of ready-to-use presentations. Autoinjector and wearable device capabilities align drug product and delivery platform manufacturing, supporting coordination as combination products advance toward market.

Operational consistency under commercial throughput is reinforced through artificial intelligence–driven visual inspection systems. These systems automate inspection of color and volume for drug substance and finished product, improving inspection consistency and reducing variability at scale.

As additional sterile lines become operational through 2026 and 2027, capacity utilization across existing vial and lyophilization infrastructure increases. This capacity reinforcement strengthens flexibility across the sterile network and reduces the likelihood that demand acceleration exposes bottlenecks.

Together, these investments support infrastructure performance under sustained scale.

Investing in stronger starts: Why early product development decisions matter

Investments in product development capabilities strengthen early-stage decision-making across oral solid dose and sterile drug product programs. These environments allow formulation and analytical strategies to be evaluated under conditions that reflect how products will ultimately be manufactured.

In oral drug development, early evaluation of molecular attributes, solubility behavior, and formulation pathways helps determine whether a molecule can be manufactured reliably as scale increases. Analytical characterization and structured experimentation expand understanding of how particle properties, excipient selection, and processing conditions influence downstream performance.

In sterile drug product development, development environments support evaluation of formulation stability, aseptic fill performance, and container compatibility across vial, lyophilized, and pre-filled syringe presentations. Assessing these parameters early helps ensure processes remain robust as programs progress into clinical manufacturing.

Early development investments help address risks such as:

- Formulation approaches that perform at laboratory scale but become difficult to manufacture reliably as scale increases
- Incomplete understanding of molecular attributes that influence manufacturability, such as polymorphism, solubility behavior, or particle properties
- Processes designed primarily for early clinical batches rather than future commercial manufacturing conditions
- Sterile drug product challenges related to formulation stability, container–closure compatibility, or fill performance across vial and pre-filled syringe presentations

By strengthening formulation and process understanding early in development, these capabilities reduce the likelihood that scale-up reveals formulation limitations or requires late-stage reformulation or process adjustment.

Expanding and aligning global capacity

Regional diversification and coordinated transfer discipline have become structural requirements within the pharmaceutical manufacturing ecosystem. Programs increasingly require continuity across locations without introducing new variability during transition. A globally distributed manufacturing network provides the foundation for that continuity, allowing capacity to be placed, transferred, and scaled across regions while maintaining operational alignment.

In biologics, capacity expansion at the Lengnau, Switzerland site and available capacity within the Groningen, Netherlands network support coordinated technology transfer between facilities. Transfer models designed to improve project efficiency accompany these expansions, reinforcing alignment as programs move into Phase II and commercial manufacturing.

In clinical trial services, infrastructure expansion strengthens regional resilience. The Japan site expansion doubles storage capacity across controlled ambient, 2–8 °C, freezer, and –80 °C conditions, increasing flexibility in the Tokyo region. The Bohemia, New York expansion doubles label manufacturing capacity, expanding on-site design and printing throughput. Planned expansion in Mexico City in late 2026 will further balance capacity as trial activity diversifies geographically.

Across sterile, oral solid dose, biologics, and clinical supply operations, standardized governance frameworks reinforce technology transfer consistency and operational discipline. Digital integration efforts expand cross-site visibility and strengthen harmonized execution practices.

When geographic placement and execution alignment advance together, regional distribution reinforces continuity across the lifecycle.

> *Related reading: Clinical trial logistics is becoming a strategic discipline: What biopharma needs to prepare for next*

Integrating digital visibility across the lifecycle

The pharmaceutical manufacturing ecosystem increasingly expects transparency across development and manufacturing stages. Digital integration reinforces alignment across these investments by expanding visibility, execution transparency, and shared operational insight.

In oral solid dose development, data generated from more than 400 solubility challenges supports predictive modeling frameworks, enabling development teams to identify formulation patterns, evaluate solubility enhancement strategies, and strengthen decision-making before material is allocated. These datasets strengthen predictive modeling and allow development teams to evaluate solubility enhancement strategies before material is allocated.

Additionally, an AI-powered digital subject matter expert (dSME) application, has been deployed across multiple development and manufacturing facilities, embedding standardized technical guidance and capturing institutional knowledge generated across programs. This shared knowledge base supports more consistent execution as programs move between sites.

Within sterile operations, AI-driven visual inspection systems automate inspection of color and volume under commercial throughput conditions, reinforcing inspection consistency and reducing human variability.

Across these systems, data generated through development and manufacturing programs feeds shared analytical frameworks that strengthen deviation analysis, trend monitoring, and operational decision-making. Shared data frameworks and execution standards extend transparency across modalities and regions, strengthening alignment between development decisions, manufacturing performance, and network execution. These systems draw on data generated across a large portfolio of development and manufacturing programs, allowing performance trends to be identified earlier and strengthening predictive models and deviation analysis.

Digital integration therefore functions as connective infrastructure across early development, commercial manufacturing, and global operations.

Conclusion

The pharmaceutical manufacturing ecosystem now requires earlier technical clarity, inspection-ready infrastructure, regional diversification, and cross-site visibility as operating norms.

Coordinated investment across development, manufacturing, and global operations supports that posture. Early modeling and structured risk assessment narrow uncertainty. Infrastructure reinforcement supports sustained performance at scale. Geographic alignment strengthens continuity across regions. Digital integration improves transparency across each stage.

Together, these structural priorities reduce the likelihood that variability compounds as programs advance toward commercial supply.

> *Related reading:*
> *Flexibility in drug development: From tactical response to strategic imperative*
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> *Quality as a strategic differentiator in drug development*
>
> *Coordinated development as an execution framework*

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