

Oral solid dose

Guided by vision: Redefining OSD development through foresight and innovation

Executive summary

Mastering oral solid dose (OSD) development requires strategic foresight and a clear focus on four key pillars: technology and expertise, global networks, customized services, and regulatory excellence. These pillars provide the foundation for navigating the complexities of oral drug development, addressing challenges early, and delivering innovative therapies to patients efficiently and effectively.

This paper examines how these four pillars work together to overcome the challenges of oral drug development. By integrating in silico modeling tools, leveraging global CDMO capabilities across formulation, process development, and commercial manufacturing, and maintaining high-quality standards, development teams can streamline processes, mitigate risks, and confidently meet evolving market demands.

Key drivers of success include:

- Predictive tools and expertise drive early problem-solving and process optimization
- A global network ensures scalability, compliance, and consistent quality across regions
- Customized services adapt to the unique demands of each program and to evolving requirements at each development stage
- Proactive quality and regulatory strategies reduce risks and enable market access

Introduction

Bringing clarity to complexity in oral drug development

Bringing a medicine to market involves countless critical decisions at every stage. Navigating these successfully requires the vision to anticipate challenges, seize opportunities, and turn complexity into a strategic advantage.

This is especially true for innovative oral solid dose (OSD) formulations, which call for a precise approach to tackling complex development stages. Achieving success demands a clear strategy to address regulatory requirements, overcome formulation challenges, and meet evolving market demands—all while racing to deliver life-changing treatments to patients.

At every stage, development teams face essential questions: Will the formulation remain stable? Can the process scale effectively? Will it meet regulatory requirements? Does the manufacturing strategy align with commercial goals?

The answers to these questions have far-reaching implications. Overlooked details or poor planning can cost millions, delay progress by years, or potentially prevent a promising treatment from ever reaching those who need it. Given that drug development already spans 10–15 years and costs an average of \$1–2 billion per approved therapy, even small missteps can have outsized consequences^[1].

Driving success through vision: Four pillars

What separates successful drug development programs from those that falter isn't just the right equipment or technology—although those are essential—it's also the technical expertise that provides foresight. The ability to anticipate challenges, identify opportunities, and eliminate obstacles has become a crucial differentiator in today's highly competitive market.

A clear vision combines foresight with action, enabling development teams to proactively address risks, optimize formulations, and streamline pathways to market. By integrating expertise, technology, and strategy, vision turns potential challenges into opportunities for success.

The statistics tell a compelling story. According to some estimates 70–90% of new chemical entities in development pipelines and up to 40% of commercialized products face solubility challenges that can compromise bioavailability and therapeutic efficacy [2].

Traditional trial-and-error approaches to solving these issues consume precious time, resources, and active pharmaceutical ingredients (API). At the same time, the industry's shift toward more complex molecules and targeted therapies has raised the stakes for getting formulation and manufacturing strategies right the first time.

Development teams that lack comprehensive foresight frequently face significant obstacles throughout the drug development process. Unexpected formulation issues can arise, often requiring costly and time-consuming late-stage reformulations. More than 30% of formulation projects face delays due to manufacturing inefficiencies during scale-up, and reformulating in later phases can increase costs by two to three times [3]. Challenges that might have been anticipated and mitigated with better planning can disrupt progress and timelines. Regulatory hurdles may delay market entry, adding to the complexity and extending timelines. Additionally, inefficiencies in manufacturing can drive up costs and compromise product quality, making it harder to achieve commercial success.

Developing the breadth and depth of expertise required to avoid these roadblocks demands focus on four key areas of operation:

1. The **technology and expertise** to identify and overcome challenges early
2. A robust **global network** for seamless scalability and supply chain management
3. **Customized services** to align with unique project needs
4. **Regulatory excellence** to ensure compliance across all stages of development

“Balancing time, cost, and risk is essential in drug development. While everyone wants the best deal for the lowest cost, understanding the trade-offs and addressing risks early can make all the difference.”

— Sanjay Konagurthu, Ph.D, Senior Director,
Science and Innovation, Pharma Services,
Thermo Fisher Scientific

These pillars form the foundation for proactive planning, risk mitigation, and accelerated timelines.

Building on decades of industry experience and insights from successful product development efforts, the following sections explore each pillar, offering practical strategies to tackle complex challenges, from addressing formulation issues to ensuring regulatory readiness. By focusing on proactive planning rather than reactive problem-solving, development teams can gain the confidence and clarity needed to make strategic decisions at every phase of the journey. In an environment where timelines are tight, budgets are constrained, and the stakes are high, having a clear roadmap can be the difference between delay and delivery.

Development insight

Proactive planning is key to overcoming complex challenges in drug development. From addressing formulation issues to ensuring regulatory readiness, teams that focus on strategic foresight rather than reactive problem-solving gain the confidence and clarity needed to make informed decisions at every phase of the journey. This approach enables smoother transitions, reduces costly setbacks, and helps maintain momentum from early development through commercialization.

Pillar 1

Technology and expertise: Innovation meets predictive insight

Up to 90% of new chemical entities face significant development hurdles before they are considered viable. Rising costs, increasingly complex molecules, and mounting pressure to accelerate timelines have made traditional trial-and-error approaches unsustainable.

In this challenging environment, technology and expertise have emerged as strategic differentiators. Predictive modeling, paired with the skills and experience needed to extract value from the data, is transforming how development teams navigate obstacles. Using *in silico* predictive modeling, development teams can identify formulation challenges early and turn insights into actionable strategies that drive progress.

Today's predictive tools empower teams to:

- Analyze molecular properties without consuming API
- Simulate formulation combinations to identify optimal technical solutions
- Leverage PBPK modeling to anticipate *in vivo* performance and inform clinical strategy
- Predict stability outcomes years in advance
- Model manufacturing processes for faster, seamless scale-up

These predictive modeling capabilities are part of a larger transformation in pharmaceutical development—one driven by artificial intelligence (AI) and the integration of advanced digital tools. While many industries are just beginning to explore AI, pharmaceutical development has moved beyond the buzzwords to achieve tangible results.

AI-driven tools now enable a seamless development pathway, from analyzing molecular properties to predicting behaviors, designing formulations, optimizing processes, and assessing risks.

The true innovation goes beyond technology, however. It is the critical integration of these advanced digital capabilities with human expertise. This pairing is the heart of what industry experts refer to as Pharma 5.0, and it is reshaping how drugs are developed to achieve better outcomes.

Development insight

The advanced digital predictive modeling capabilities of Thermo Fisher's Quadrant 2™ platform have resolved more than 400 complex solubility challenges reducing development time and API consumption while increasing the probability of success.

“Data from advanced analytics and machine learning only becomes actionable when interpreted by experts. It's about bridging the gap between predictive insights and experimental validation to deliver meaningful results.”

— Dr. Anil Kane, Senior Director,
Global Technical Scientific Affairs,
Pharma Services, Thermo Fisher Scientific



Phase-appropriate innovation

To maximize the potential of these innovative technologies, strategies must align with the unique demands of each phase of development, as shown in Table 1.

Table 1. Considerations for each phase of development.

Development phase	Focus areas	Key technologies and approaches	Considerations
Early phase	Speed and flexibility	<ul style="list-style-type: none">• Rapid digital screening• Digital modeling without API• Basic stability assessment• Formulation development technology selection	<ul style="list-style-type: none">• Minimize API consumption• Fast proof-of-concept• Multiple formulation options
Mid phase	Optimization and scale	<ul style="list-style-type: none">• Process refinement• Comprehensive stability studies• Manufacturing modeling• Modeling of drug behavior in the human body	<ul style="list-style-type: none">• Scale-up planning• Tech transfer preparation• Regulatory compliance strategy
Late phase	Commercial success	<ul style="list-style-type: none">• Process validation• Long-term stability testing• Manufacturing optimization	<ul style="list-style-type: none">• Global regulatory requirements• Cost optimization• Supply chain planning

Tailoring the technological approach to each phase ensures that development teams can maximize efficiency and avoid unnecessary delays or costs.

“The sooner we address challenges in development, the better. Problems that aren’t solved early often snowball, creating larger obstacles later. Our goal is to resolve these issues during development to ensure a smoother pathway forward.”

— Dr. Anil Kane

The power of prediction

Modern predictive tools have transformed key development challenges. By leveraging advanced technologies and expert insights, development teams can address solubility, stability, and process hurdles with greater precision and efficiency. These tools enable:

Solubility enhancement

- Predict optimal enabling technologies
- Simulate API-polymer interactions
- Rank-order excipient combinations
- Model dissolution performance

Stability assessment

- Compress 2 years of testing into 3–4 weeks
- Predict shelf-life with accuracy
- Inform packaging decisions
- Reduce development costs

Process optimization

- Develop processes virtually
- Assess scale-up risks
- Optimize manufacturing
- Plan tech transfer effectively

These capabilities showcase the potential of predictive tools to streamline development and reduce inefficiencies. A direct comparison of outcomes with and without these tools highlights their transformative impact, as shown in Table 2.

Table 2. Aspects with and without predictive tools.

Aspect	With predictive tools	Without predictive tools
Approach to solubility	Predicts optimal technologies and simulates API-polymer interactions	Relies on trial-and-error testing for excipient combinations and technology selection, leading to longer timelines
Stability Assessment	Compresses two years of testing into 3–4 weeks and accurately predicts shelf-life	Conducts full two-year shelf-life studies, delaying packaging decisions
Packaging decisions	Informs decisions with predictive stability tools to ensure real-world viability	Delayed due to lengthy stability testing and lack of data-driven insights.
Process development	Identifies risks and optimizes manufacturing processes through virtual development	Faces risks and inefficiencies during scale-up due to limited pre-planning
Scale-up	Anticipates risks early with virtual assessments and ensures equipment compatibility, minimizing batch failures	Encounters unexpected failures during scale-up, causing costly rework
Tech transfer	Plans effectively, ensuring a smooth transition to manufacturing equipment	Lacks visibility into compatibility problems with commercial equipment resulting in delays during tech transfer
Timeline	Stays on schedule, reducing time-to-market	Extends project timelines by a year due to inefficiencies
Cost efficiency	Reduces development costs through streamlined processes and accurate predictions	Increases costs due to rework, delays, and inefficiencies
Market performance	Helps keep timelines on track	Threatens ability to meet timelines

The benefits of predictive tools and expertise extend beyond individual development challenges, offering a comprehensive framework for success. When advanced technology and deep expertise converge, development teams unlock significant advantages:

- Confident decision-making grounded in robust, data-driven predictions
- More strategic allocation of resources to optimize outcomes
- Faster development timelines, keeping projects on track
- Reduced risk of late-stage failures, saving time and costs

Key takeaway

The integration of predictive tools and expertise enables precise decision-making, faster timelines, and reduced costs, empowering development teams to overcome challenges and deliver results at every stage.

Pillar 2

Global network: Seeing beyond borders

Success in modern drug development requires more than localized expertise. It demands a global perspective. As markets become increasingly interconnected, adhering to diverse and complex regulations while maintaining consistent quality standards is essential for delivering safe, effective treatments worldwide.

A single drug's journey often crosses multiple continents, regulatory frameworks, and manufacturing locations. To succeed, teams need a clear vision that encompasses all of these dimensions from the outset. This entails regulatory insight and operational excellence.

Regulatory insight

- Understanding requirements across major markets
- Navigating multiple regulatory frameworks
- Anticipating regional compliance needs
- Planning for market-specific demands

Operational excellence

- Developing products in the markets where they will be sold
- Accelerating tech transfer timelines via harmonized processes across sites
- Ensuring consistent quality standards across sites
- Maintaining flexible manufacturing capacity to adapt to changing demands

By addressing regulatory and operational challenges with a global perspective, teams can build the foundation for success. But to truly unlock efficiency and quality, these efforts must be supported by a robust and integrated global network.

The power of an integrated network

To successfully bring a drug to market on a global scale, development teams need a network that can integrate capabilities across regions to create a seamless, unified process. Such a network delivers value by accelerating development timelines and ensuring consistent quality.

Development acceleration

- Parallel pathway planning
- Strategic resource allocation
- Reduced time to market
- Cost-effective development

Quality assurance

- Consistent global standards
- Harmonized processes and documentation
- Unified quality systems
- Seamless, reliable tech transfer

The key advantage of such a network is the ability to align development and manufacturing capabilities across regions. This alignment enables teams to accelerate drug development to IND and NDA milestones while maintaining cost-effective, consultative approaches that support long-term success.



The importance of region-specific insights

Understanding regional regulations early in the development process is essential for avoiding costly delays and ensuring smooth market entry. By proactively addressing these requirements, development teams can:

- Prevent regulatory delays
- Optimize submission strategies
- Reduce development costs
- Accelerate local market access

The ability to develop and manufacture products in target regions reduces costs and provides crucial insights into local regulatory and quality requirements from the earliest stages of development.

These region-specific considerations—outlined in Table 3—are key to building effective development strategies. Each region presents unique regulatory requirements and quality standards. Understanding these nuances early enables development teams to tailor their strategies to specific markets, ensuring compliance and reducing the risk of delays.

Table 3. Regulatory considerations by region.

Region	Key regulatory body	Primary considerations	Quality standards
North America	FDA	<ul style="list-style-type: none">Established submission pathwaysClear guidance documentationStructured review processes	<ul style="list-style-type: none">cGMP complianceQuality by Design (QbD)Robust validation requirements
Europe	EMA	<ul style="list-style-type: none">QP requirementsCentralized and national proceduresCountry-specific requirementsPost-Brexit considerations	<ul style="list-style-type: none">EU GMP standardsDetailed quality documentationEnvironmental requirements
Asia Pacific	NMPA (China) PMDA (Japan)	<ul style="list-style-type: none">Regional-specific regulationsLocal language requirementsMarket access pathways	<ul style="list-style-type: none">Region-specific GMPLocal quality requirementsSite certification needs

Global network: The way forward

A well-integrated global network ensures teams can leverage region-specific insights to maximize development efficiency and minimize risks. By strategically utilizing global capabilities, teams gain:

- Accelerated development pathways
- Improved market access strategies
- Robust risk mitigation approaches
- Cost optimization opportunities

When regional expertise is combined with a globally integrated approach, development teams are better positioned to navigate complexities, reduce inefficiencies, and bring products to market faster, with confidence in their compliance and quality.



Key takeaway

In addition to technical expertise, success in drug development depends on the vision to understand global regulations, quality standards, and market demands, and the foresight to navigate their complexities with precision.

Pillar 3

Customized services: Accelerating development through tailored support

The varied nature of drug development means that no single approach fits every program. Each program and organization faces unique challenges, demanding a nuanced approach to support and partnership. As shown in Table 4, small biotechs often require comprehensive support, mid-size pharma may benefit from targeted assistance, and large pharma typically seeks specialized expertise to navigate global supply chain, harmonization, and capacity management.

Table 4. Needs of considerations by organization types.

Organization type	Primary needs	Key considerations
Small biotech	Comprehensive support	API conservation, cost efficiency, expertise access, regulatory support, clear and effective development strategies, IND submission strategies
Mid-size pharma	Targeted assistance	Timeline optimization, process and cost efficiencies, regulatory support
Large pharma	Specialized expertise	Global harmonization, capacity management, Supply chain optimization

The most effective development strategies evolve as programs progress. Early-phase work requires rapid screening capabilities and flexible approaches to overcome initial formulation challenges. As programs advance, focus shifts toward process optimization and scale-up considerations. By late-phase development, attention turns to commercial readiness and global compliance requirements.



Flexibility and adaptability: Value drivers

Engaging a partner with an adaptable approach to drug development offers distinct advantages, especially when services are customized to the unique needs of each customer and development phase. Beyond transactional support, a successful partnership requires a shared vision and seamless collaboration to prevent inefficiencies, such as hands-off transitions or knowledge gaps during the development journey.

To meet these demands, a CDMO must offer tailored services at every stage, providing access to expertise, diverse technologies, and the flexibility to adapt to evolving requirements. This adaptability ensures that drug development progresses efficiently, even as challenges or technical needs shift. Key advantages of an adaptable partnership include:

Technical expertise

- Access to specialized knowledge when needed
- Seamless integration with internal teams
- Rapid problem-solving capabilities
- Proactive formulation and process development approach

Operational excellence

- Scalable resource deployment
- Efficient timeline management
- Cost-effective development strategies

Strategic support

- Guidance at critical decision points
- Risk assessment and mitigation
- Path-to-market planning

The impact of customization

Properly tailored development services provide significant benefits to organizations. Resources are utilized more effectively, ensuring no effort is wasted, while development timelines are shortened, allowing treatments to reach patients sooner. Tailored services also minimize API consumption, a crucial factor in maintaining cost efficiency, and increase the likelihood of success by addressing challenges proactively. Just as importantly, customization ensures regulatory compliance is upheld at every stage, reducing the risk of delays and positioning organizations for smooth market entry.

Industry insight

Modern drug development demands partners who can adapt their approach to each program's unique challenges while maintaining consistent quality standards.

Customized services: The way forward

Future success in drug development will hinge on the ability of partners to deliver truly adaptable and tailored services. This means working with organizations that can quickly adapt to changing requirements, ensuring development strategies remain aligned with evolving program needs. Flexible engagement models are equally critical, allowing for seamless scaling of resources and services as projects progress.

Consistency across service levels is non-negotiable, as maintaining quality at every stage of development is essential to meeting regulatory expectations and achieving commercial success. The most effective partners also offer integrated solutions that streamline processes and reduce complexity, helping to accelerate timelines and control costs. Finally, as drug development increasingly spans global markets, partners must be equipped to support worldwide needs with localized expertise, ensuring compliance and market access wherever the product is destined.



Key takeaway

The right partner combines tailored support, consistent quality standards, flexible engagement models, and global expertise. By aligning with partners who adapt to evolving needs, organizations can navigate the complexities of drug development efficiently and confidently, ensuring a smoother journey to market and effective management of internal resources.

Pillar 4

Regulatory excellence: A commitment to quality

While other aspects of drug development may be flexible, quality standards must remain consistently high across every stage, market, and process. Patients depend on it, and regulatory bodies demand it.

Quality as a compass

High-quality development and manufacturing standards are the foundation of any successful drug development program. Thermo Fisher Scientific Pharma Services exemplifies this commitment, with a strong track record of regulatory excellence. Since 2011, that expertise has contributed to 135 manufacturing contracts for FDA-approved products. This success stems from consistently meeting the highest quality standards set by global regulatory bodies, including the FDA, EMA, and China FDA.

The pursuit demands a Quality by Design (QbD) approach that considers regulatory requirements from the earliest stages of development, building quality into the process. This approach emphasizes critical quality attributes (CQAs) and proactive risk management to ensure robust and reliable outcomes.

CQAs encompass product performance characteristics, process parameters, control strategies, and stability requirements. By identifying and managing CQAs early, teams can ensure robust product quality and reliability throughout development.

Proactive risk management involves early identification of critical parameters, implementation of control strategies, continuous monitoring, and adaptive quality systems. These practices help mitigate risks before they can disrupt timelines or outcomes.

Development insight

Quality must be embedded in every step of the development process, from initial formulation through commercial manufacturing. This approach minimizes risk, accelerates development, and ensures compliance at every stage.

Key takeaway

Excellence in quality and regulatory compliance goes beyond meeting minimum standards. It establishes a foundation that drives efficient development, enables successful commercialization, and ultimately improves patient outcomes.

Mapping the regulatory landscape

Navigating the regulatory landscape is one of the most complex aspects of drug development. Achieving regulatory approval requires a thorough understanding of global and regional requirements, robust quality systems, and effective risk management practices. Without these foundations, programs face potential delays, compliance challenges, and barriers to market entry.

Key regulatory considerations span several critical areas, as outlined in Table 5.

Table 5. Regulatory considerations.

Regulatory aspect	Key considerations
Global requirements	<ul style="list-style-type: none">FDA, EMA, and regional authority standardsMarket-specific documentation needsEvolving regulatory landscapes
Quality systems	<ul style="list-style-type: none">cGMP complianceQuality management systemsDocumentation requirements
Risk management	<ul style="list-style-type: none">Critical quality attributesControl strategiesContinuous improvement

Strong regulatory capabilities and quality systems provide tangible benefits, such as faster regulatory approvals, reduced compliance risks, and more efficient development processes. These strengths ensure alignment with diverse regional requirements, paving the way for smoother market access and global reach.

Regulatory excellence: The way forward

As regulatory requirements continue to evolve and increase in complexity, organizations must prioritize proactive quality strategies, robust control systems, and comprehensive global regulatory knowledge. Continuous improvement and integrated quality systems are vital to navigating these demands successfully and achieving sustainable long-term outcomes. These foundational elements are also key to preparing strong regulatory packages and increasing the likelihood of successful IND and NDA submissions.

A clear path to success

Turn vision into action

Successful drug development requires clarity of vision—anticipating challenges, identifying opportunities, and navigating complexity with precision. Success is achieved when predictive tools, global expertise, advanced technologies, and quality systems come together seamlessly to remove barriers and drive progress.

This vision takes shape through tailored solutions, innovative tools, and strategic regulatory approaches. The depth and breadth of these capabilities empower development teams to turn scientific potential into impactful therapies while streamlining processes and maintaining compliance throughout each stage.

The way forward requires adaptability and foresight. By aligning the right resources and expertise, teams can simplify even the most complex challenges, meet critical milestones, and deliver treatments to patients with confidence and reliability.

Ready to transform your OSD development strategy?

Connect with us to discover how our advanced technologies, global networks, customized services, and regulatory excellence can help streamline your development process and deliver results.

Learn more at **thermofisher.com/patheon**
or email us at **pharmaservices@thermofisher.com**
or call **+1 919 226 3200**

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References

1. Santos, R., Ursu, O., Gaulton, A., Bento, A.P., Donadi, R.S., Bologa, C.G., et al. (2022). A comprehensive map of molecular drug targets. *Nature Reviews Drug Discovery*, 16(1), 19–34. PMC9293739
2. Wu, Ke, Soon Hwan Kwon, Xuhan Zhou, Claire Fuller, Xianyi Wang, Jaydutt Vadgama, and Yong Wu. 2024. "Overcoming Challenges in Small-Molecule Drug Bioavailability: A Review of Key Factors and Approaches" *International Journal of Molecular Sciences* 25, no. 23: 13121. <https://doi.org/10.3390/ijms252313121>
3. Farid, Suzanne S., Melissa Baron, Christina Stamatis, Wei Nie, and John Coffman. 2020. "Benchmarking Biopharmaceutical Process Development and Manufacturing Cost Contributions to R&D." *mAbs* 12 (1): 1754999. <https://doi.org/10.1080/19420862.2020.1754999>