Consultancy:
Technical Insights Series

Investor Readiness in Biotech: Why CMC, DMPK and Clinical Pharmacology Data can make or break the investment case

Introduction

For emerging biotech companies, investor discussions are often focused on the strength of the science, the clinical opportunity, and the size of the market. Yet, as investors become increasingly selective, the quality of the underlying development plan — particularly around the DMPK, clinical pharmacology and CMC aspects of emerging assets is playing a much more central role in due diligence.

A promising molecule may attract initial interest, but investors need confidence that the asset can be developed, manufactured, scaled, regulated, and ultimately deliver the required exposure and clinical benefit in patients through a commercially viable product. This means companies must be able to clearly explain not only what the product does, but how it will progress through development and where the principal technical risks sit.

To explore this topic, Pharmaserviceshub spoke with Marcel de Matas, Chief Business Officer and Founder at Seda about the importance of investor readiness and Seda's service designed to help companies assess how well their development story, CMC package, and clinical pharmacology strategy will stand up to scrutiny.

Investor readiness is a phrase that is being used more frequently in biotech. From your perspective, what does "investor-ready" really mean when applied to DMPK, CMC, product development, and clinical pharmacology?

Investor readiness means being able to clearly explain how an asset will progress from its current stage of development to the next key milestone and ultimately to patients. It goes beyond the underlying science and requires a coherent, evidence-based plan covering product development, clinical pharmacology, manufacturing, regulatory strategy, timelines, costs and risks.

From a CMC and clinical pharmacology perspective, an investor-ready programme is one where the company can clearly explain why a formulation has been selected, how dose has been justified, what the key risks are, and how they will be managed. Investors do not expect all the answers at an early stage, but they do expect a clear rationale and a credible plan.

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Why are investors now looking more closely at CMC, DMPK and clinical pharmacology data, rather than focusing solely on the strength of the underlying bioscience or clinical concept?

Historically, early-stage biotech investment was often driven primarily by the novelty of the science and the strength of the underlying biological rationale. Whilst these factors remain fundamental, investors are now placing much greater emphasis on whether a programme can realistically be translated into a successful medicine.

Part of this shift reflects a changing regulatory landscape. Initiatives such as the FDA's Project Optimus have reinforced the importance of dose optimisation and dose justification, particularly in oncology. It is no longer sufficient to demonstrate activity; companies are increasingly expected to show a robust scientific rationale for dose selection, supported by pharmacokinetic, pharmacodynamic and exposure-response data. As a result, DMPK and clinical pharmacology are becoming central components of development strategy rather than supporting disciplines.

At the same time, investors are becoming more focused on future commercial competitiveness. A promising molecule may face significant challenges if the product profile does not meet the needs of patients, healthcare providers or payers. Questions around route of administration, dosing frequency, treatment burden, manufacturability and scalability can all have a major impact on adoption and long-term commercial value. For example, a treatment that allows self-administration at home may offer significant advantages over one that requires lengthy hospital-based infusions.

CMC, biopharmaceutics, DMPK and clinical pharmacology data provide important evidence that these factors are being considered early and systematically. Together they help demonstrate that the company has a credible strategy for delivering the right exposure, in the right patients, using a product that can be manufactured, supplied and differentiated in the marketplace.

Ultimately, investors are looking for more than compelling science. They are looking for confidence that management understands the decisions, risks and trade-offs required to transform a promising asset into a clinically successful, commercially attractive and approvable medicine.

What are the most common technical or strategic gaps you see when early-stage biotech companies prepare for investor engagement?

One of the most common gaps is an insufficient understanding of the path to the next development milestone, including timelines, costs, risks and dependencies.

Another is the lack of a clearly articulated development rationale. Companies can often describe what they plan to do, but not always why specific decisions have been made around dose, formulation, route of administration or clinical strategy.

We also see companies aiming for the minimum CMC package needed to enter the clinic, without considering whether the dosage form is capable of answering critical development questions, achieving target exposures or supporting future commercial objectives.

Finally, many teams underestimate the impact of inevitable changes in process, manufacturing site, materials or formulation, and the comparability and bridging work these changes can require.

Ultimately, investors are looking for confidence that management understands not only the science, but the practical path to value creation.

How can weak, incomplete, or poorly presented development data affect investor confidence, valuation, due diligence timelines, or deal progression?

Investors understand that early-stage development is accompanied by uncertainty. What tends to concern investors most is not necessarily the presence of risk, but a lack of understanding of that risk.

Management teams seeking investment should be able to clearly explain how the next major development milestone will be achieved, what assumptions underpin the development strategy, what the principal risks are, and how those risks will be managed if they arise. This provides confidence that the programme is being developed in a structured and informed manner.

Weak, incomplete or poorly articulated development data can create uncertainty around the feasibility of the development plan, the robustness of dose selection, the suitability of the formulation, the scalability of manufacture or the likelihood of regulatory success. This can prolong due diligence, increase requests for additional information, affect programme valuation and, in some cases, delay or prevent a transaction from progressing.

In contrast, a well-presented development package helps investors understand not only the opportunity, but also the pathway to realising that opportunity.

At what point should a biotech company begin preparing its CMC, DMPK and clinical pharmacology package for investor scrutiny? Is this something companies often leave too late?

Preparation should begin much earlier than many companies realise. Investor readiness should not be viewed as a separate activity undertaken immediately before a fundraising round; it should evolve alongside the development programme.

Companies often focus heavily on generating scientific data whilst delaying consideration of the development pathway, dose justification, formulation strategy or manufacturing requirements. By the time investor discussions begin, it can be difficult to address gaps in these areas quickly. Early strategic planning enables companies to identify risks, develop mitigation plans and build a stronger narrative around how the asset will progress to the next value inflection point.

When investors review a development programme, what are the key questions they are likely to ask around dose, formulation, manufacturability, scalability, and regulatory risk?

Although every programme is different, the questions are often remarkably consistent.

Investors typically want to understand:

- How has the proposed human dose been selected and justified?
- What evidence supports the relationship between dose, exposure and anticipated clinical response?
- Is the formulation capable of delivering the required exposure profile consistently?
- Is the route of administration appropriate for patients, healthcare providers and the target market?

- Are there any known biopharmaceutic, bioavailability, stability or manufacturability challenges?
- What formulation or manufacturing changes are anticipated as development progresses?
- How will any future comparability or bridging activities be managed?
- Can the product be scaled from early clinical development into later-stage clinical studies and commercial manufacture?
- What are the key technical, regulatory and operational risks?
- What activities are required to reach the next major development milestone and what will they cost?

Increasingly, investors are also interested in whether the product profile will be commercially competitive. Questions around dosing frequency, treatment burden, self-administration, device requirements and patient convenience can be as important as traditional development considerations.

Ultimately, investors are trying to determine whether the programme has a realistic, executable and commercially relevant development strategy.

Seda's approach brings together CMC and clinical pharmacology expertise. Why is it important to assess these areas together rather than in isolation?

Many of the most important development decisions sit at the interface between product development, biopharmaceutics, DMPK and clinical pharmacology.

A common misconception is that CMC and clinical pharmacology are largely independent disciplines. In reality, decisions made in one area often have significant consequences for the other. Formulation design influences drug release, absorption, biodistribution and ultimately clinical performance. Equally, clinical pharmacology objectives frequently drive formulation requirements, manufacturing strategies and product design decisions.

This becomes particularly important as programmes evolve. Changes in manufacturing process, manufacturing site, raw materials, formulation composition or dosage form are often unavoidable during development as knowledge increases and products mature. However, these changes can alter product performance and may require bridging studies to demonstrate comparability.

The timing of those changes, and the amount of supporting evidence needed to justify them, should be considered strategically. The requirements are highly product-specific and depend on factors such as product complexity, development stage, route of administration and regulatory expectations. In some cases, relatively straightforward analytical or pharmacokinetic bridging may be sufficient. In others, particularly for complex dosage forms, drug-device combinations, long-acting injectables, locally acting products or targeted delivery systems, considerably more evidence may be required, potentially including biopharmaceutic studies, modelling and simulation, biodistribution data or additional clinical work.

Importantly, systemic exposure alone may not always provide the complete answer. For some products, including those where local tissue delivery, targeted exposure or controlled release is important, understanding biodistribution and site-specific drug delivery can be equally critical. This creates a much stronger link between product development, DMPK and clinical pharmacology than is often recognised.

By considering these disciplines together from the outset, companies can make more informed decisions about product design, anticipate future development challenges and build a more robust strategy for dose justification, regulatory interactions and product lifecycle management. This helps reduce the risk of costly delays and creates a clearer path towards the next value inflection point.

What does Seda's investor readiness review service involve, and what type of output should a biotech expect to receive from the process?

The review is designed to provide an independent assessment of how well a programme's development strategy is positioned for investor engagement.

Typically, we review the available technical information relating to CMC, DMPK, clinical pharmacology and development strategy, together with any investor-facing materials where appropriate. The aim is not to conduct a detailed due diligence exercise, but rather to identify areas that may attract questions or concern during investor discussions.

The output is a concise summary of observations, key risks, areas requiring clarification, and opportunities to strengthen the development narrative. We also highlight potential mitigation strategies and recommendations for future development activities.

How does an independent review help management teams identify gaps or risks before they become issues during investor due diligence?

Management teams are often deeply immersed in their programmes and may naturally focus on the data they know best. An independent review provides an external perspective based on experience across multiple development programmes and therapeutic areas.

This can help identify assumptions that have not been sufficiently challenged, development risks that have not been fully considered, or areas where the rationale is not clearly articulated. Addressing these issues before investor engagement can improve the quality of discussions and increase confidence in the development strategy.

Many biotech companies have a development plan, but not always a clearly articulated development rationale. How important is it to explain the "why" behind the plan?

It is critical.

Investors are rarely interested in activities for their own sake; they want to understand how each activity contributes to reducing risk and increasing asset value. A development plan should therefore explain not only what will be done, but why those activities are being undertaken and how they support overall programme objectives.

When the rationale is clear, investors gain confidence that development decisions are based on scientific and strategic considerations rather than precedent or convenience. This often leads to more productive discussions and a stronger investment case.

What role does product design play in investor readiness, particularly when considering exposure, route of administration, manufacturability, robustness, and patient use?

Product design is a fundamental component of investor readiness because it influences many of the factors that ultimately determine clinical and commercial success.

The most appropriate product design will depend on the molecule, modality, target patient population and intended route of administration. A well-designed product should be capable of delivering the required exposure profile, supporting patient needs, and being manufactured consistently and economically.

Importantly, product design extends far beyond simply selecting a formulation. Decisions made early in development can have significant implications for dose justification, exposure-response understanding, manufacturability, scalability, patient acceptance and commercial competitiveness.

For example, regulatory authorities are placing increasing emphasis on dose optimisation and dose justification. At the same time, healthcare systems, clinicians and payers are becoming increasingly focused on convenience and treatment burden. A product that achieves the desired clinical outcome through a simple self-administered injection may ultimately be more attractive than a product that requires lengthy hospital-based infusions, even if the underlying efficacy is similar.

Investors increasingly recognise these factors and are looking for evidence that product design decisions are being made with both current development objectives and future commercial requirements in mind.

How can modelling, formulation development, laboratory data, and clinical pharmacology insight help create a more credible and investable development strategy?

These disciplines help transform assumptions into evidence-based development decisions.

Modelling and simulation can be used to evaluate dose selection strategies, understand exposure-response relationships, predict clinical performance and explore alternative development scenarios before committing significant resources. Formulation and laboratory studies generate critical information on product performance, stability, manufacturability and biopharmaceutic behaviour, whilst clinical pharmacology provides a framework for understanding how formulation, dose and patient factors influence clinical outcome.

An important advantage of integrating these disciplines is the ability to anticipate future development challenges. Modelling, biopharmaceutics and clinical pharmacology can play a crucial role in designing formulation bridging strategies, evaluating the impact of manufacturing changes and reducing uncertainty around comparability assessments.

Together, these approaches reduce risk, support more rational decision-making and strengthen confidence that development activities are aligned with programme objectives. Investors are generally more confident in programmes where critical decisions are supported by data, scientific understanding and a clear development rationale rather than assumptions.

What should investors expect to see in a well-prepared technical data room from a CMC and clinical pharmacology perspective?

The level of detail will naturally depend on the stage of development, but investors should expect to see a coherent package that demonstrates both scientific understanding and a credible development strategy.

From a CMC perspective, this may include product and formulation information, manufacturing strategy, analytical and stability data, development plans, risk assessments and an understanding of future scale-up or comparability considerations.

From a DMPK and clinical pharmacology perspective, investors should expect to see ADME data, pharmacokinetic information, exposure-response understanding, dose justification, modelling outputs, translational assumptions and a clear rationale for future studies.

Importantly, the package should explain how formulation, product performance, clinical pharmacology and manufacturing strategy fit together. Investors are not simply looking for data; they are looking for evidence that the company understands how that data supports key development decisions.

The strongest technical data rooms tell a consistent story, clearly explain the path to the next major development milestone and demonstrate that major risks have been identified and appropriately managed.

For virtual or lean biotech companies, what capabilities should they look for in an external partner providing investor readiness support?

Companies should ideally seek support from organisations with substantial experience, track record and history of having successfully guided projects progressing from discovery through to first time in human. These groups have not only the knowledge but the wider network of experts to ensure investor readiness.

How can a service provider help translate complex technical data into a clear investor-facing narrative without oversimplifying the science?

A key challenge in investor communication is striking the right balance between scientific accuracy and accessibility.

An experienced service provider can help distil complex technical information into the development decisions that matter most to investors. Rather than focusing on individual experiments in isolation, the **emphasis should be on what the data means, how it reduces risk, and how it supports progress towards the next value inflection point.**

The objective is not to simplify the science, but to communicate its significance clearly and consistently to audiences with varying levels of technical expertise.

Looking ahead, do you think investor readiness reviews will become a more standard part of biotech fundraising, licensing, and partnering preparation?

Yes, I believe they will become increasingly common.

Investors, licensing partners and due diligence teams are becoming more sophisticated in their

evaluation of development programmes. At the same time, regulatory expectations continue to evolve, particularly in areas such as dose justification, exposure-response understanding and evidence-based decision making.

As a result, **companies are being expected to demonstrate not only strong science, but also clear development rationale, robust product design decisions and a realistic path to execution.** We are already seeing increasing demand from emerging biotech companies seeking support with investor-facing materials and development strategy reviews.

Whilst not every company will require a formal investor readiness assessment, most would benefit from independent expert input before entering major fundraising, licensing or partnering discussions. Programmes that can clearly articulate their development strategy, risk management approach and rationale for key decisions are likely to be at an advantage during due diligence and negotiation.

Seda provides pharmaceutical development and clinical pharmacology expertise, with a focus on helping clients maximise the value of development assets by reaching value inflection points, efficiently, successfully and cost-effectively. Its expertise spans CMC, DMPK, clinical pharmacology, regulatory requirements, product design, product performance, product authorisation, and product supply.

Seda is an integrated CRDMO following receipt of its MHRA manufacturer licence in February 2025, supporting companies from early-stage drug development through clinical phases to registration.

Summary

Investor readiness is no longer simply about preparing a compelling pitch deck. It requires a coherent, evidence-backed development story that connects the science, product design, CMC strategy, clinical pharmacology plan, regulatory pathway, and manufacturing assumptions and commercial objectives. Seda's investor readiness review service is positioned to help companies test that story before entering investor discussions. By combining pharmaceutical development, CMC, modelling, laboratory, and clinical pharmacology expertise, the review can help identify technical gaps, clarify development priorities, and strengthen the rationale behind the next value inflection point. Seda's stated purpose is to apply pharmaceutical development and clinical pharmacology expertise to help clients maximise the value of their development assets.

For investors, this type of review can support a clearer understanding of programme risk and development credibility. For biotechs, it offers an opportunity to improve the quality of investor conversations by ensuring that the technical foundations of the asset are robust, clearly presented, and aligned with the commercial and regulatory path ahead.

Ultimately, the message for emerging companies is clear: strong science may open the door, but a well-structured, investor-ready development package can help sustain confidence through due diligence and beyond.