



White Paper

DNA TO IND

The Early-Phase Playbook:

How to Build a CMC Strategy That Enables Fast IND Without Rework Later



A Practical Framework for Early-Phase Programs Selecting the Right CDMO Partner

INTRODUCTION

For the entire biopharma industry, early development is a defining moment. The decisions made in the first months of a program—about the molecule, the cell line, the analytical package, and the manufacturing strategy—set the trajectory for everything that follows. Yet these decisions are often made under intense pressure with timelines looming and a lack of information. Investors expect rapid progress toward first-in-human studies. Budgets are constrained. And early-stage teams, many of whom come from academic or discovery settings, must suddenly navigate the structure, rigor, and complexity of a GMP-aligned development pathway.

This combination of urgency, limited resources, and unfamiliar requirements creates fertile ground for avoidable missteps. Program teams aim to conserve capital, move quickly, and demonstrate meaningful milestones. But speed achieved the wrong way introduces fragility, not momentum. A rushed choice of molecule or cell line, a process not sufficiently developed to withstand GMP execution, or an underbuilt analytical package can lead to batch failures, regulatory delays, and expensive rework that erodes both timelines and credibility.

This whitepaper offers a practical guide for emerging programs on how to build a right-sized, future-ready CMC strategy—one that supports speed without sacrificing the scientific and operational foundations required for long-term success. Drawing on insights from experienced technical and operational leaders, it outlines the common pitfalls early teams encounter, the

Fast timelines, tight budgets, and complexity shape early CMC decisions.

1 The Early-Phase Reality: Speed, Cost, and Complexity

Early-phase development carries a unique tension: teams are expected to move faster than ever before, yet they are working with immature molecules, incomplete data, and evolving scientific hypotheses. Many programs today originate from academic labs or small founding teams, often led by scientists who are brilliant in their discipline but unfamiliar with manufacturing constraints. As one subject matter expert observed, early-stage biotechs are “desperate to get to first-in-human as quickly as possible,” and this urgency can distort decision-making. Timelines become compressed to the point where foundational scientific steps are abbreviated or skipped, not because teams are careless, but because the funding environment rewards velocity.

Compounding the challenge is cost. Many founders underestimate the true investment required for a robust early-phase CMC program. A typical CMC budget—running from DNA to GMP material, including process development, cell line development, analytical methods, and release testing—can easily run into the mid-single-digit millions. For a young company managing burn rate and milestones, this can feel daunting. As a result, teams sometimes choose the least expensive path rather than the most scientifically sound one, not realizing that cost savings during development often reappear later as far more expensive failures.

A third pressure point often surprises newer teams: the complexity introduced by quality systems. Even in early phase, development and manufacturing occur within a GMP framework that demands structure, documentation, and compliance. For companies used to research environments, the volume of records, deviations, change controls, specifications, and traceability requirements can be overwhelming. Some CDMOs exacerbate this complexity by applying commercial-grade systems to early-phase projects, slowing progress and confusing customers who lack the context to understand why those requirements exist.

Under these combined pressures, early-phase teams often make decisions that feel efficient in the moment but create downstream risk. The key to avoiding these pitfalls lies in adopting a guiding philosophy that balances speed with long-term viability.



*The best CMC strategies
are built for now and
ready for what is next.*



2 Right-Sized, Future-Ready: The Guiding Philosophy

A successful early-phase CMC strategy is founded on two principles: it must be **right-sized** for the stage of development, and it must be **future-ready** for the demands that will arise as the program advances.

Right-sizing means building processes, systems, and documentation that are appropriate for early clinical development—not underpowered to the point of fragility but not overengineered with the weight of commercial expectations. A right-sized approach focuses on manufacturability, safety, and regulatory adequacy without burdening programs with unnecessary cost or complexity. It prioritizes the work that removes risk: ensuring the molecule is viable, the cell line is stable, the process is robust enough to survive scale-up, and the analytics are sufficient to characterize the product.

Future-ready design, by contrast, looks beyond the immediate milestone. It anticipates the requirements of later-stage development, scale-up, and eventual commercialization. Many of the most painful setbacks in CMC stem from decisions made early that lock programs into suboptimal paths. Choosing a nonideal molecule, selecting a poorly performing cell line, or developing a process that only works under narrow conditions can create constraints that are extremely difficult—and expensive—to undo later. As one expert noted, “A poor cell line follows you forever. You can fix a process later, but you cannot easily fix the cell line.”

A future-ready approach considers scalability from the start: Are the unit operations reproducible? Will the equipment used in development align with equipment used at clinical scale? Do the analytical methods generate data that will withstand regulatory scrutiny? Does the CDMO have facilities and expertise that ensure continuity as the molecule progresses?

When early programs embrace both principles—right-sized execution and future-ready design—they avoid the technical debt that slows many biotech companies later in their lifecycle.

The biggest risks are not later. They are locked in by early decisions.

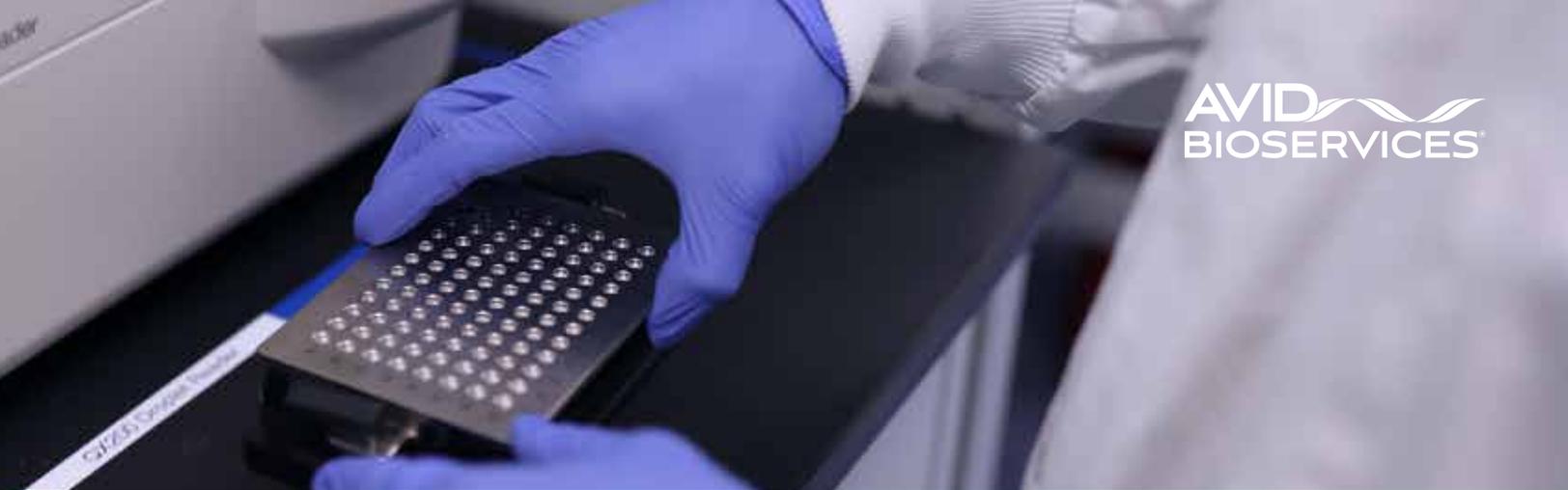
3 Making the Decisions That Matter Most

Among the many choices emerging biotechs face, three decisions have disproportionate impact: selecting the molecule, selecting the cell line, and defining the scope of process development.

Molecule selection is often treated as a foregone conclusion, especially when originating from academic labs. Yet molecules vary widely in manufacturability, stability, and developability. Without appropriate comparative studies or developability assessments, teams may advance a molecule that performs acceptably at bench scale but fails under manufacturing conditions or exhibits undesirable attributes in stability or formulation. These issues, once discovered, can force programs back to the start—after millions have been spent.

Cell line selection carries similar weight. Founders, eager to begin development, sometimes accept the first reasonable cell line candidate rather than taking time to evaluate expression levels, stability, glycosylation pattern, and long-term manufacturability. The consequences can be severe. Cell lines are notoriously difficult to change once a program has advanced; doing so often requires repeating toxicology studies and re-establishing comparability—a costly and time-consuming process. In the words of one SME, selecting the wrong cell line is “like choosing the wrong life partner”—a decision that shapes the entire future of the program.

Process development is the third major decision point. While early programs do not need exhaustive optimization, they do need enough development work to identify and remove the risks that could jeopardize a GMP manufacturing run. Teams that skip or minimize this step often discover too late that conditions that seemed adequate in development fail under GMP conditions, leading to batch failures that cost millions and set the program back months. The goal of early PD is not perfection—it is de-risking.



What works at small scale must be built to succeed at GMP scale.



4 Designing for Scalability and IND Readiness

Scalability is one of the most overlooked elements of early CMC strategy. A process that works beautifully at 3 liters may behave very differently at 200 or 2000 liters. Mixing dynamics change. Oxygen transfer changes. Sensitivity to feed timing or temperature shifts may become amplified. Teams that do not design with scale in mind often find themselves running into avoidable manufacturing challenges during clinical production.

Scalability is not simply about technical transfer—it is also about asset alignment. Processes developed on one type of bioreactor or purification system do not always translate cleanly to another. When early-phase facilities and late-phase or commercial facilities use mismatched platforms, teams face additional risk during tech transfer. Early-phase biotechs rarely think to ask whether the CDMO’s early and late facilities use similar equipment or whether the small-scale models have been validated against large-scale behavior. Yet these questions directly influence the probability of a successful GMP campaign.

Analytical readiness is equally important. Release and stability testing require methods that are appropriate for IND submission, and many teams underestimate the time and effort required to develop, qualify, and implement them. Insufficient analytical planning is one of the most common causes of CMC-related delays.



*Early-phase success
depends as much on CDMO
model as on science.*

5 The Role of CDMO Operating Models in Early-Phase Success

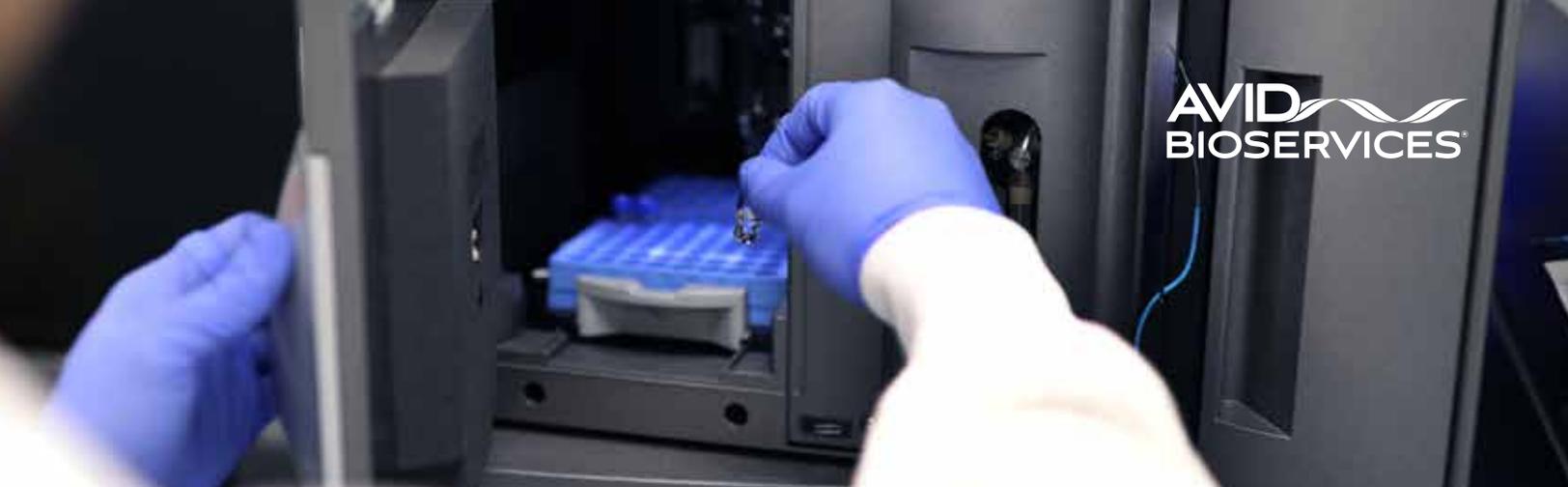
A CDMO's structure and operating model can either accelerate or hinder early-phase programs. Many traditional CDMOs run early-phase and commercial operations within the same facility, using the same documentation systems, the same deviation processes, and the same equipment flows. While this model brings rigor, it also introduces inefficiencies that early programs often do not need—and cannot afford.

Purpose-built early-phase facilities offer a clearer path. These environments are designed to be GMP-compliant but streamlined, using phase-appropriate systems that meet regulatory expectations without burdening programs with commercial-scale documentation and controls. They often use simplified batch records, leaner change control processes, and flexible specifications that reflect the evolving nature of early data. This approach preserves scientific rigor while supporting the speed and agility that early programs require.

Equally important is the composition of the team. CDMOs with high turnover struggle to offer continuity, knowledge retention, and a consistent approach to problem-solving. Those with long-tenured experts bring not only experience but institutional wisdom—the accumulated lessons of hundreds of molecules, campaigns, and technical challenges. Stability within the technical staff creates stability in outcomes.

Facility condition matters as well. Emerging biotechs are often unaware of how much facility age, equipment maintenance, and historical deviations can influence their program. Older facilities may struggle with environmental controls or equipment reliability, leading to downtime that directly impacts customer timelines. Newer facilities, by contrast, typically offer cleaner risk profiles and more predictable execution.

Finally, cross-functional and cross-trained teams provide operational resilience. When staff understand upstream, downstream, analytical, and manufacturing perspectives, they can troubleshoot holistically and keep programs moving even when unexpected events arise.



Early-phase success comes from clear decisions and the right partners.

6 Common Pitfalls and How to Avoid Them

Across hundreds of early-phase programs, the same patterns of failure appear again and again. Teams select a molecule without properly evaluating its developability. They rush into cell line development with insufficient data. They treat process development as a box to check rather than a risk-removal tool. They underestimate the analytical effort required to support IND. Or they choose a CDMO based solely on cost or timeline promises, without assessing the quality of the facility, the continuity of the team, or the alignment of equipment and platforms across scales.

Another frequent pitfall is treating the CDMO as a transactional vendor rather than a scientific partner. When customers withhold information, restrict scope, or resist scientific dialogue, they unintentionally limit the CDMO's ability to guide them away from pitfalls. As one SME explained, "If you treat a CDMO as only a pair of hands, you will not get the full benefit of their expertise."

Avoiding these pitfalls does not require more money—it requires better decision-making, clearer expectations, and choosing partners who are structured to support early-phase needs.

7 How to Evaluate the Right CDMO Partner

Selecting the right CDMO is one of the most consequential decisions an emerging biotech will make. The ideal partner brings deep technical expertise, phase-appropriate systems, and a culture of partnership. They operate facilities that are reliable, aligned across scales, and designed for early-phase agility. They maintain teams with low turnover, ensuring the people who start the program are the ones who finish it. They communicate proactively, identify risks early, and treat each program as a long-term relationship rather than a transaction.

Emerging biotechs should ask questions not only about capabilities, timelines, and price but also about facility age, historical deviations, equipment platforms, analytic experience, and team continuity. They should look for signs of operational maturity, such as cross-functional collaboration, transparent project management, and a willingness to challenge scientific assumptions when necessary.

Perhaps most importantly, they should select a CDMO that can help them build a future-ready foundation—a partner who not only executes the work but strengthens the scientific and operational integrity of the program.

Avid Bioservices' Early Phase Center of Excellence in Costa Mesa, CA

Avid created the **Costa Mesa, CA Early-Phase Center of Excellence** to give innovators a purpose-built, future-ready environment that eliminates unnecessary risk and accelerates progress.

We understand that future-readiness requires more than capacity. It requires intentional alignment across development and manufacturing.

The Costa Mesa facility was purposefully designed with future scale in mind. Process development, analytical strategy, and manufacturing platforms are harmonized with our Tustin, CA CGMP facility, creating continuity from first engineering runs through late-phase and commercial production. For sponsors who begin at the Costa Mesa facility, the transition to scaled manufacturing in Tustin is a seamless tech transfer, a progression within an architecturally aligned system. Equipment platforms, control strategies, and process philosophies are intentionally matched to reduce scale-up risk, minimize comparability burden, and eliminate unnecessary redevelopment. The result is speed to IND without sacrificing the structural integrity required for long term commercial success.

Our **Costa Mesa, CA Early-Phase Center of Excellence** combines the advantages every early-stage program needs but rarely finds in one place:

- Right-sized GMP systems designed for Phase 1
- State-of-the-art facilities and brand-new equipment
- Perfect alignment with Avid's late-phase Myford manufacturing assets
- Deep, stable scientific expertise that guides—not just executes
- A culture of proactive partnership and transparent communication

If you are preparing to advance a molecule into early development or evaluating CDMO partners for an upcoming program, now is the ideal time to assess whether your CMC strategy is truly right-sized and future-ready. Avid's early-phase experts are available to discuss your program, explore development considerations, and help you avoid the common pitfalls that lead to rework, delays, and unexpected cost.

To learn more about Avid's new **Costa Mesa Early-Phase Center of Excellence**—or to schedule an introductory discussion with our technical and program leadership teams—contact us today:



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