AVID BIOSERVICES®

White Paper

BUILT FOR SCALE

Choosing the right CDMO for Late-Phase programs

What it takes to transition from clinical success to reliable scalable manufacturing

Late-Phase Is Where Risk Becomes Reality

INTRODUCTION

In early development, speed is everything. Programs are designed to move quickly—to generate clinical material, reach the clinic, and prove the molecule is safe and efficacious.

As the programs enter pivotal phase, the equation fundamentally changes.

The question is no longer “Can we make this molecule?” It becomes: “Can we make it consistently, at scale, and with robust manufacturing process with scale enough to supply commercial demand—without risking the asset?”

This shift—from speed to reproducibility, robustness, and risk mitigation—is where many programs succeed...
or quietly struggle.

For sponsors approaching Late-Phase development, selecting the right CDMO is one of the most consequential decisions they will make. The right partner doesn’t just manufacture product—they help ensure the program can withstand the demands of commercialization.

From Speed to Certainty: What Changes in Late-Phase

As programs move into Late-Phase, priorities evolve in ways that are often underestimated.

In early development, teams are focused on generating material quickly. Process understanding is limited, analytical methods are fit for purpose, and some process variability is expected and tolerated, as long as the product quality is maintained.

Late-Phase manufacturing requires a level of understanding that goes beyond demonstrating that a process works

Late-Phase introduces a different standard. Regulatory expectations increase, the demand for material grows, and consistency becomes essential. Sponsors begin to think beyond clinical milestones toward commercial viability. This requires deeper process understanding, stronger analytical rigor, and far more comprehensive documentation.

What was acceptable in early phase becomes a source of risk. Variability that once seemed manageable can now impact timelines, approvals, and long-term performance. The focus shifts from moving fast to proving that the process is controlled, predictable, and ready for scale.

The Rise of Process Understanding and Data Rigor

Late-Phase manufacturing requires a level of understanding that goes beyond demonstrating that a process works.

Sponsors must be able to explain how modulating process parameters affect critical product quality and show that the process performs consistently within defined manufacturing ranges. Changes within defined manufacturing in conditions—temperature, pH, loading conditions or feed strategy—must be understood with respect to there impact on product quality

Analytical methods must also evolve. What begins as fit-for-purpose analytical testing must become fully validated, capable of delivering consistent and reproducible results across operators and environments.

This progression is accompanied by a significant requirements for documentation required for filling marketing application. Late-Phase programs require detailed records that support process characterization, validation, and regulatory review. The completeness and clarity of this data become critical during inspection.

At this stage, the goal is no longer to demonstrate possibility. It is to prove consistency.

The ability to move from agility to discipline is a defining characteristic of successful Late-Phase programs.

Operational Evolution: From Agility to Discipline

The transition from clinical to Late-Phase is as much operational as it is technical.

Early-Phase teams are designed for speed. They are flexible, adaptable, and comfortable working with uncertainty. This allows programs to move quickly, but it also means that processes are still evolving.

Late-Phase teams operate differently. The emphasis shifts to control, repeatability, and precision. Processes must be executed consistently, documentation must be thorough, and variability must be minimized.

This requires a different mindset and often a different team structure. Experience becomes critical—not just in executing processes, but in anticipating challenges, understanding risk, and designing for consistency from the outset.

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What Sponsors Should Look for in a Late-Phase CDMO

Selecting a CDMO for Late-Phase development requires evaluating capabilities that directly impact scalability, consistency, and regulatory readiness.

A strong partner understands the complexities of scale-up. Many process variables behave differently at larger volumes, and small issues can become significant at scale. Experience in anticipating and managing these changes is essential.

Continuity across development and manufacturing is equally important. When processes are built on aligned platforms and consistent approaches, transitions are smoother and variability is reduced. This alignment helps ensure that what is developed can be reliably manufactured.

Late-Phase development is where programs are tested—not just scientifically, but operationally.

Regulatory experience is another critical factor. Late-Phase programs culminate in inspections where both the process and the facility are evaluated in detail. A CDMO that understands what regulators expect—and how to prepare for those expectations—can significantly reduce risk.

Process characterization and validation capabilities also play a central role. Sponsors need a partner that can define process parameters, assess risk, and establish control strategies that support consistent performance at scale.

Finally, the most effective CDMOs combine experience with adaptability. Late-Phase programs are complex and rarely follow a single path. A partner that can apply deep expertise while working collaboratively to solve program-specific challenges is essential.

Choosing the Right Partner for What Comes Next

Late-Phase development is where programs are tested—not just scientifically, but operationally.

It is the stage where consistency must be proven, variability must be controlled, and every element of the process must stand up to scrutiny. Success requires more than capability. It requires experience, discipline, and foresight.

For sponsors, this makes partner selection critical.

The right CDMO brings not only the ability to manufacture, but the insight to anticipate challenges, the structure to ensure consistency, and the experience to navigate the path to commercialization.

Because in Late-Phase, the goal is no longer just progress.

It is readiness.

Why Choose Avid for Last-Phase Biologics Manufacturing

Selecting the right partner in Late-Phase is less about capacity alone and more about confidence. Confidence that your process will perform as expected, that timelines will hold, and that there will be no surprises as you approach commercialization.

At Avid, our focus is on delivering that confidence.

We are a biologics CDMO with a manufacturing facility built specifically to support programs as they transition into and through Late-Phase. Our approach is grounded in key principles that align directly with what this stage demands:

Designed for consistency at scale
Late-Phase success depends on repeatability. Our development and manufacturing environments are intentionally aligned using consistent platforms, equipment, and processes to enable smoother scale-up and more predictable performance across batches.

A focus on predictable execution
At this stage, execution matters as much as process design. Our teams operate with a high degree of discipline and transparency, ensuring that programs progress with clarity and minimal disruption. It's not just about moving quickly – it's about delivering what's expected, when it's expected.

Seamless transition from development to manufacturing
Continuity is a critical advantage in Late-Phase. With integrated process development and CGMP manufacturing capabilities, we reduce friction during tech transfer and scale up, helping programs move forward without unnecessary rework or delays.

Experience where it matters most
We work with a wide range of biologics programs at Late-Phase, including from Phase III through PPQ and into commercial manufacturing. This experience informs how we anticipate challenges, manage risk, and guide programs toward successful outcomes.

Let's talk about your program

If you are preparing for Late-Phase or approaching commercial readiness, we would welcome the opportunity to discuss your program and how we can support your next stage of development.

To learn more about Avid's Manufacturing lines in Tustin, California—or to schedule an introductory discussion with our technical and program leadership teams—contact us today:

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