ARTIS BIOSOLUTIONS

WHERE GENETIC MEDICINES BEGIN

How to Choose the Right CDMO

A Complete Guide for Advanced Therapy Programs

THE FIVE-PART CDMO SELECTION SERIES

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How to Choose the Right CDMO

A Complete Guide for Advanced Therapy Programs

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What Is in This Guide

Five parts, a full question bank, an RFP outline, a fill-in scorecard, and a reference glossary. Each section stands on its own, so you can jump straight to what you need.

Foreword

If you are reading this guide, you are almost certainly facing one of two situations. Either you are actively evaluating CDMOs and comparing a small set of options, or you are anticipating the decision and trying to figure out what to look for before the evaluation begins.

In either case, the same observation applies: CDMO selection is one of the highest-leverage decisions an advanced therapy program leader makes, yet it is often made with less structured guidance than it warrants. Capability decks tend to look similar. Sales conversations tend to make every CDMO sound capable of running every program. And the dimensions that differentiate strong development partners from weaker ones, scientific depth, development integration, process philosophy, partnership behavior, are difficult to evaluate in a single meeting.

This guide is our attempt to make that evaluation more structured. It is organized around the criteria we have found most reliably predictive of program success, the questions we recommend asking, and the framework we use in our own conversations on either side of these conversations.

> *The CDMO that is right for your program will demonstrate that throughout the evaluation. The one that is not, will as well, if you know what to look for.*

Who This Guide Is For

This guide is intended primarily for program leaders, CMC leads, and process development scientists responsible for selecting a CDMO for an advanced therapy program. Most of our readers work in cell therapy, gene therapy, or complex cell systems, such as stem cell programs, though the framework applies broadly to any modality in which manufacturing complexity is a meaningful component of program risk.

If you are early in your career and have not yet led a CDMO selection, the guide is also written to serve as a primer on both the structure of advanced therapy manufacturing and the dimensions that matter most when evaluating a partner.

If you are on the CDMO side, we hope this guide is useful to you as well. The criteria here are those sponsors are increasingly using, and the questions are those strong sponsors will ask. The implicit message, that scientific depth, integration, and partnership behavior matter more than facility square footage and ISO classification, is one we believe strengthens the industry.

How to Use This Book

Each of the four parts of the main framework can be read independently. If you are short on time, Part 4 (the partnership model and evaluation questions) and the Capstone (the decision framework) are the highest-leverage sections to read first. Part 1 provides the regulatory and manufacturing context that informs why the rest of the framework matters; Parts 2 and 3 build out the evaluative criteria themselves.

The Appendices are designed to be reference material you can return to during an active evaluation. Appendix A is a complete question bank, organized by category; Appendix B is an RFP template outline; Appendix C is a blank scorecard you can use to track candidates against the framework; Appendix D maps CDMO engagement to program stage; and Appendix E is a glossary of terms used throughout the book. The Resources section points to FDA guidance, industry references, and additional Artis BioSolutions materials.

Whether you read this guide cover to cover or use it as a working reference during an active evaluation, the goal is the same: a more rigorous, more confident, and ultimately more successful CDMO selection process.

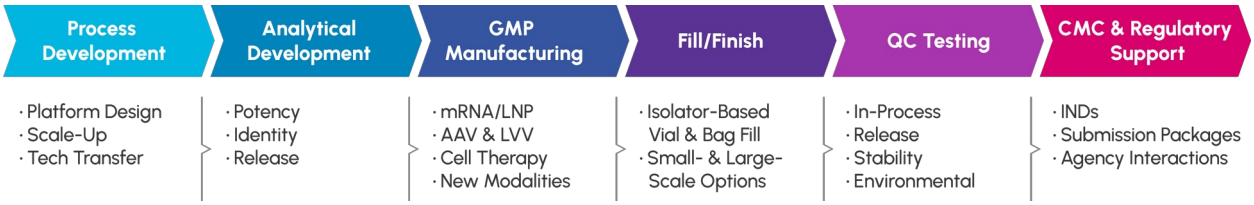
- The Artis BioSolutions Team

2026

About This Guide

Selecting a contract development and manufacturing organization (CDMO) is one of the most consequential decisions a program leader will make. The right partner accelerates timelines, strengthens regulatory position, and brings the manufacturing expertise that transforms research-grade processes into reliable clinical execution.

This guide, developed by the Artis BioSolutions team, is organized into a four-part framework that covers the full landscape of CDMO evaluation for advanced therapy programs, from understanding the manufacturing environment to asking the questions that a capability presentation cannot. A fifth capstone section translates the framework into a practical decision-making process, and five appendices provide reusable working tools for active evaluations.



The integrated path from process development through regulatory submission.

Each section can be read independently or as part of the full sequence. Whether you are evaluating CDMOs for the first time, refining an existing process, or building internal criteria for a formal RFP, this guide provides a clear, practical framework.

How the Book Is Organized

Part 1: The Advanced Therapy Manufacturing Landscape

Why manufacturing investment early in a program pays dividends throughout development. The regulatory context: what FDA data tells us about CMC risk. How to think about the relationship between process development and clinical outcomes.

Part 2: Modality Expertise and Development Integration

Why modality-specific experience is the primary filter in CDMO evaluation. What integrated teams across process development, analytics, and GMP look like. How to assess scientific depth through the evaluation process.

Part 3: Process Philosophy, Materials Strategy, and Facility Readiness

How a development-forward process philosophy shapes GMP outcomes. Why materials strategy decisions made in process development matter at the clinical stage. Facility infrastructure and quality systems: what to look for and what to ask.

Part 4: Partnership Model and the Questions That Reveal the Most

What a high-quality CDMO partnership looks like in practice. The evaluation questions that surface scientific depth and organizational maturity. How to use the evaluation process to identify the right fit for your program.

Capstone: From Evaluation to Decision

A practical scorecard for synthesizing what you have learned. A sequencing model for running the evaluation itself. Common decision pitfalls and how to avoid them.

Appendices and Resources

Appendix A: A complete bank of 60+ evaluation questions, organized by category. Appendix B: An RFP template outline for formal CDMO solicitations. Appendix C: A blank scorecard worksheet for tracking candidates against the framework. Appendix D: When to engage a CDMO at each stage of program development. Appendix E: A glossary of advanced therapy CMC terminology. Resources: FDA guidance, industry references, and additional Artis BioSolutions materials.

PART ONE

1 The Advanced Therapy Manufacturing Landscape

Understanding the environment your program operates in, before you choose a partner.

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The Advanced Therapy Manufacturing Landscape

Your science is ready. The mechanism is well-characterized, the preclinical data are compelling, and the clinical development path is coming into view. The next question, and one of the most consequential you will face, is who to bring alongside you to build the manufacturing and development infrastructure that gets your therapy to patients.

Selecting a contract development and manufacturing organization (CDMO) is both a scientific and strategic decision. The right partner accelerates your timeline, strengthens your regulatory position, and brings the manufacturing expertise that transforms research-grade processes into reliable clinical execution. A strong fit means you gain a true extension of your team: scientists and engineers who are just as invested in your program's success as you are.

Before you can evaluate a CDMO effectively, it helps to understand the environment in which your program operates. Advanced therapy development is a uniquely complex manufacturing challenge, and the regulatory landscape clearly reflects that complexity.

Why Advanced Therapies Are Different

Advanced therapies, including cell therapies, gene therapies, viral vectors, and complex cell systems such as stem cell programs, pose manufacturing challenges that are fundamentally distinct from those of traditional biologics. The biology is more sensitive, the processes are more operator-dependent, and the path from development to GMP execution requires a level of integration that many CDMOs are still building toward.

In a traditional small-molecule or recombinant-protein program, manufacturing is largely a chemistry or expression problem. You optimize conditions, validate the process, and scale. In advanced therapies, you are manufacturing living cells or biology-dependent vectors, systems that respond dynamically to process conditions, in which small deviations can meaningfully affect product quality, potency, and safety.

This means the CDMO you choose is not simply executing a defined protocol. They are a scientific partner who must understand your biology deeply enough to develop processes that are robust, reproducible, and ready for regulatory scrutiny. The distinction matters enormously when it comes time to evaluate your options.

> *The decisions made in process development directly shape the success of GMP manufacturing. The strongest programs build that foundation early, with the right team alongside them.*

What the Regulatory Data Tells Us

The FDA data on advanced therapy development makes the stakes clear. Chemistry, manufacturing, and controls (CMC) strategy is consistently among the most consequential elements in regulatory review, and programs that invest early in manufacturing infrastructure move most efficiently through that process.

74%	of FDA Complete Response Letters issued between 2020 and 2024 involved manufacturing or quality considerations, highlighting how central CMC strategy is to regulatory outcomes.
~40%	of IND submissions placed on clinical hold or requiring additional information cite CMC as a primary area for strengthening, underscoring the value of early and thorough process development.
8.4 months	is the average time required to resolve CMC-related inquiries from the FDA, compared to 4.8 months for protocol-related questions, reflecting the technical depth these reviews require.

These figures point clearly to where manufacturing investment pays off. Programs that engage deep manufacturing expertise early, build robust CMC packages, and select development partners with strong translational experience move efficiently and confidently through this landscape.

For program leaders, this data reinforces a counterintuitive truth: the CDMO selection decision is not just a manufacturing decision. It is a regulatory strategy decision. The partner you choose will shape your CMC package, your IND readiness, and your ability to respond to FDA inquiries with data-supported confidence.

How to Think About This Decision

CDMO selection is often framed as a capability question: Does this organization have GMP suites? Do they have experience in my modality? Do they have capacity? These are valid questions, but they are not sufficient. The capability baseline is table stakes.

The more useful frame is alignment. Does this organization's scientific depth, development philosophy, team structure, and partnership model align with the complexity of your program? The strongest CDMO partnerships are built on genuine scientific engagement, not just manufacturing execution.

In the sections that follow, we walk through the specific criteria that separate a translational development partner from a contract manufacturer, the questions that surface scientific depth and organizational maturity, and the practical framework for making a decision you can be confident in.

Key Questions to Bring into the CDMO Landscape

As you enter the evaluation process, a few foundational questions will help orient your thinking:

- What is the FDA's current view of manufacturing quality in programs like mine, and how does a strong CDMO address that specifically?
- What does a translational CDMO bring to a program that a standard contract manufacturer does not?
- How early in my program does CDMO selection matter, and what does early engagement change?
- What does a development partner who is genuinely invested in program success look like in practice?

These are not rhetorical questions. The best CDMOs will have direct, experience-grounded answers to all of them. In the next part, we move from the landscape to the first and most important evaluative criterion: modality-specific expertise.

PART TWO

Modality Expertise and Development Integration

2

Why direct experience with your biology matters more than any capability list.

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Modality Expertise and Development Integration

In Part 1, we established why the advanced therapy manufacturing landscape is uniquely complex and why CDMO selection is as much a regulatory strategy decision as it is a manufacturing one. In this part, we move to the first and most consequential criterion in any CDMO evaluation: modality-specific expertise.

A CDMO's overall capability profile, facility size, ISO classifications, number of GMP suites, and client roster tell you something. But it does not tell you whether the scientists who would work on your program understand your biology. That distinction is where evaluations tend to fall apart, and where the most consequential differences between CDMOs become visible.

Modality-Specific Expertise: Matching Capability to Your Biology

Advanced therapy manufacturing is not a single discipline. The expertise required to develop and manufacture a CAR-T cell therapy differs substantially from what is needed for an MSC program, a viral vector, or an iPSC-derived product. Process conditions, critical quality attributes, analytical requirements, and regulatory considerations vary meaningfully across these modalities, and experience in one does not automatically translate to competence in another.

When evaluating CDMOs, direct experience with your specific modality is among the most important criteria. This means experience that is scientific and operational, not just commercial. A CDMO that has listed your modality in their capabilities but lacks scientists who have navigated its technical complexity will struggle to be a genuine development partner when challenges arise, and in advanced therapy development, challenges always arise.

Stem cell programs illustrate why this matters. MSC and iPSC-derived products are among the most process-sensitive therapies in development. Identity, potency, and safety are all tightly coupled to process conditions, meaning that a CDMO's depth of biological understanding will

directly influence the quality of decisions made at every stage, from vessel selection and media formulation to scale-up strategy and lot release testing.

> *A CDMO with genuine depth in your modality will engage your questions with specificity and enthusiasm, drawing on real program experience rather than describing general manufacturing capabilities.*

Productive Questions for the CDMO Evaluation

The following questions are designed to surface whether a CDMO has genuine depth in your modality, or is extending a general manufacturing capability into a space where their scientific experience is more limited:

Program Experience

"What programs in this specific modality has your team taken from process development through GMP manufacturing?" The answer you are looking for is specific: named program types, key process challenges encountered, how they were resolved, and what the team learned. General statements about capability without specific program experience should be weighted accordingly.

Regulatory Outcomes

"Have you supported IND filings in this modality? What does your CMC track record look like?" Regulatory experience in your modality demonstrates scientific depth. A CDMO that has taken programs through the IND process understands what the FDA looks for and how to build a CMC package that holds up under review.

Scientific Depth

"What are the most technically challenging aspects of this biology, and how does your team approach them?" This is the question that most reliably distinguishes genuine expertise from described capability. Scientists who know your biology will engage this question with specificity and with the kind of candor that comes from having worked through real problems.

Pay attention not just to what the CDMO says, but how they say it. Genuine expertise has texture, specific examples, acknowledgment that the science is still evolving, and clear reasoning about trade-offs. The absence of that texture is informative.

Integration Across Process Development, Analytics, and GMP

One of the clearest structural differentiators between CDMO partners is whether process development, analytical development, and GMP manufacturing operate as a genuinely integrated team, or as sequential handoffs between separate groups.

In the handoff model, process development builds the process and documents it, then transfers it to an analytical team that develops the assays, who then transfer the package to GMP for

execution. At each transition, institutional knowledge is compressed into documentation, and the scientists who developed the process become less available. When questions arise during GMP execution, the team that runs the manufacturing run may not have full visibility into why certain decisions were made.

In an integrated model, these functions work together from the start. The analytical scientists who develop release assays are informed by process development data as it is generated. The GMP team participates in late-stage process development so that manufacturing execution is informed by direct experience, not only documentation. And when technical questions arise during clinical runs, the scientists with the deepest process knowledge are already part of the team.

> *Integration does not simplify the science. It means the full complexity is visible and managed from the start, with the right people already informed.*

The implications for program outcomes are significant. Integrated development produces more robust processes because the people asking the analytical questions are the same people who understand the process. It produces faster timelines because the iterative loop between process development and analytical development is compressed. And it produces stronger GMP execution because the team has continuity from development through clinical manufacturing.

What to Look for in an Integrated CDMO Model

When evaluating a CDMO's integration model, look for evidence rather than description. A few indicators worth probing:

Signs of Genuine Integration

The scientists who developed the process are still engaged through GMP execution, not just available for questions. Assay development timelines are explicitly aligned with process development milestones, not treated as sequential. GMP staff participate in late-stage development activities, so execution is informed by direct experience. Technical questions during manufacturing runs go directly to the development scientists, not through a project management layer. The program team you meet during evaluation is the team that would run your program.

This last point is worth emphasizing. The scientists who participate in your evaluation conversations should be representative of the team that would work on your program, not a presentation team assembled for business development purposes. The quality of that scientific conversation is among the most useful data points in the entire evaluation.

Assessing Integration During the Evaluation

Ask the CDMO to walk you through how a program moves from process development to GMP execution. Listen to how they describe the transitions. Do they describe them as handoffs or as a continuous process with the same core team? Do they describe cases where analytical development and process development ran in parallel, and how they coordinated? Do GMP scientists participate in that explanation?

The most revealing question on integration is often a simple one: "Who is in the room when a technical question arises during a GMP run, and how does that work?" The answer tells you a great deal about whether the CDMO's integration model is structural or aspirational.

PART THREE

Process Philosophy, Materials Strategy, and Facility Readiness

3

The operational foundations of a strong CDMO partnership.

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Process Philosophy, Materials Strategy, and Facility Readiness

In Part 2, we explored modality-specific expertise and the structural importance of development integration. In this part, we go deeper into two additional dimensions that distinguish the strongest CDMO partners: the process development philosophy they bring to your program, and the facility and quality infrastructure that supports clinical manufacturing.

These are not abstract criteria. They are the factors that determine whether your first GMP run goes smoothly, whether your IND package holds up under FDA review, and whether the manufacturing partner you have chosen is genuinely ready for the complexity of your program.

Process Development Philosophy: Building for GMP from Day One

Indicators of a Development-Forward Process Philosophy

How to tell a partner who builds for GMP from day one from one who prepares for it later.

- **CPPs defined at the RUO stage**
  Critical process parameters are identified early, establishing the scientific foundation for GMP process control.
- **Every vessel transition evaluated first**
  Flask to bag to bioreactor: each change is assessed for biological implications before it is made.
- **Scale increases assessed in full**
  Downstream and fill / finish impact is considered before any GMP commitment, not after.
- **Teams trained at scale before the run**
  Manufacturing teams are prepared at the relevant scale, so execution is informed from the first GMP run.
- **Documentation built GMP-ready**
  Decisions are recorded with GMP readiness in mind, reducing the documentation burden at tech transfer.

The approach a CDMO takes to process development tells you a great deal about how manufacturing will go. There is a significant difference between a CDMO that develops a process and then prepares it for GMP, and one that builds GMP readiness into every stage of development from the beginning.

The strongest development partners operate from the second model. They evaluate process changes, vessel transitions, and scale increases with the full clinical manufacturing context in

mind from the outset. They define critical process parameters during the research-use-only stage, so that the process understanding on which GMP execution depends is established before scale-up decisions are made. They treat every phase of development as preparation for the phase that follows.

This philosophy shows up in specific operational practices:

Indicators of a Development-Forward Process Philosophy

Critical process parameters (CPPs) are identified during RUO stage, establishing the scientific foundation for GMP process control. Every vessel transition, from flask to bag to bioreactor, is evaluated for biological implications before the change is made. Scale increases are assessed for full operational impact, including downstream and fill/finish considerations, before GMP commitment. Manufacturing teams are trained at the relevant scale prior to GMP runs, so execution is informed and consistent from the first run. Process development decisions are documented with GMP readiness in mind from the start, reducing documentation burden at technology transfer.

The practical difference this philosophy makes becomes visible at scale. Consider what scaling an iPSC program from four vessels to eight involves. It is not simply an increase in capacity. It represents a meaningfully different manufacturing day, with different processing timelines, expanded downstream operations, and greater demands on team coordination. A CDMO that approaches this with thorough pre-run analysis and structured operator preparation executes reliably. One that treats scale-up as primarily a logistical exercise works through those details as they arise, during GMP execution, under time pressure, with your program on the line.

> *A development-forward process philosophy means every question about scale, materials, and process control is answered before GMP execution begins, not during it.*

Questions That Surface Process Development Philosophy

These questions are particularly useful for assessing how a CDMO approaches the development-to-GMP transition:

- At what stage do you typically define critical process parameters, and what does that process look like in practice?
- Walk us through your approach to a vessel transition. What does the evaluation process look like before you move forward?
- How do you structure process development activities so that GMP teams have direct familiarity with the process before manufacturing begins?
- Can you describe a program where a process decision made in early development had a meaningful impact on GMP execution, either positively or as a lesson learned?

A CDMO with a genuinely development-forward philosophy will engage with these questions with the specificity that comes from having consistently built processes this way.

Materials Strategy: Designing for Clinical Manufacturing from the Start

Materials qualification is one of the most impactful and most frequently underestimated decisions in early process development. Research-grade materials that work well in the laboratory often require replacement or requalification before clinical manufacturing, because the sourcing, testing, and documentation requirements for GMP-grade materials are fundamentally different.

When this transition is left to the technology transfer stage, it creates real problems. Swapping a critical raw material at that point can require partial or full process re-characterization, disrupting timelines and generating regulatory complexity. Addressing it during process development, with full process context available, means the bill of materials is GMP-ready from the first clinical run.

A CDMO with strong translational expertise will approach materials strategy proactively and comprehensively:

What a Strong Materials Strategy Looks Like

Clinical-grade raw material equivalents are evaluated as part of process development, not introduced at the technology transfer stage. Residual testing and clearance assessments are incorporated into process design as a planned element, aligned with lot release requirements. In-house CMC and regulatory specialists are positioned to anticipate FDA requirements and build them into the development plan from the outset. The bill of materials is reviewed with GMP readiness in mind at each development milestone, not only before the transition to manufacturing. Suppliers for critical raw materials are identified and qualified as part of the development timeline.

Materials strategy is an area where engaging a CDMO early in development pays particularly high dividends. The decisions made about sourcing, qualification, and documentation in the research phase establish the supply chain and regulatory foundation for clinical manufacturing. A CDMO that treats materials strategy as a development-phase priority, rather than a transfer-phase problem, gives your program a meaningful structural advantage.

Facility Infrastructure and Quality Systems

A CDMO's physical infrastructure and quality management systems are the foundation on which everything else rests. Before selecting a partner, it is worth understanding both in detail and going beyond the capability deck to ask the specific questions that reveal operational maturity.

Facility Considerations

Suite classification and availability. What is the ISO classification of the GMP suites, and how many independent suites are available for your program? Programs that require long development timelines or multiple manufacturing runs benefit from dedicated suite access; shared suite environments introduce scheduling complexity that can affect timelines.

Modality support. Does the facility genuinely support your specific program type, including the specific culture formats, process equipment, and fill/finish capabilities your biology requires? Modality support at the marketing level and modality support at the operational level are not always the same thing.

Capacity and scheduling. What is the current capacity outlook and typical program scheduling lead time? A CDMO with strong demand may have significant lead times for GMP suite access, which will affect your program planning.

Quality and Regulatory Considerations

Audit track record. Has the facility been audited by sponsors for GMP manufacturing and release testing? What has the experience of those audits been like? A track record of successful sponsor audits is evidence of operational maturity, not just documented processes, but processes that hold up under external scrutiny.

FDA engagement. Has the CDMO engaged directly with the FDA through a Pre-IND, Type B, or Design Review Meeting for programs in your modality? What came from those engagements, and how has that feedback shaped the CDMO's approach? Direct FDA engagement is a meaningful indicator of regulatory depth and the ability to anticipate review requirements.

QMS maturity. Is the quality management system mature and operating at scale, or still in active development? For programs targeting IND filing within 12 to 18 months, a CDMO whose QMS is still being built out represents material risk.

PART FOUR

Partnership Model and the Questions That Reveal the Most

4

How to tell whether a CDMO is actually the right fit.

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Partnership Model and the Questions That Reveal the Most

In the first three parts of this guide, we covered the manufacturing landscape for advanced therapies, the importance of modality-specific expertise and development integration, and the process philosophy and infrastructure criteria that distinguish the strongest CDMO partners. In this part, we turn to the two remaining dimensions: the partnership model and the evaluation questions that surface what formal presentations rarely do.

These are the criteria that are most difficult to assess from a capability document and most important to get right. Capability infrastructure can be described on a slide. Partnership quality is revealed through conversation, behavior, and the character of the answers a CDMO gives when questions become specific.

Partnership Model: What Working Together Actually Looks Like

Beyond capabilities and infrastructure, the character of a CDMO partnership significantly influences program outcomes. The difference between a partner who executes what you specify and a partner who brings a scientific perspective to every program decision is not marginal. In advanced therapy development, where the science is complex and the challenges are real, that difference shows up in how quickly problems are identified, how reliably manufacturing runs go, and how confidently you can respond to regulatory inquiries.

The most productive CDMO relationships share a set of structural characteristics that are worth looking for explicitly during the evaluation:

Characteristics of a High-Quality CDMO Partnership

The CDMO brings scientific perspective to program decisions, offering clear recommendations, identifying tradeoffs, and sharing the reasoning behind their approach. You have direct access to the scientists running your program, not just project managers or account leads. Communication is proactive: the CDMO surfaces questions and concerns before they become problems, not after. The engagement model is flexible enough to support your program wherever you are, first-time process development, IND preparation, or GMP scale-up. Program team continuity: the scientists you meet during evaluation are the scientists who would work on your program.

That last point deserves emphasis. In the evaluation process, you will spend time with scientists who are enthusiastic, knowledgeable, and engaged. The question worth asking explicitly is whether those individuals would be assigned to your program or whether a different team takes over once the contract is signed. This happens more often than program leaders expect, and it is worth surfacing directly.

> *Ask to speak directly with the scientists who would be assigned to your program. The depth and quality of that conversation is often the most informative part of the evaluation.*

Evaluating Partnership Quality Before the Contract

Partnership quality is not observable from a capability presentation, but it is observable from how a CDMO engages during the evaluation. Pay attention to the following:

How do they handle hard questions? A partner who responds to difficult technical questions with specificity and candor, including acknowledgment of the limits of their experience, is demonstrating the communication style that you will depend on when challenges arise. Deflection or vague reassurance is a signal.

How do they approach disagreement? Ask them directly: "How does your team handle a situation where the scientifically preferred path differs from the sponsor's initial direction?" The answer reveals their willingness to advocate for the science, their communication style under tension, and whether they operate as a genuine partner or as a service provider.

How do they describe the programs that did not go perfectly? Every experienced CDMO has worked through programs with technical challenges. The way they describe those experiences, whether they engage them with honesty, reflect on what they learned, and explain how their approach changed, tells you about their organizational culture. Reluctance to acknowledge past challenges is worth noting.

The Questions That Reveal What a Capability Presentation Cannot

The following questions are consistently useful across CDMO evaluations, regardless of modality or program stage. They are designed to surface scientific depth, process maturity, and

organizational culture in ways that formal presentations rarely do. Use them as conversation starters; the goal is not a scripted answer, but a genuine exchange that reveals how the team thinks.

On Scientific Depth and Program Experience

"Share an example of a technically complex program your team has worked through. What made it challenging, and what did the team learn from it?"

This question works because it invites the CDMO to speak from experience. Specificity, candor, and reflection are good signs. Generic answers about embracing complexity or experienced teams are not. Listen for the scientific content of the answer, whether the challenge described is genuinely technical, whether the team's response demonstrates analytical rigor, and whether there is a clear through-line from challenge to learning to practice change.

On Process Development Philosophy

"At what stage do you typically define critical process parameters, and what does that process look like in practice?"

The right answer here is early. CPP definition during the RUO stage is a hallmark of a development-forward philosophy. If the CDMO describes the CPP definition as part of the GMP process itself or as occurring during technology transfer, that is a signal of their development approach.

On Technology Transfer and Transparency

"Walk us through your technology transfer process. What does the sponsor see at each stage, and where are the key decision points?"

This question reveals two things: the operational maturity of the CDMO's transfer process, and their transparency model with sponsors. A CDMO with a well-structured technology transfer will clearly describe it, identify decision points, and explain how sponsor visibility is maintained throughout. One that describes technology transfer as primarily a documentation exercise may be less oriented toward partnership.

On Problem-Solving and Root Cause Analysis

"How does your team approach process investigation and root cause analysis when a manufacturing run does not go as expected?"

Manufacturing challenges happen. The question is how a CDMO responds when they do. Look for a structured approach: clear escalation paths, defined investigation protocols, and a culture of rigorous root cause analysis rather than anecdotal troubleshooting. Ask for a specific example. The process by which a team works through a difficult run tells you as much about their capabilities as the run that goes perfectly.

On FDA Engagement and Regulatory Depth

"What has your FDA engagement on programs in this modality looked like, and how has that feedback shaped your approach?"

CDMOs with genuine regulatory depth have a track record of FDA engagement that they can speak to specifically, pre-IND meetings, design review meetings, and responses to CRL questions. They also have a clear view of how that engagement has informed their development and manufacturing approach. This is not a common capability; a CDMO that can speak to it with specificity has earned a meaningful differentiator.

PART FIVE

From Evaluation to Decision: A Practical Framework

5

Turning the framework into a decision you can stand behind.

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Capstone: From Evaluation to Decision

Over the four parts of this guide, we have built a complete framework for evaluating a CDMO for advanced therapy development. The remaining question is the most important one: how do you turn that framework into a decision?

By the time you finish a CDMO evaluation, you will have absorbed a lot of information from a small number of organizations. The challenge is not gathering more data. It is organizing what you have learned in a way that makes the right partner visible. What follows is the framework we recommend: a scorecard for synthesizing the evaluation, a sequencing model for the evaluation process, and a short list of decision pitfalls to avoid.

The Evaluation Scorecard

The seven criteria below cover the dimensions developed across this guide. The weighting reflects our view of relative importance for advanced therapy programs at the IND-enabling stage. Adjust weighting for your specific program context: a viral vector program will weight different criteria than a stem cell program; a tech transfer engagement will weight different criteria than first-in-modality process development.

Criterion	Weight	What Strong Looks Like	What Should Concern You
Modality expertise	High	Specific named programs in your modality taken through IND.	General capability claims with no concrete program references.
Development integration	High	Same scientists from PD through GMP; analytics in parallel.	Sequential handoffs; documentation-as-transfer.
Process philosophy	High	CPPs defined in RUO; vessel transitions evaluated up front.	CPPs deferred to GMP; scale-up treated as logistics.
Materials strategy	Medium-High	Clinical-grade equivalents qualified in development.	Materials revisited at tech transfer, not in development.
Facility & QMS	Medium-High	Mature QMS, sponsor-audited, FDA-engaged.	QMS still being built; no sponsor audit history.
Partnership model	High	Direct scientist access; proactive communication.	Account leads as primary interface; presentation team ≠ program team.

Criterion	Weight	What Strong Looks Like	What Should Concern You
Cultural fit	Medium	Candor about prior challenges; clear reasoning.	Defensive about programs that did not go perfectly.

Use the scorecard as a conversation tool, not a spreadsheet. The signals in the right two columns are the kind of evidence you should be able to point to from your evaluation conversations. If you cannot, you do not yet have enough data on that criterion. (A blank version of this scorecard, structured as a worksheet you can fill in for each CDMO candidate, is provided in Appendix C.)

> *The decision becomes easier when the criteria are explicit. Most difficult CDMO decisions are difficult because the criteria were never named clearly enough to compare candidates against.*

Sequencing the Evaluation

How you sequence the evaluation matters as much as which criteria you assess. A common pattern, capability deck first, then technical conversation, then pricing, then references, tends to give CDMOs the format they are most prepared for. A more discriminating sequence puts scientific conversation earlier and gives the evaluation more signal per hour invested.

Stage 1: Modality fit and scientific conversation

Start with a structured technical conversation. Bring two or three of the modality-specific questions from Part 2 of this guide, and one or two of the process philosophy questions from Part 3. Ask to speak with the scientists assigned to your program, not the BD lead. The depth and texture of this conversation is the single highest-leverage data point in the evaluation.

Stage 2: Integrated capability assessment

Once the scientific conversation has established that the CDMO is a credible candidate, move to capability. Walk through the facility, equipment, QMS, regulatory history, and team structure. Treat this as confirmation of what was suggested by the scientific conversation, rather than as a separate evaluation track. Capability without scientific depth is not enough; scientific depth without capability is not enough either.

Stage 3: Partnership and process

Ask the partnership questions from Part 4 directly. How does the team handle disagreement? Who is in the room during a GMP investigation? How do they describe a program that did not go perfectly? This stage is about how the CDMO will operate, not what they can do.

Stage 4: References and confirmation

Save references for last and ask specific questions when you call them. Generic reference checks rarely produce useful information. Ask references about the specific dimensions where you still have uncertainty: how the CDMO handled a technical setback, whether the team you met during evaluation stayed on the program, and how regulatory questions were navigated.

Decision Pitfalls Worth Avoiding

A few patterns recur in CDMO selection decisions that go badly. They are worth naming because they are easy to fall into:

Mistaking capability for fit. A CDMO can be highly capable and still not be the right partner for your program. Capability is a necessary condition. Modality fit, integration, and partnership quality determine whether the capability translates into program outcomes.

Optimizing for the lowest stage-gate cost. Cost matters, but the cost of a program that runs for 8 months because of a CMC question is far higher than the cost differential between two CDMOs. Evaluate cost in the context of expected timeline and regulatory risk, not in isolation.

Underweighting program team continuity. The team you meet during evaluation may not be the team that runs your program. This is one of the most consequential and most under-asked questions in CDMO selection. Surface it explicitly.

Skipping the difficult-program question. Every experienced CDMO has worked through programs that did not go as planned. The way they describe those experiences is among the most informative signals in an evaluation. Skipping the question, or accepting a polished non-answer, removes one of the few windows into how a partner behaves under pressure.

Confusing enthusiasm with depth. Enthusiastic generalities are easy. Specific, scientific, candid answers are harder to produce and more informative. Calibrate on the texture of the answers, not the energy of the conversation.

When You Have Enough to Decide

You have enough to decide when, for each of the seven scorecard criteria, you can point to a specific moment in the evaluation that informed your view. Not a general impression, a moment. A scientist's answer to a specific question. A facility tour observation. A reference call detail. A way the CDMO handled a follow-up request.

If you cannot point to those moments, the next evaluation step is not another presentation. It is a targeted conversation with the right people about the specific criteria for which you do not yet have evidence.

The decision itself, when it comes, tends to feel less like a tradeoff and more like recognition. The right partner for your program will have shown you who they are throughout the evaluation. Trust what you have seen.

Choosing the Partner That Fits Your Program

The strongest CDMO partnerships share a consistent set of characteristics: genuine modality expertise, seamless integration across development and manufacturing, a process philosophy built for clinical execution from the start, and a collaborative approach that makes your team more capable throughout the engagement.

Programs that move efficiently from development to clinic do so because their manufacturing partner understands the science, anticipates the complexity, and brings the experience to execute reliably at every stage. A capability presentation can describe these qualities. The evaluation process is how you find out whether they are real.

Use the questions in this guide and the criteria across all five sections to build an evaluation process that surfaces what you need to know. Ask for program-specific examples. Request time with the scientists, not just the project leads. Push on the hard questions. And pay attention not just to what a CDMO says, but to how they engage.

The CDMO that is right for your program will demonstrate that throughout the evaluation. The one that is not will, too.

WHO WE ARE

About Artis BioSolutions

Artis BioSolutions partners with advanced therapy developers across process development, analytical development, GMP manufacturing, and IND-enabling CMC support. Our integrated team draws on deep drug development expertise across process development, analytical science, quality, and regulatory affairs, working as a true extension of your organization at every stage of the program.

If your program is in cell therapy, gene therapy, viral vector development, or complex cell system development, we would welcome a conversation about whether the framework in this guide, applied to our team, our facility, and our scientific depth, supports your program's needs. The evaluation criteria in this book are the criteria we believe should be applied to any CDMO partner, including us.

OUR LOCATIONS

An Integrated US and EU Platform

Boston, MA, Advanced Therapy Hub

- 44,000 sq ft purpose-built facility, opened in 2022 within Boston's life sciences and hospital ecosystem
- 14,000 sq ft of GMP cleanroom space across 9 suites (8 ISO 7, 1 ISO 8)
- Cell therapy, viral vector, and complex cell system programs including stem cells and CAR-T
- Large-scale processing up to 200L in stirred-tank bioreactors
- Isolator-based fill/finish with closed robotic vial filling
- In-house bioanalytical and microbiology QC, cGMP warehousing, and controlled-rate freezing
- FDA Design Review Meeting completed, with a track record of successful sponsor audits

Bilbao, Spain, Synthetic DNA

- 37,000 sq ft production facility for cell-free synthetic DNA manufacturing
- Proprietary enzymatic production platform, no plasmid dependency at any stage
- 4 cGMP processing suites, 1 fill/finish suite, and 8 preclinical and R&D labs
- Gram-scale DNA production capacity
- GMP-ready synthetic linear DNA, whether DNA is the therapeutic product or the starting material

FAQ

Frequently Asked Questions

The following questions are the most frequently asked by program leaders evaluating CDMOs for advanced therapy programs. They are grouped here as a reference and complement to the criteria covered in this guide.

What makes a CDMO well-suited for advanced cell and gene therapy programs?

The most important qualities include direct experience with your specific modality, integrated teams across process development, analytical development, and GMP manufacturing, a development philosophy that builds GMP readiness from the earliest stages, a qualified materials strategy developed in process development rather than at the transfer stage, and a partnership model that provides direct access to the scientific team throughout the program. For complex biology, such as stem cells, depth of process understanding and the ability to anticipate scale-related complexity are particularly valuable.

How do CMC considerations affect IND timelines?

CMC strategy directly influences IND timelines. Programs with well-developed process characterization, qualified materials, validated analytical methods, and clear regulatory alignment tend to move through FDA review efficiently. Engaging a CDMO with strong CMC and regulatory expertise early in development allows these elements to be built into the program from the start, rather than addressed reactively during the IND preparation phase.

What is the difference between a translational CDMO and a standard contract manufacturer?

A translational CDMO integrates process development, analytical development, and GMP manufacturing as a unified capability, with teams that work together from early development through clinical execution. A standard contract manufacturer typically performs manufacturing according to processes provided by the sponsor. For advanced therapies, the translational model offers significant advantages in process understanding, regulatory readiness, and resolving technical questions at any stage of the program.

When is the right time to engage a CDMO for a cell therapy program?

The most productive CDMO engagements begin at or before the process development stage. The decisions made in process development, including cell source selection, vessel strategy, raw material qualification, and analytical method development, establish the foundation for GMP manufacturing. Engaging a CDMO at this stage means those decisions are made with clinical manufacturing requirements fully in view. CDMOs can also add meaningful value at later stages, including technology transfer, GMP scale-up, and IND-enabling manufacturing. See Appendix D for a stage-by-stage view of when CDMO engagement adds the most value.

What questions should I ask a CDMO during evaluation?

Productive evaluation questions include: What programs in my specific modality has your team taken from development to GMP? Can you describe a technically complex program and how your team navigated it? How do you approach critical process parameter identification, and at what stage? What does your technology transfer process look like in practice? How has your team engaged with the FDA on programs in this modality, and what has that experience looked like? Appendix A provides a complete bank of evaluation questions organized by category.

What does a risk-informed approach to GMP scale-up look like?

A risk-informed approach means that every change, whether in vessel count, culture format, batch size, or process step, is evaluated for its biological and operational implications before implementation. This includes defining critical process parameters during development, assessing scale assumptions with downstream considerations in mind, and ensuring operators are trained and prepared at the new scale before GMP runs begin. The result is GMP execution that is well-characterized and consistently reproducible.

What should I expect in terms of timelines for CMC-related FDA review?

CMC-related questions from the FDA typically require more time to address than protocol questions, given the technical depth involved. Industry data indicate that CMC inquiries take an average of 8.4 months to resolve, compared to 4.8 months for protocol questions. The most effective programs build their CMC packages carefully during development with thorough process characterization, validated analytical methods, qualified raw materials, and clear regulatory documentation, so that FDA review can proceed efficiently and any questions can be addressed with well-developed, data-supported responses.

How does the scorecard adapt to different program stages?

The relative weighting of criteria shifts depending on where your program is. For a program entering process development for the first time, modality expertise, development integration, and process philosophy are the most heavily weighted dimensions; you are choosing a partner to build the process with you. For a tech transfer engagement, facility readiness, materials strategy, and QMS maturity move higher in priority; the process is largely defined, and execution risk dominates. For a late-stage program scaling to commercial, facility capacity, quality systems, and supply chain depth become foundational. The criteria themselves do not change; their weights do.

What if we are evaluating CDMOs, but our process is not yet defined?

This is in many ways the ideal time to engage a CDMO. The decisions made during process development establish the foundation for everything that follows, and a translational CDMO contributes most when they are involved in those decisions rather than handed a finished process. If you are early, prioritize partners whose scientific depth and development integration are strongest. The capability infrastructure becomes more decisive later; the development partnership matters most now.

APPENDIX A

The Complete Question Bank

The questions below are organized into ten categories that together cover the dimensions developed throughout this guide. They are designed to be used flexibly, selected for the specific evaluation, sent in advance of meetings as an RFP supplement, or kept on hand during conversations as a reference.

A few notes on use. First, do not ask all of them. A typical evaluation meeting can productively cover six to ten of these questions; sending the rest as written follow-ups is more useful than rushing through them in person. Second, pay attention to how the CDMO routes the questions internally, who answers each one, tells you something about how their organization is structured and where the depth lives. Third, the most informative questions are the ones that invite specific stories rather than positions; weigh those answers accordingly.

Category 1: Modality and Scientific Experience

1. What programs in our specific modality have your team taken from process development through GMP manufacturing?

2. What are the most technically challenging aspects of our biology, and how does your team approach them?

3. How many programs in this modality are currently active in your facility, and what stages are they at?

4. Have any of those programs gone through full IND-enabling activities with you? What was the CMC outcome?

5. Where is the boundary of your modality experience? Are there subtypes within this modality where your experience is limited or evolving?

6. What scientific publications, conference presentations, or regulatory engagements has your team contributed to in this area?

Category 2: Development Integration

7. How are your process development, analytical development, and GMP teams organized? Are they one team, or separate functions that hand off to each other?

8. When a technical question arises during a GMP run, who is in the room, and how does that work in practice?

9. Walk us through a recent program where assay development ran in parallel with process development. How did the teams coordinate, and what did that produce?

10. Are the scientists who develop our process the same scientists who would be present at GMP execution?

11. How is institutional knowledge preserved between process development and clinical manufacturing on a long-running program?

Category 3: Process Development Philosophy

12. At what stage do you typically define critical process parameters, and what does that process look like in practice?

13. Walk us through how you approach a vessel transition. What is evaluated before you move forward?

14. How do you evaluate a proposed scale increase before committing to it for a GMP run?

15. Can you describe a program where a decision in early development had a meaningful impact on GMP execution, positive or negative?

16. How are GMP teams trained at the relevant scale before manufacturing begins?

17. What does process characterization documentation look like at the end of your development phase? Can we see a redacted example?

Category 4: Analytical and Release Strategy

18. When are analytical methods developed and qualified relative to process development milestones?

19. How do you handle potency assay development for a program in our modality? What is your typical timeline?

20. What is your approach to identity, purity, and safety testing for advanced therapy products?

21. How are reference materials and control standards established for a new program?

22. What analytical methods do you outsource versus run in-house, and what is the rationale?

Category 5: Materials Strategy

23. At what stage do you evaluate clinical-grade equivalents for research-grade raw materials?

24. How are residual testing and clearance assessments built into process design?

25. Who manages supplier qualification for critical raw materials, and what does that process look like?

26. What is your contingency plan if a key raw material becomes unavailable mid-program?

27. How is the bill of materials reviewed across the development-to-GMP transition?

Category 6: Facility, Equipment, and Capacity

28. What is the ISO classification of the GMP suites that would support our program, and how many independent suites would be available?

29. What culture formats, process equipment, and fill/finish capabilities does the facility support for our specific biology?

30. What is the current capacity outlook for our intended start date, and what is the typical scheduling lead time?

31. Are GMP suites dedicated to a single program at a time, or shared, and how is changeover managed?

32. How is environmental monitoring designed, and how does it interact with our specific manufacturing operations?

Category 7: Quality and Regulatory

33. Is your quality management system fully operational at scale, or still in active development? What recent improvements have been made?

34. Has the facility been audited by sponsors for GMP manufacturing and release testing? What were the outcomes?

35. Has the CDMO engaged directly with the FDA through a Pre-IND, Type B, or Design Review Meeting for programs in our modality? What came of those engagements?

36. How has FDA feedback in this modality shaped your development and manufacturing approach?

37. What is your approach to handling deviations during GMP manufacturing? Can you walk us through a recent example?

38. How is regulatory documentation structured across the development-to-GMP transition?

Category 8: Partnership Model and Communication

39. Who would be our primary scientific contact, and how often would we expect to interact with the scientists working on our program?

40. How is communication structured between the sponsor and CDMO during active development?

41. How do you handle a situation where the scientifically preferred path differs from the sponsor's initial direction?

42. What does proactive communication look like in your model? Can you give us an example of a concern that was surfaced before it became a problem?

43. How is program team continuity managed across development and GMP phases? Is the team we meet during evaluation the team that would run our program?

44. What governance structure do you propose for our program, and how do decisions get escalated?

Category 9: Problem-Solving and Resilience

45. Share an example of a technically complex program your team has worked through. What made it challenging, and what did the team learn from it?

46. How does your team approach process investigation and root cause analysis when a manufacturing run does not go as expected?

47. Describe a program that did not go perfectly. What happened, and what changed in your approach as a result?

48. What is your escalation path when a GMP run encounters a critical excursion?

49. How are out-of-specification investigations structured, and what does the sponsor see throughout that process?

Category 10: Commercial Terms and Engagement

50. What does your typical engagement model look like for a program at our stage?

51. What flexibility is there in scope as the program evolves? How are scope changes priced and approved?

52. What is included in standard pricing, and what is treated as out-of-scope?

53. How are intellectual property rights handled around process improvements developed during the engagement?

54. What does your standard quality agreement and technical agreement look like? Are there modifications you would suggest for our modality?

55. What is your view on the right cadence of governance meetings and program reviews?

Reference Call Questions

When you reach the reference stage of an evaluation, generic questions produce generic answers. The following are designed to surface specific, useful information from sponsors who have worked with the CDMO.

56. How did the team you met during the evaluation compare with the team that ran your program?

57. Describe a moment during the program when something did not go as expected. How did the CDMO respond?

58. How was scientific communication handled? Did you have direct access to the scientists when you needed it?

59. How were regulatory questions navigated? Did the CDMO bring meaningful expertise to FDA interactions?

60. If you were starting the evaluation over again, what would you have weighted more heavily? What would you have weighted less?

61. Would you select this CDMO again for a similar program? Why or why not?

These questions are not a checklist to work through end-to-end. They are a library to draw from, depending on where you are in the evaluation and which dimensions still need evidence. The Capstone scorecard in the main framework provides the structure for organizing the answers you collect.

APPENDIX B

RFP Template Outline

This appendix provides an outline for a CDMO Request for Proposal (RFP). It is designed for advanced therapy programs and structured to elicit responses on the dimensions developed throughout this guide. The outline is intentionally structural rather than literal; the goal is to help you build an RFP that surfaces what you need to know, not to prescribe specific wording.

RFPs do not always make sense at every stage. For early process development engagements, a more conversational evaluation is often more productive than a formal RFP. For tech transfer engagements, IND-enabling manufacturing, or any program with a defined scope of work and a meaningful number of viable candidates, the RFP format is helpful, both because it standardizes comparisons and because it forces clarity on what the program actually needs.

Section 1: Program Background

The opening section orients the CDMO and sets the context for the proposal. It should include sufficient information for the CDMO to scope their response accurately, without disclosing more than is appropriate at this stage.

- Brief description of the therapeutic program, modality, and target indication.
- Current development stage and recent milestones.
- Anticipated regulatory pathway and target IND filing date, if known.
- Sponsor profile: organization size, prior CDMO engagements, internal team structure.

Section 2: Scope of Work

Describe what you are asking the CDMO to do. The clearer this section is, the more comparable the responses will be. For advanced therapy programs, the scope typically falls into one or more of the following categories:

Process development. Cell source selection, process design, vessel strategy, scale-up assumptions, analytical development.

Analytical development and QC. Method development and qualification, release assay strategy, stability program design.

GMP manufacturing. Number of runs, scale, format, fill/finish requirements, and expected timeline.

CMC and regulatory support. IND CMC section authoring, regulatory strategy, and FDA engagement support.

Technology transfer. Inbound transfer from sponsor or another CDMO; outbound transfer to a future commercial partner.

Section 3: Capability Information Requested

This section asks the CDMO to provide structured information about their organization. The questions below mirror the criteria developed in this guide:

- Direct experience in the specific modality, including named program types, stages reached, and regulatory outcomes.
- Team structure across process development, analytical development, QC, and GMP, and the degree of integration between them.
- Facility infrastructure: ISO classifications, number of suites, modality-specific equipment, fill/finish capability, capacity outlook.
- Quality management system maturity and recent audit history (sponsor audits and regulatory inspections).
- FDA engagement history relevant to the modality, including pre-IND, Type B, or design review meetings.
- Partnership model: governance structure, communication cadence, scientific access, and program team continuity.

Section 4: Technical Approach Requested

Ask the CDMO to describe how they would approach the specific program, not just what they could do in general. This is where strong CDMOs differentiate themselves; it is also where the gap between capability and fit becomes visible.

- Proposed process development plan, including critical process parameter identification approach and key technical risks.
- Materials strategy: research-to-clinical-grade material qualification, residual testing strategy, supplier qualification approach.
- Analytical strategy: assay development timeline, release method strategy, stability program design.
- Scale-up plan: proposed scale increases, vessel transitions, and operator training approach.
- Tech transfer plan: phasing, milestones, sponsor visibility at each stage.
- Regulatory strategy: anticipated CMC challenges, planned FDA interactions, and IND timing alignment.

Section 5: Team and Continuity

This section is often underweighted in RFPs, but it is among the most predictive of program outcomes.

- Proposed program team: roles, individuals, and time allocations.
- Continuity assurance: which proposed team members would remain on the program from PD through GMP.

- Scientific access model: how the sponsor would interact with the technical team during active development.
- Coverage and contingency: how the CDMO would handle key-person continuity risk during a long-running engagement.

Section 6: Commercial Terms

Commercial terms are necessary, but they should not be the first thing in the RFP, and they should not be evaluated in isolation from the technical and partnership dimensions above.

- Pricing structure for the proposed scope, with clear delineation of in-scope and out-of-scope activities.
- Payment milestones and scheduling assumptions.
- Treatment of scope changes, including pricing methodology and approval process.
- Intellectual property terms relevant to process improvements developed during the engagement.
- Standard quality agreement, technical agreement, and any proposed modifications for the modality.

Section 7: Process and Timing

This section sets expectations for the evaluation process itself:

- RFP response deadline.
- Anticipated evaluation timeline, including any technical conversations, facility visits, and reference calls.
- Decision criteria and weighting (in summary form).
- Target decision date.
- Primary contact for clarifying questions during the RFP response period.

> *The strongest RFP responses combine specific program experience, a clear technical approach, and direct evidence of the dimensions that matter most. A response that emphasizes general capability over program-specific thinking is itself a signal.*

A Note on Reviewing RFP Responses

Read RFP responses with the scorecard from the Capstone section in hand. For each candidate, note the specific evidence in the response that supports each criterion. Where you cannot find that evidence, flag it as a topic for the follow-up technical conversation. The RFP response is not

the evaluation; it is the start of the evaluation, and its main function is to surface the questions worth pursuing further.

Watch for responses that read as boilerplate adapted to your program rather than written for it. Program-specific thinking is the most reliable signal of an organization that engages substantively with the science. Responses that recycle general capability language across categories tend to indicate either a less-engaged organization or a candidate where the response was generated by business development rather than the technical team.

APPENDIX C

Evaluation Scorecard Worksheet

Use one copy of this worksheet per CDMO candidate. Complete one per evaluation conversation if you are running parallel evaluations; complete one summary version at the close of the evaluation to support the final decision.

Scoring guidance: 5 = clear strength supported by specific evidence; 4 = strong with minor gaps; 3 = adequate; 2 = concerning with mitigating factors; 1 = significant gap. Weighting reflects the relative importance of each criterion for the specific program; adjust based on program stage and modality.

Candidate Information

Candidate name	
Date of evaluation	
Lead scientific contact	
Modality / program type	
Stage of engagement	

Scorecard

Criterion	Weight	Evidence Observed	Score (1, 5)
Modality expertise	High		
Development integration	High		
Process philosophy	High		
Materials strategy	Medium-High		
Facility & QMS	Medium-High		
Partnership model	High		

Criterion	Weight	Evidence Observed	Score (1, 5)
Cultural fit	Medium		

Synthesis Notes

Use the space below for synthesis notes that do not fit cleanly into the criteria table. These can include emerging concerns, references to specific moments in the evaluation, and observations about the CDMO's engagement style.

What is the single most compelling piece of evidence supporting this candidate?

What is the single most significant concern?

What evidence is still missing? Where does the next evaluation step need to focus?

APPENDIX D

When to Engage a CDMO, A Stage-by-Stage Guide

Where you are in the program determines what you need from a CDMO and which criteria weigh most heavily in the evaluation. This appendix maps CDMO engagement to four common program stages, identifying the activities that benefit most from each engagement type, the criteria that matter most at each stage, and the questions that are most productive to ask.

Stage 1: Pre-Process Development

At this stage, the program has compelling preclinical data and a target modality, but the manufacturing process has not yet been defined. The cell source may be selected; the vessel strategy and scale assumptions usually are not.

What a CDMO contributes here. A strong CDMO at this stage helps shape the foundational decisions, cell source qualification, vessel strategy, analytical method strategy, and materials selection, that determine how the process will scale and how regulatory-ready the package will be. This is the highest-leverage point at which to engage a translational CDMO.

Criteria that matter most. Modality-specific scientific depth, development integration, and process philosophy. Facility and QMS maturity matter less at this stage; they become more decisive later.

Questions worth prioritizing. What programs in our modality has the team taken from this stage to GMP? At what point do you typically define critical process parameters? How would you approach our vessel strategy, given what we have shared about the biology?

Stage 2: Process Development and Optimization

At this stage, an early process is in place, but key parameters are still being optimized. The program is moving toward defined critical process parameters and a stable process for tech transfer to GMP.

What a CDMO contributes here. Direct execution of process development work, often in parallel with analytical development. The strongest CDMOs build GMP readiness into this phase rather than treating it as separate from manufacturing, defining CPPs during RUO, qualifying clinical-grade materials, and training operators at the relevant scale.

Criteria that matter most. Process philosophy, development integration, materials strategy. Modality expertise remains important; facility readiness begins to matter as the GMP transition approaches.

Questions worth prioritizing. How are CPPs identified and locked? How does analytical development run alongside process development? What is your approach to materials qualification at this stage?

Stage 3: IND-Enabling and Tech Transfer

At this stage, the process is defined, and the program is moving toward GMP manufacturing in support of an IND filing. Tech transfer activities, CMC documentation, and regulatory strategy dominate the timeline.

What a CDMO contributes here. Execution of GMP manufacturing runs, authoring of CMC documentation, support for FDA interactions, and management of the development-to-GMP transition. A CDMO with FDA engagement history in the modality contributes meaningfully here.

Criteria that matter most. Facility infrastructure, QMS maturity, regulatory depth, and tech transfer maturity. Modality expertise and the partnership model remain important throughout.

Questions worth prioritizing. Walk us through your tech transfer process. What FDA interactions have you had on programs in this modality, and what came of them? How is CMC documentation structured across the transition?

Stage 4: Clinical Manufacturing and Scale-Up

At this stage, the program is in clinical manufacturing. Subsequent runs may involve scale increases, format changes, or additional clinical sites. The focus shifts from establishing capability to maintaining reliability and managing change.

What a CDMO contributes here. Consistent GMP execution, structured management of process and scale changes, ongoing analytical and quality support, and partnership in any FDA inquiries that arise during clinical development.

Criteria that matter most. Facility capacity, QMS maturity, partnership model, problem-solving and root-cause analysis discipline. Cultural fit and communication style become increasingly important as the engagement extends in time.

Questions worth prioritizing. How is change control structured for scale-up or format changes? How do you approach process investigation when something does not go as planned? What does long-term governance look like for a program at this stage?

> *The earlier you engage a translational CDMO, the more value the partnership produces. The criteria that matter most shift across program stages; the value of getting the partnership right does not.*

Engagement Patterns Worth Considering

The four stages above are not mutually exclusive. Many programs engage a CDMO at one stage and continue with the same partner through subsequent stages; others engage different partners for different stages. A few engagement patterns are worth naming explicitly:

End-to-end partnership. A single CDMO handles process development through clinical manufacturing. Highest continuity, lowest tech transfer risk, requires a CDMO whose strengths span the full range of activities.

Development-to-clinical handoff. Process development is performed by one partner (often the sponsor's internal team or an academic partner) and transferred to a CDMO for GMP manufacturing. Tech transfer maturity becomes decisive in CDMO selection.

Specialty add-on. The primary CDMO handles most activities, but specific functions (fill/finish, specialized analytical methods, particular regulatory support) are sourced from specialty partners. Requires careful coordination.

Geographic or capacity diversification. Multiple CDMOs run the same process in parallel to manage capacity risk or geographic reach. The standardization of processes and analytical methods becomes the central challenge.

The right pattern depends on the program, the stage, and the relative weight of continuity, specialization, and risk diversification. None is inherently superior; each has tradeoffs that should be made explicit in the evaluation.

APPENDIX E

Glossary of Terms

The terms below are defined as they are used in advanced therapy CMC and CDMO selection contexts. Where industry usage varies, the definition reflects how the term is used in this guide.

Advanced therapies

An umbrella term for cell therapies, gene therapies, viral vectors, and complex cell systems, including stem cell programs. Distinguished from traditional biologics by the sensitivity of the biology to process conditions and the operator-dependent nature of manufacturing.

Analytical development

The discipline responsible for designing, qualifying, and validating the methods used to characterize a product. In advanced therapy programs, analytical development typically runs in parallel with process development and includes assays for identity, purity, potency, and safety.

Bill of materials (BOM)

A complete list of the raw materials, consumables, and reagents used in a manufacturing process. In a clinical-ready BOM, every material has a qualified clinical-grade equivalent and a documented supplier relationship.

CAR-T (chimeric antigen receptor T cell therapy)

A class of cell therapies in which a patient's T cells are genetically engineered to express a receptor targeting a specific antigen, then reinfused. Manufacturing is operator-dependent, typically autologous, and relies on viral vector, mediated gene transfer.

CDMO (contract development and manufacturing organization)

An external partner that performs development and manufacturing services for a sponsor. A translational CDMO integrates process development, analytical development, QC, and GMP manufacturing as a unified capability.

CMC (chemistry, manufacturing, and controls)

The body of information that describes how a drug substance and drug product are manufactured, characterized, and controlled. CMC content is a primary component of IND, BLA, and equivalent regulatory submissions.

Complete Response Letter (CRL)

A formal communication from the FDA indicating that an application cannot be approved in its current form, with specific deficiencies identified. CRLs frequently cite CMC issues; programs with strong CMC packages built early are less likely to receive them.

Critical process parameter (CPP)

A process parameter whose variability has been demonstrated to have an impact on a critical quality attribute, and which therefore should be monitored or controlled to ensure the process

produces the desired quality. Defining CPPs during RUO development is a hallmark of a development-forward process philosophy.

Critical quality attribute (CQA)

A physical, chemical, biological, or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

Design Review Meeting

A specific type of FDA interaction in which the agency provides feedback on a sponsor's product, process, and regulatory strategy in advance of formal submission. Direct engagement with the FDA through such meetings demonstrates regulatory depth on the CDMO side.

Drug product

The finished dosage form (vial, syringe, IV bag) containing the drug substance is formulated and ready for administration.

Drug substance

The active pharmaceutical ingredient, in advanced therapy contexts, often the cells, vector, or other biological material, prior to final formulation and fill.

Fill/finish

The set of operations that convert a drug substance into a final drug product, including formulation, filling into final containers, inspection, and labeling. In cell therapy contexts, fill/finish must be designed around the cells' sensitivity to processing conditions and timing.

GMP (Good Manufacturing Practice)

The system of quality regulations and procedures that governs the manufacture of pharmaceutical and biological products. GMP manufacturing produces material suitable for clinical or commercial use.

IND (Investigational New Drug application)

The submission to the FDA that authorizes a clinical study of an investigational product. CMC content is one of the three primary IND sections, along with pharmacology/toxicology and clinical protocol.

iPSC (induced pluripotent stem cell)

A type of stem cell derived from a differentiated adult cell through reprogramming. iPSC-derived programs are among the most process-sensitive advanced therapies and require deep biological understanding from the CDMO.

ISO classification

The cleanroom classification system specified in ISO 14644-1. ISO 7 and ISO 8 are commonly used for advanced therapy GMP manufacturing, with ISO 7 representing a cleaner environment.

Lot release

The set of testing and review activities required to confirm that a manufactured lot meets specifications and is suitable for clinical or commercial use. Release methods must be developed and qualified before lot release can be performed.

MSC (mesenchymal stromal cell)

A type of multipotent stem cell used in a wide range of advanced therapy programs. MSC programs are notably process-sensitive, with identity, potency, and safety tightly coupled to process conditions.

Potency assay

An analytical method that measures the biological activity of a product. Potency assays are often the most technically challenging methods to develop in advanced therapy programs and are a frequent focus of FDA review.

Pre-IND meeting

A formal FDA interaction held in advance of IND submission to align on regulatory expectations, study design, and CMC strategy. CDMOs with pre-IND engagement experience in a specific modality bring meaningful regulatory depth.

Process characterization

The set of activities that establishes a quantitative understanding of how process parameters affect product quality. Robust process characterization is the foundation of a defendable CMC package.

Process development (PD)

The set of activities that takes a research-grade process and develops it into a process suitable for clinical manufacturing. Strong process development is iterative, data-driven, and informed by manufacturing realities from the start.

QC (quality control)

The function is responsible for testing materials, in-process samples, and final products against established specifications. In an integrated CDMO model, QC operates as part of the broader analytical and quality team rather than as a separate function.

QMS (quality management system)

The set of policies, procedures, and processes that govern quality at a manufacturing organization. A mature QMS is one that operates consistently at scale, has a track record of successful sponsor audits, and supports the regulatory framework appropriate to the products being manufactured.

RUO (research use only)

A material classification indicating suitability for research but not for clinical or commercial use. Many advanced therapy programs begin with RUO materials and require qualification of clinical-grade equivalents before GMP manufacturing.

Scale-up

The increase in batch size or vessel count from development scale to clinical or commercial manufacturing scale. In advanced therapy contexts, scale-up is rarely linear; it requires re-evaluation of process timing, downstream operations, and operator coordination.

Sponsor

The organization that holds the IND (or equivalent regulatory submission) and is responsible for the development of the product. In CDMO engagements, the sponsor contracts the CDMO to perform specific activities while retaining regulatory and program ownership.

Technology transfer (tech transfer)

The structured process of moving a manufacturing process from one site (or one organization) to another. Tech transfer maturity is one of the operational dimensions that distinguishes strong CDMOs from weaker ones.

Translational CDMO

A CDMO model in which process development, analytical development, QC, and GMP manufacturing operate as an integrated capability, with the scientists who develop a process remaining engaged through GMP execution. Distinguished from a contract manufacturer, which typically executes manufacturing based on a process provided by the sponsor.

Type B meeting

A category of formal FDA interaction (under FDA Guidance for Industry: Formal Meetings) used for specific milestones in a development program, including pre-IND, end-of-Phase-1, and pre-NDA/BLA discussions.

Viral vector

An engineered virus used to deliver genetic material into target cells. Common viral vectors in advanced therapy include lentivirus, adeno-associated virus (AAV), and retrovirus. Viral vector manufacturing has its own set of CMC complexities that are distinct from those in cell therapy manufacturing.

Resources and Further Reading

The resources below are organized by category and are intended to complement the framework in this guide. Links are provided where relevant; URLs change over time, so a brief search of the title is often the most reliable way to find current versions of regulatory and industry references.

FDA Guidance Documents

FDA guidance for industry on advanced therapy manufacturing is the most authoritative reference for CMC expectations. The documents below are the most frequently cited starting points; many additional modality- and topic-specific guidance documents apply depending on the program.

- **Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products, FDA Guidance for Industry**
- **Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs), FDA Guidance for Industry**
- **Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products, FDA Guidance for Industry**
- **Potency Tests for Cellular and Gene Therapy Products, FDA Guidance for Industry**
- **Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products, FDA Guidance for Industry**
- **Center for Biologics Evaluation and Research (CBER) homepage**

ICH Regulatory Framework Documents

The International Council for Harmonisation (ICH) guidelines provide the foundational framework for development, manufacturing, and quality across global markets. The documents below are the ones most relevant to advanced therapy programs.

- **ICH Q8(R2): Pharmaceutical Development, the foundational quality-by-design framework that informs how CQAs and CPPs are identified and controlled.**
- **ICH Q9: Quality Risk Management, risk-based approaches to development and manufacturing decisions, including scale-up and change control.**
- **ICH Q10: Pharmaceutical Quality System, the framework for QMS design and operation that underlies modern GMP practice.**
- **ICH Q11: Development and Manufacture of Drug Substances, applicable to chemical and biotechnological drug substances, with relevance to advanced therapy process development.**
- **ICH Q12: Lifecycle Management, frameworks for managing post-approval changes, which inform how change control should be structured from the outset.**

Industry References and Organizations

The following organizations publish standards, guidance, and reference material that complement FDA and ICH documents. They are particularly useful for industry-specific best practices and emerging consensus on technical topics.

- **International Society for Cell & Gene Therapy (ISCT)**
- **American Society of Gene & Cell Therapy (ASGCT)**

- **Alliance for Regenerative Medicine (ARM)**
- **Biotechnology Innovation Organization (BIO)**
- **Parenteral Drug Association (PDA)**
- **International Society for Pharmaceutical Engineering (ISPE)**

Further Reading on CDMO Selection and CMC Strategy

The topics covered in this guide are part of a broader body of literature on advanced therapy manufacturing, CMC strategy, and CDMO partnerships. The categories below are starting points for deeper study; specific titles vary year to year as the field evolves.

- **Industry analyst reports on the advanced therapy CDMO market (BioPlan Associates, Frost & Sullivan, BCC Research).**
- **Trade publications covering CMC strategy and manufacturing (BioProcess International, Cell & Gene, Genetic Engineering & Biotechnology News).**
- **FDA-sponsored conference proceedings and workshop summaries on advanced therapy development are available through the FDA website.**
- **Peer-reviewed literature on potency assay development, process characterization, and scale-up for cell and gene therapy products.**

Artis BioSolutions Resources

For programs evaluating whether Artis BioSolutions is the right partner, the following resources may be helpful as a complement to this guide:

- Artis BioSolutions company overview and capabilities
- Process and analytical development services
- Cell and gene therapy manufacturing
- CMC regulatory and IND-enabling services
- Contact our team for a program-specific conversation

> *If, after reading this guide, you would like to discuss how the framework applies to your specific program, the Artis BioSolutions team would welcome the conversation. The criteria in this book are the criteria we believe should be applied to any CDMO partner, including us.*

Thank you for reading.

We hope this guide is useful for your next evaluation.

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CONTACT

Let's Talk About Your Program

If your program is in cell therapy, gene therapy, viral vector, or complex cell system development, we would welcome the conversation about how this framework applies to your program.

CONTACT US

Our team would love to hear from you.

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ARTIS BIOSOLUTIONS

WHO WE ARE

Artis BioSolutions is a Synthetic DNA and Advanced Therapy Platform

We build the DNA that powers genetic medicine and translate it into clinical grade therapies through integrated manufacturing.

The advanced therapy industry has relied on fragmented supply chains, legacy plasmid DNA, and disconnected vendors to move therapies from genetic concept to the clinic. Artis was built to replace that model with the first integrated platform to combine proprietary enzymatic synthetic DNA production with advanced therapy development and GMP manufacturing, with operations in the United States and the European Union.