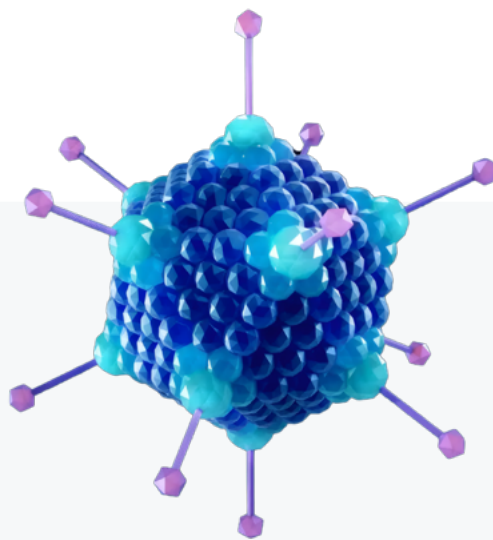


Choosing a CDMO That Can Grow with a Viral Program



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Key Takeaways

- Viral modalities require CDMO selection criteria that account for greater product and process diversity than highly platformed biologics.
- Relevant viral experience should be judged by its ability to support pattern recognition, risk identification, and informed problem-solving, even when an exact product precedent does not exist.
- Technology transfer and analytical development are central to determining whether a viral process can be adapted to new equipment, scale, and GMP requirements without compromising product quality.
- Developers should distinguish between capabilities a CDMO must possess today and later-stage or commercial capabilities for which it can demonstrate a realistic expansion pathway.
- Quality systems, project management, integrated operations, QP continuity, leadership, and organizational stability can determine whether technical capability translates into reliable execution.



Viral Manufacturing Changes the Selection Question

Quality, capacity, technical fit, timelines, track record, and cost are fundamental considerations in selecting any contract development and manufacturing organization (CDMO). For viral modalities, however, familiar criteria often carry greater weight because the products and manufacturing processes remain less standardized than those for more mature biologics platforms.

The category itself includes very different products. Adeno-associated virus (AAV) vectors, lentiviral vectors, viral-vector vaccines, and oncolytic viruses share some manufacturing principles, equipment, and analytical methods, but substantial differences remain among and within those groups. AAV manufacturing has moved increasingly toward platform approaches, yet production may still rely on triple-plasmid transfection, baculovirus systems, or other helper systems. Lentiviral vector manufacturing can likewise use transient transfection or producer cell lines. Oncolytic viruses remain particularly diverse and product specific.

That diversity changes the selection question. Drug developers need to determine whether a CDMO has enough relevant experience to understand the product, recognize likely risks, transfer the process into its manufacturing environment, and support changing needs over the course of development.

Much of that evaluation concerns the CDMO's ability to manage transitions. An early process may need to become a robust good manufacturing practice (GMP) process. Operations developed on one set of equipment may need to work on another. Development assays must mature into qualified and eventually validated methods. Clinical-scale processes may need to support larger-scale and commercial supply. A CDMO that is well suited to a viral program should be able to identify what must change during those transitions, what should remain controlled, and how to make those decisions without losing sight of product quality.

Relevant Experience Creates Pattern Recognition

Direct experience with the same type of virus is valuable whenever it exists. A CDMO that has already manufactured a closely comparable product may enter technology transfer with familiarity with the relevant production challenges, cell substrate, analytical needs, critical process parameters (CPPs), and critical quality attributes (CQAs).

For newer viral products, particularly oncolytic viruses, exact precedent may not exist. In those cases, the useful question is how closely the CDMO's accumulated experience maps onto the new program. Experience with the same viral family, a comparable cell line, similar upstream or downstream operations, or relevant analytical methods may provide meaningful evidence even when the precise product is new.

The broader value of experience is pattern recognition. A team that has worked across diverse viral products has encountered more combinations of process behavior, analytical challenges, equipment constraints, and scale-up problems. That history can help it identify gaps earlier, recognize which process changes deserve closer scrutiny, and distinguish expected adaptation from a more fundamental mismatch between product and facility.

Track record should therefore be judged by relevance as well as volume. The number of years a CDMO has operated matters less than whether its teams have successfully transferred and manufactured similar processes, supported clinical programs, worked through comparable technical problems, and delivered material reliably without compromising quality or compliance.



Due Diligence Should Reduce Uncertainty Step by Step

The selection process should become progressively more detailed. Some companies begin with a request for information (RFI) to screen potential providers before issuing a more technical request for proposal (RFP). The RFP then establishes the baseline against which shortlisted CDMOs can be compared.

A useful RFP has to provide enough information for each CDMO to evaluate the same program rather than fill gaps with different assumptions. That includes the viral modality and production system, biosafety requirements, current process and scale, analytical package, level of process readiness, and anticipated clinical trajectory. Earlier companies and academic spinouts may not yet have all of that information organized in a form suitable for outsourcing, making experienced chemistry, manufacturing, and controls (CMC) support valuable when preparing the request.

Some criteria can be resolved immediately. If a genetically modified product requires biosafety level 2 handling, for example, facilities without the necessary capabilities can be excluded before deeper technical evaluation. Technical discussions and site visits should then test the substance behind the written proposal. Developers can examine whether the scale and equipment suit the process, whether the necessary manufacturing spaces are available, and whether the people responsible for process development, analytics, manufacturing, quality, and project management have sufficient depth. The site visit can also reveal aspects of leadership, communication, and working culture that are difficult to judge from a capabilities presentation.

The purpose of due diligence is to reduce the uncertainties most likely to affect execution once the transfer begins.

Technology Transfer Reveals Whether the Fit Is Real

Technology transfer is where an apparently strong match between product and CDMO is tested against the details of the process. Viral programs may arrive at very different levels of readiness. Some are close to an engineering run, while others require considerable process development before GMP manufacturing can begin. The earlier and less defined the process, the more important the receiving team's technical experience becomes.

A rigorous transfer examines the process as a whole. Upstream operations, bioreactor steps, filtration, chromatography, and other unit operations need to be documented in sufficient detail, with available CPPs and relevant process knowledge captured for each. Where information is incomplete, the gaps have to be identified, discussed, and closed in a way that supports the intended transfer strategy.

Those gaps do not necessarily mean that the originating process was poorly developed. Early research and development may simply have been conducted at a scale, on equipment, or under conditions that did not require all of the information needed for routine GMP execution at another facility. Technology transfer often exposes that difference.

Equipment is a common source of adaptation. A process developed with one bioreactor cannot always be reproduced by applying the same numerical settings to a different system. Operating parameters may need to be translated to recreate the relevant process conditions. Similar questions can arise across filtration, chromatography, and other unit operations.

Scale introduces another layer. Manual steps that are manageable during early development may become impractical when far larger quantities of cells or materials are involved. A CDMO may therefore recommend changes even when the original process has already generated acceptable material.

Those recommendations should be evaluated collaboratively. At the beginning of a transfer, the drug developer may know substantially more about the specific product than the receiving organization. At the same time, an experienced CDMO may recognize GMP, equipment, or scalability issues that were not important at the originating scale.

The important question is whether the CDMO can make a convincing technical case for a proposed change. The teams should assess its rationale, potential effect on the process and CQAs, the risks associated with changing or retaining the existing approach, and the development work and timeline consequences involved. The ability to reason through adaptation is a more useful selection criterion than a promise to reproduce every incoming process exactly as received.





Process and Analytical Readiness Must Advance Together

Process changes cannot be assessed confidently without analytical methods capable of determining their effect on the product. Analytical development should therefore be evaluated as part of manufacturing fit rather than as a separate QC service.

Some methods transfer readily. Compendial assays generally require relatively straightforward verification. Product-specific, non-compendial methods can require additional work to demonstrate acceptable performance at the receiving laboratory, particularly when instruments or configurations differ. The extent of qualification should remain appropriate to the clinical phase, with fuller qualification and validation occurring later in development.

Potency is especially important for viral products because the relevant biological activity can be product specific. Infectious titer may be a central measurement, but other methods can assess physical particles or genome copies, transgene expression, cell killing, or additional biological functions related to the mechanism of action.

For an oncolytic virus, infectivity may therefore represent only part of the analytical picture. Depending on how the product is intended to work, potency development may need to address downstream biological effects as well. Early alignment with regulators on the potency strategy can help prevent a program from reaching later development with assays that no longer answer the questions needed for qualification, comparability, or release. Analytical capability becomes particularly important during process transition. When equipment, scale, or operating parameters change, the analytical package provides the evidence needed to determine whether the resulting product remains within the intended quality profile. A process is difficult to scale or transfer with confidence if the available methods cannot show whether those changes matter.

Choose for the Next Transition, Not Only the Next Batch

Early-stage companies naturally focus on reaching the next clinical milestone. A CDMO that can produce phase I material may therefore appear sufficient even if its later-stage capabilities are less clear.

A change after phase I can sometimes be reasonable or unavoidable. The original provider may lack the future manufacturing scale, drug product capability, or commercial pathway the program ultimately requires. Once development progresses further, however, another transfer becomes increasingly disruptive. By phase II, there is considerably greater value in working with an organization capable of supporting phase III and potentially commercial manufacturing.

That does not mean every future capability has to be installed at the time of selection. Maintaining every possible bioreactor scale or equipment configuration in anticipation of hypothetical demand would be neither realistic nor economical. Developers should distinguish between capabilities that must exist today and those for which the CDMO needs to demonstrate a defined pathway.

A provider may not currently operate the largest scale a successful program could eventually require, for example, but it should be able to explain whether the facility can accommodate that scale, what modifications or investments would be required, and how long implementation would take. A well-developed expansion strategy can be more meaningful than idle capacity installed without a defined program need.

The same principle applies to commercial readiness. A site approaching its first commercial program cannot demonstrate the same manufacturing history as an established commercial facility, but it can show that it understands the gap between its current state and the requirements ahead. A formal gap assessment, realistic remediation plan, clear timeline, adequate resources, and access to commercial expertise provide practical evidence of preparedness.

Future plans also require organizational commitment and the resources to execute them. Those factors become increasingly important as developers evaluate whether the relationship can continue beyond the immediate clinical requirement.

Continuity of Knowledge and Control Supports Reliable Execution

The organizational structure surrounding the technical work can determine how effectively that work is carried out. Keeping seed materials, drug substance, drug product, analytical development, quality control, release testing, stability, and storage within a single site can reduce the number of interfaces that need to be managed. When that is not possible, coordination within one organization can still offer advantages over dividing the program among unrelated providers in different locations.

Fewer interfaces can also help preserve process and analytical knowledge as responsibilities move from development into manufacturing, testing, and release. Each handoff creates another point at which information has to be transferred accurately and interpreted consistently.

A multi-site organization therefore needs more than common ownership. Shared quality governance, suitable global procedures, clear responsibilities, and consistent local implementation provide evidence that separate facilities operate within a connected system rather than as independent businesses under the same brand. Quality systems require the same scrutiny beneath the organizational structure. GMP requirements and formal procedures can be audited, but documentation alone does not show how well the system functions in practice. Experienced auditors can evaluate how deviations, change controls, investigations, training, and other quality processes are implemented and determine whether the organization has accumulated the depth expected of an established operation.

The availability of an experienced, full-time Qualified Person (QP) can provide another form of continuity. A QP who works closely with the site's programs accumulates familiarity with its products, processes, and recurring challenges, adding product-specific knowledge to the release function.

Digital quality and laboratory systems can further support continuity by maintaining controlled records across long development timelines. Viral programs may generate years of process, analytical, quality, and manufacturing history, making disciplined information management increasingly important over time.

Project management is another critical part of that information flow. Developers can evaluate the experience and tenure of the project management team, the tools used to track actions and risks, and the degree to which project managers understand the technical dependencies within the program.

Their value becomes clearest when something goes wrong. Delays, unfavorable results, deviations, and unexpected technical findings are unavoidable possibilities in complex development. What matters is whether those issues are communicated promptly, accurately, and with a clear explanation of their consequences. External transparency depends on effective internal communication among process development, manufacturing, analytics, quality, and other functions. The project manager should be able to bring those inputs together rather than simply coordinate meetings and maintain a schedule.

Leadership and corporate stability provide another layer of continuity. Site leaders influence investment, priorities, staffing, and decision-making, while the financial position of the larger organization affects whether long-term commitments can be sustained. If a CDMO closes a facility, changes strategy, or exits a capability, the resulting unplanned transfer can affect clinical supply and development timelines. Organizational stability therefore belongs alongside technical and quality due diligence.

Operational performance metrics can provide an additional source of evidence. Measures covering areas such as safety, quality, delivery, and cost can help developers understand how a site manages performance over time, particularly when those metrics are reviewed systematically by site and corporate leadership.



Building an Integrated Viral Manufacturing Pathway at Recipharm Advanced Bio

Recipharm Advanced Bio's Cuxhaven site has been structured to reduce many of the interfaces that can complicate viral programs. The site supports seed materials, drug substance and drug product manufacturing, analytical and quality control activities, release testing, stability studies, and long-term storage, allowing many programs to remain within one location as their needs change.

Where additional capabilities are needed, Recipharm can coordinate activities across sites within its broader network. This approach extends the range of development and manufacturing options available while retaining organizational connections among the teams involved.

Cuxhaven also operates within Recipharm's global quality framework while maintaining local implementation, combining site-level product knowledge with quality systems and commercial experience drawn from the larger CDMO organization. Broader corporate resources can support sites preparing for new levels of commercial responsibility through activities such as gap assessments and mock inspections.

For viral programs that may change considerably between early development and commercialization, this breadth is most valuable when it preserves technical knowledge, quality oversight, and organizational continuity as the process, analytical package, and manufacturing needs develop.

Selecting for the Ability to Manage Change

The fundamentals of CDMO selection remain relevant for viral modalities, but the diversity of these products makes the quality of technical judgment especially important. Current equipment and capacity establish whether a provider can begin the work. They provide only part of the answer to whether it can support the product through the transitions that follow.

A durable fit depends on relevant viral experience, disciplined technology transfer, strong process and analytical development, suitable scale pathways, mature quality and project management systems, and an organization capable of sustaining future needs.

The strongest partner can understand the process as it exists today while anticipating what will be required tomorrow, adapting what must change, preserving what must remain controlled, and maintaining the knowledge needed to do both throughout development.

About Us

Recipharm is a leading Contract Development and Manufacturing Organisation (CDMO) employing over 4,500 employees. Recipharm provides expertise in development and manufacturing across oral dosage sterile, fill & finish, and biologics; clinical trial material development and manufacturing services; and, pharmaceutical product development. Its Biologics segment works with customers to develop and commercialise advanced therapy medicinal products (ATMPs): pre-clinical to clinical and commercial development and manufacture for new biological modalities. The company operates development and manufacturing facilities in France, Germany, India, Italy, Portugal, Spain, Sweden and the US.

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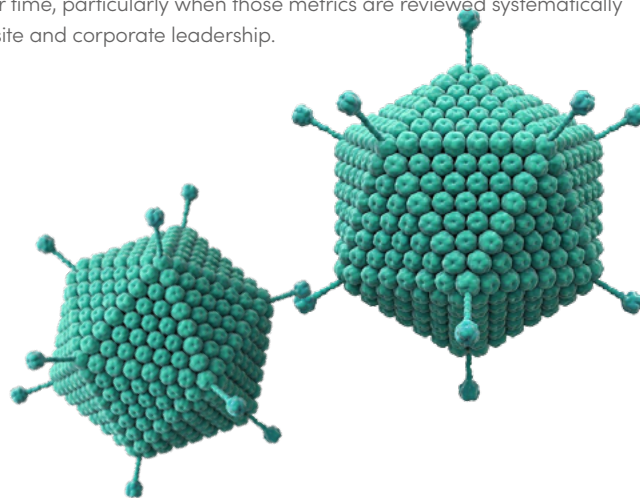
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About Recipharm

Recipharm is a leading contract development and manufacturing organisation (CDMO). We operate development and manufacturing facilities in France, Germany, India, Italy, Portugal, Spain, Sweden and the US and are continuing to grow and expand our offering for our customers. We are supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 30 years, we have partnered with our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. We conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do.