Biologics CDMO: Four Critical Aspects of Clinical Development, Manufacturing, and Analysis

How to choose a skillful biomanufacturing partner that fits with your timelines, budget, specifications, and regulatory needs

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INTRODUCTION

Selecting the most suitable contract development and manufacturing organization (CDMO) for outsourcing a biologic is imperative, however the evaluation process involves a multitude of considerations. The CDMO must have the ability to develop, manufacture, and release the desired product at the appropriate scale in the timeline required. A robust cGMP compliant quality management system with an understanding of phase-appropriate cGMP guidance is also a necessity. In addition, the manufacturer should employ a skilled, flexible, and collaborative project team with program management, support, and oversight. Some highly desirable differentiators include extensive process development, optimization, and scale-up experience in addition to an integrated "one-stop shop" service menu to support all—or most—aspects of product development. Capabilities to manufacture and test multiple therapeutic modalities is another advantage.

Four critical aspects of the selection process encompass the important factors that can influence the outcome of the partnership:

1. Understanding the importance of the right fit
2. Taking advantage of innovative technologies
3. Utilizing a fully integrated CDMO
4. Providing an effective Request for Proposal (RFP).

DETERMINING THE RIGHT FIT

When selecting a CDMO to accelerate a clinical candidate, due diligence should be exercised to determine if the manufacturer's timing, capacity, technical expertise, international regulatory compliance, quality management system, budget, and collaborative approach can meet the needs of the project. Organizations should be aware of both their immediate needs as well as potential long-term needs. The two

key elements of fit, namely, technical fit and organizational fit, must be evaluated for each CDMO candidate.

Technical Fit

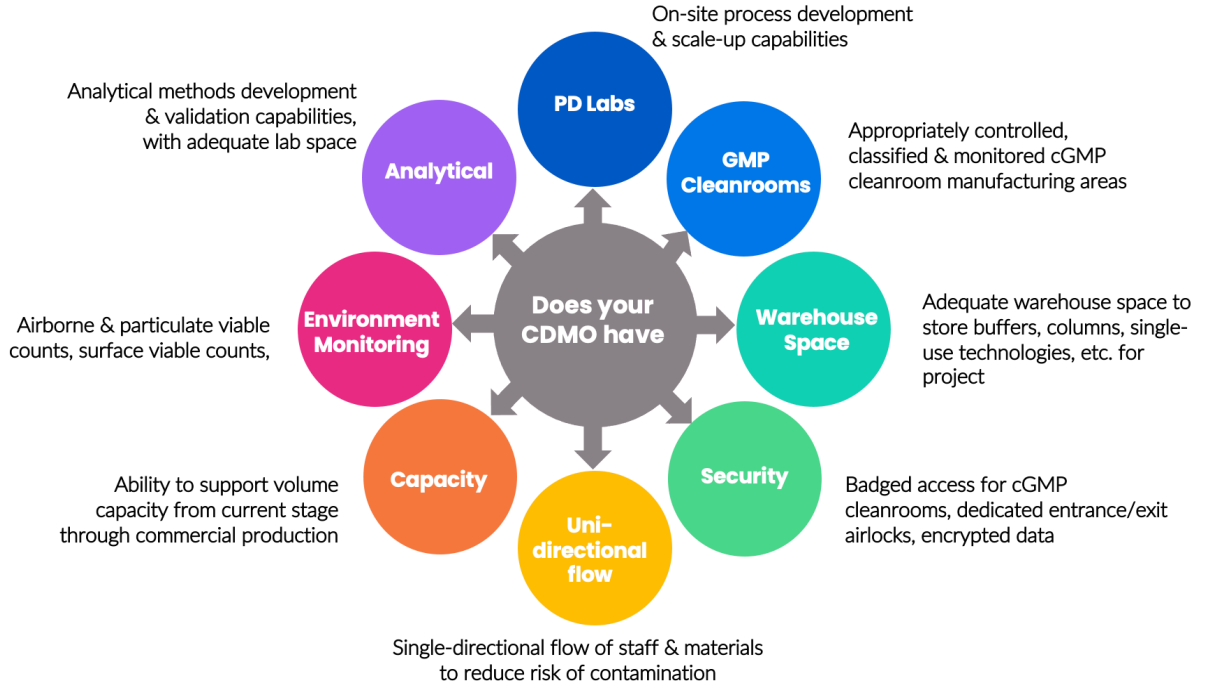
During assessment of a CDMO's technical fit, typical questions may include:

- Is the CDMO equipped for the manufacture of the specific product modality?
- Does the project require considerable process development and optimization?
- What work is needed prior to cGMP manufacturing?
- What is the manufacturing scale needed at each phase of product development?
- Does the CDMO possess the analytical testing capabilities necessary to support all aspects of intermediates and product testing, including in-process testing, product characterization and QC release testing, as well as stability monitoring?
- Are the controlled clean room environments fully capable of minimizing the chances for product contamination from personnel or the environment, or cross-contamination with other concurrently manufactured products?

FIGURE 1 illustrates several CDMO capabilities and facility design features that enhance their ability to consistently provide material that meets all requirements for safety, quality, identity, and potency. Aspects of a good technical fit include everything from material management and warehousing to process and analytical development capabilities, to the cGMP-compliant cleanroom manufacturing space, and ultimately to testing capabilities.

Cleanroom manufacturing environments are the usual focus of the selection process, such that the overall facility layout and workflow outside of the clean room spaces is often overlooked. Having adequate workspaces for all aspects of the CDMO operations contributes to the overall level of

FIGURE 1: Technical Right Fit



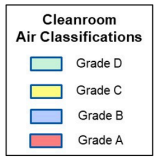
cGMP compliance and logical workflows for maximizing operational efficiencies. In addition, it helps reduce costs, delays, unwanted errors, and process deviations. Scorpius's new 22,000 square foot clinical biomanufacturing facility in San Antonio, Texas has adequate space for all functions that support cGMP manufacturing. This includes sufficient office space, a break area, and meeting rooms, with separate process development and analytical/QC laboratories. Scorpius's new facility also includes a conveniently located mechanicals area and a warehouse space which is utilized as warehousing for ongoing activities. The new facility supports biomanufacturing capabilities up to 1000 liters and is optimized for operational efficiency.

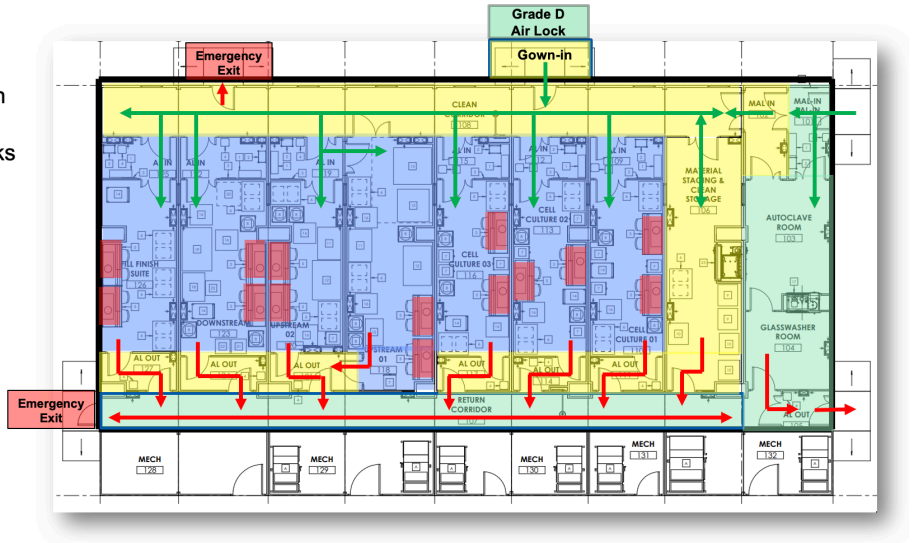
A detailed layout of Scorpius's controlled clean room environments is depicted in **FIGURE 2**. This is a multi-product, multi-use clinical manufacturing facility. The design features are aimed at minimizing the potential for contamination and cross-contamination, with complete segregation of individual clean rooms. The cGMP manufacturing environments utilize a prefabricated clean room system, or pods, from G-CON Manufacturing to support areas for autoclaving, parts washing, and materials staging. These are adjacent to seven multipurpose flexible process areas, each with a dedicated air handling unit and entry and exit airlocks. Varying air classifications, which are dictated by specific process operations, are indicated by different colors and range from Grade D environments to Grade A biosafety cabinets. It is important to note that transitions between areas of different classifications should not be more than one grade level, for example, transitioning from a Grade D area to a Grade B area requires an intermediate Grade C space separating the two. Additionally, the Scorpius clean rooms are fabricated with highly durable cleanable materials and surfaces. Combined with employing unidirectional flow of all materials and personnel, this helps to reduce the chance for contamination or cross-contamination events in order to meet the specifications and maintain the integrity of the clean room environments.

FIGURE 2: Cleanroom Design Features

Critical Design Features:

- Single-grade air classification transitions
- Dedicated entry & exit airlocks
- Door interlock system
- Uni-directional flows
- Cleanable finishes





A rigorous environmental control program is essential. This comprises of several components including employee gowning requirements, cleaning with validated disinfectant cleaners at specified frequencies, and an ongoing environmental monitoring program. The latter monitors all cleanroom environmental parameters including total airborne particle counts as well as both airborne and surface viable microorganism counts. Cleanroom control and monitoring systems must be validated.

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Organizational Fit

Aspects of organizational fit involve the capability, expertise, and systems that support the entire manufacturing process. Considerations may include:

- Can the CDMO meet the timeline requirements within budgetary constraints?
- Do they provide a robust quality management system (QMS) that effectively provides phase appropriate cGMP oversight to all aspects of GMP operations?
- Are they capable of both manufacturing and testing the product?
- Do they have formulation capabilities such as six sigma DOE to study the effects of multiple excipient variables at several concentrations on the biological activity and/or structure of the product?
- Can they produce both bulk drug substance as well as final drug product?
- What is their limitation for vial filling? Do they have automated high-volume systems, or do they perform manual fills? Will an additional CMO be needed for final fill and finish of the drug product?
- Can they provide regulatory support?
- Do they follow Quality by Design (QbD)?
- Do they have a Type V Facility Master File with the FDA, and have they been inspected or audited for any reason?

Specialized staff, unit operations, and testing capabilities are required for cell and gene therapy products versus recombinant protein production. Therefore, it is important to make sure the CDMO possesses the requisite skill sets and capabilities. For example, if the need is for production of a recombinant therapeutic protein in *E. coli* at the 500-L scale but the CDMO specializes in adherent mammalian cell therapy products expanded in cell factories, they are probably not the correct choice for the job. Note that expertise in a variety of manufacturing operations and drug modalities reduces need to qualify additional CDMOs.

What cannot be emphasized enough is the existence of a robust cGMP compliant, phase-appropriate quality management system. The QMS provides quality and compliance oversight of all cGMP operational activities, including document management control for all policies, procedures, and processes, deviation control and/or CAPA for any nonconformance, and employee training. It continually improves organizational effectiveness and efficiency. All of the aforementioned QMS functions contribute to the goal that manufactured products meet both customer and regulatory agency requirements.

Regulatory support capability is a highly beneficial differentiator to look for in a CDMO. Various global regulatory agencies may have considerably different cGMP requirements, guidance, and/or expectations that pertain to cGMP facilities, systems manufacturing processes, and QC testing requirements. Therefore, selecting a CDMO partner

with significant knowledge and experience in interacting with global regulatory agencies could be a big advantage, as that can smooth the transition from discovery into human clinical trials and commercialization. A CDMO's commitment to QbD is another benefit which facilitates rapid regulatory approval by providing data-driven, science-based risk management. QbD can be applied to support project initiation through commercial process validation. It may also be helpful to ask if the CDMO has supported customers from a Chemistry, Manufacturing, and Control (CMC) perspective in agency meetings or in preparing regulatory filings. The importance of a proper fit with a CDMO cannot be overstated, as it can impact every stage of the project.

INNOVATIONS & INTEGRATIONS

Innovative technologies can help mitigate risks, reduce timeline delays and cost, and ensure the quality of the manufactured product. The use of scalable closed biomanufacturing unit operations is a clear advantage over more open processing, significantly reducing the chance for potential product contamination. Single-use disposable technologies provide an additional benefit by reducing the potential for carryover, contamination, and cross contamination, as well as reducing the need for labor intensive and costly cleaning validation studies. Employing innovative process control strategies can also provide a biomanufacturing advantage.

A fully integrated "one-stop shop" CDMO is an end-to-end service provider that eliminates the need to find and manage multiple contract manufacturing and/or contract research organization (CRO) relationships. By providing support for all aspects and phases of product development, a fully integrated CDMO can help minimize the risk, cost, and timeline while safeguarding product quality. Aspects of integration include the ability to develop processes and manufacture products of varying modalities such as cell and gene therapy products, monoclonal antibodies (mAb), recombinant therapeutic proteins, multiple expression systems, and vaccines. In addition, having the analytical testing capabilities onsite to support varying product types and stages of development provides a significant benefit. The capability to analyze patient samples generated during the clinical trials might also be a desirable service. Additional integrated support services may include having experience in interactions with regulatory agencies as well as the submission of regulatory filings such as Investigational New Drug Applications (INDs) and Biologics License Applications (BLAs).

Process Development for cGMP Biomanufacturing

There are numerous key process development and cGMP manufacturing capabilities to be considered when assessing a partnership with a CDMO. Therefore, questions should be asked by the client at the beginning and during the selection process that can help guide them from process development to clinical- and commercial-scale manufacturing. These include:

- Does the CDMO have integrated process development, analytical, and operation groups?
- Are their equipment platforms consistent across scales?
  - Are they manufactured by the same vendor from the bench scale production and development studies where scale effects and can be potentially minimized?
  - Are different vendors used at the bench versus during production where scaling issues and surprises may arise?
- What phases of manufacturing does the CDMO support?
  - Research and Development (R&D)?
  - Phase 1 / 2 / 3?
  - Commercial manufacturing?
- Are the facilities fit-for-purpose regarding therapeutic modality, equipment, and scale? Does their equipment match the scale of the client's expectations?
- What innovative instrumentation and techniques do they utilize to help mitigate risk and manage time, such as single-use systems, closed processing, and process analytical technologies (PAT)?

FIGURE 3: Key Criteria for Integrated Development & Manufacturing

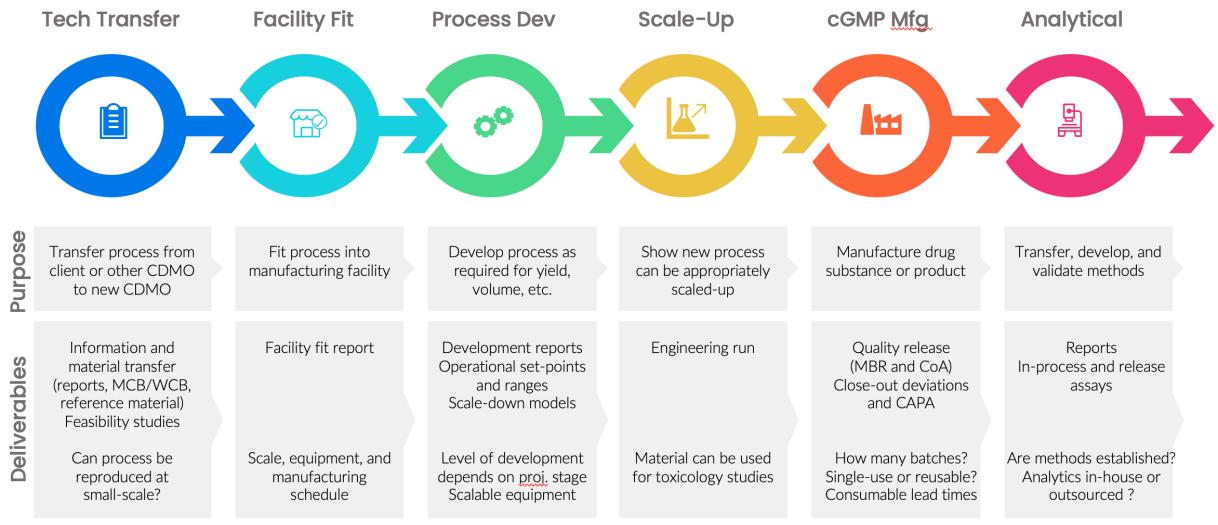

FIGURE 3 summarizes the many interrelated aspects of each stage of the project, beginning at Tech Transfer and proceeding all the way through to cGMP manufacturing and analytical testing. The stages of the project are all interdependent and, while each node introduces risk, every one of them is pivotal to program success. Tech Transfer includes information and material transfer from the client to the CDMO, such as reports, process descriptions, or physical materials such as master and/or working cell banks and reference materials. These help in identifying some of the process parameters that are required to demonstrate feasibility. The main objective of this step is to determine whether the process can be transferred and reproduced at small scale at the CDMO.

Next, during Facility Fit and Process Development, the CDMO begins to understand the current process and how it will fit into the facility. This identifies the unit operations, scale, equipment, and manufacturing schedule that will be used. This information is paramount to the process development group because they will develop the process as required for performance and yield and ensure that each quality attribute for the specific program is met to guarantee batch success. Development reports, operational set points and ranges, and scale-down models are some of the key deliverables during process development. The depth and scope of process development depends on the project stage and the evolution of the project.

After the Process Development stage is complete, manufacturing is performed to confirm the new process can be appropriately scaled into the facility. The runs at this scale are classified as Engineering runs. These allow the CDMO to manufacture the drug substance and/or drug product using the same equipment that is used during cGMP manufacturing. Frequently, the material generated from these Engineering runs can be used for toxicology studies that are prerequisites for clinical trials. Next, the manufacturing of clinical grade drug substance or drug product is completed. The deliverable from the cGMP Manufacturing is quality release, which includes analytical testing, certificate of analysis (COA), batch records release, and the closing out of any deviations and CAPAs that may have occurred during processing.

Finally, the Analytical group will test and confirm that each quality attribute and specification is met to ensure release. It should be noted that the analytical group is integral throughout the evolution of a project from Tech Transfer to completion. They are involved from beginning to end, demonstrating analytical feasibility during Tech Transfer, supporting the Process Development group during scale up and manufacturing, while also performing release assays for batch release.

For the integration of process development plans and workflows, process flow diagrams help identify important unit operations that need development for manufacturing success. The workflows for each stage should be in-place to enable rapid process development and scale-up for clinical manufacturing.

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It should be determined whether the CDMO's equipment and hardware are scalable and single-use or multi-product. Other questions to consider: are the transferred unit operations amenable to manufacturing? Unit operations such as mixing, precipitation, filtration, and conjugation reactions may not be the easiest steps to scale-up for large scale productions. Thus, it is important to consider the development and the facility fit assessment during tech transfer. Some unit operations may need to be further characterized or redeveloped to ensure successful scale up from the scaled down models used in process development. The CDMO should generate robust data sets to demonstrate that predictable scale up results are achieved during Engineering runs and cGMP manufacturing.

The manner in which the operational ranges are established is another important aspect in process development. Scorpius utilizes design of experiments (DoE) to identify significant effects and interactions that may affect the performance of each unit operation. The DoE can also predict edges of failure for potential parameters that may impact product quality and/or performance. Lastly, if critical quality attributes (CQAs) are not identified for the product, how does the CDMO define them? This is an interplay between the client and the CDMO's process development and analytical group to characterize and understand each quality attribute during the development stage.

Single-use technologies should be applied during both upstream and downstream processing to mitigate contamination risk and increase speed and flexibility. At Scorpius, single-use technologies (SUT) have been implemented in almost every aspect of drug substance manufacturing to minimize contamination and eliminate product carryover. SUT is applied to cell culture and fermentation as well as recovery in upstream processing. Downstream applications include chromatography, filtration, buffer preparation, and formulation. Key questions to ask a prospective CDMO include what platform(s) they support in their process development/biomanufacturing suites and what supply they maintain in their warehouse for long-lead time consumables, such as bioreactor/fermenter bags. Also, what are the lead times on the other non-platform single-use technologies needed for the program?

As at Scorpius, every CDMO should employ Process Excellence (PEX) tools, such as LEAN and Six Sigma, to help create effective, efficient processes and ensure every batch meets its specifications. These tools help the manufacturer reduce cost and waste while delivering consistent outputs with minimal

variation. The DMAIC framework helps Define problems, Measure the current process, Analyze the root cause of the issues, Improve the process, and Control it in a very iterative approach. PEX tools enable continuous improvement for optimal results. It should be noted that the contribution of the analytical group plays a key role in these endeavors.

Bioanalytical Support

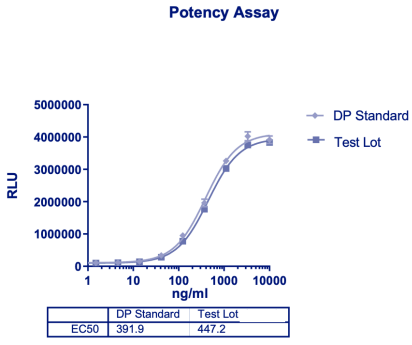
Utilizing a single CDMO with bioanalytical services to support a therapeutic can reduce cost and timelines. Having integrated bioanalysis simplifies tech transfers, method developments, and validations, while eliminating shipping delays. In this manner, comprehensive bioanalytical capabilities allow for seamless progression of the therapeutic candidate throughout its lifecycle to support large molecule biologics. As such, the contract facility should have the full suite of capabilities and experience to fulfill the analytical needs of the project. This includes innovative and high throughput platforms and experienced staff to help mitigate risk and streamline the process. Projects involving biologics and biosimilars entering drug development programs require a variety of robust and sensitive assays that can precisely measure their activity, potency, and characterize their biochemical properties. These should be offered as well as a large menu of innovative assays. Moreover, the CDMO of choice should know how and when to qualify and validate assays. The optimal manufacturing partner will have a single organization to support the drug end-to-end, from manufacturing to market.

Not to be overlooked is the capability to develop novel product-specific test methods that can be used in the R&D phase of product development as well as additional product characterization testing to be utilized in later studies, such as potency and structural analysis. On the other end of the spectrum is the development of test methods to analyze patient samples generated during clinical trial evaluation such as immunogenicity, pharmacokinetics/pharmacodynamics (PK/PD) modeling, and functional immune profiling. Assay development is a critical capability for developing and implementing analytical test methods that are fit-for-use in characterizing specific product attributes. Six Sigma tools including DOE are often used during this stage to examine the effects of assay variables. They also enable the optimization of specific method parameters, such as reagent and sample concentration, pH and ionic strength of buffers, incubation times, and temperature. The CDMO should be able to provide detailed functional analysis of the product. In addition, they should have a certified PK/PD modeling analyst. Certification validates that the data analyst has the necessary skills and resources to determine the drug's clinical pharmacology. The CDMO should be using industry leading software to analyze the drug safety and efficacy throughout the different phases of clinical research.

Having integrated bioanalysis simplifies tech transfers, method developments, and validations, while eliminating shipping delays.

Powerful software tools are necessary to handle the vast amounts of data that are generated, as well as track samples, generate certificates of analysis, and manage reports. Electronic notebooks (ELNs) and a laboratory information management system (LIMS) help standardize workflows, tests, and procedures while providing accurate controls of the process. Instruments may be integrated into the LIMS software to automate the collection of test data, ensuring they are properly calibrated and operated by trained staff. Without the right software, inefficiency in workflows and processes could result in incomplete characterization and a loss of critical knowledge about the drug, ultimately hindering the progression of the product from proof of concept to commercialization.

FIGURE 4: Integrated Analytical Services at your CDMO



Characterization & QC release testing for mammalian Master Cell Bank (MCB)

Cell Bank Release Testing / Characterization				
Test	**Description**	**Specification**	**MCB**	**WCB**
Mycoplasma	Agar cultivable & non-cultivable mycoplasma / mycoplasmastasis	Not detected / No inhibition	X	X
Sterility	USP/EP	No growth	X	X
Bacteriostasis/Fungistasis	USP/EP	No inhibition		
Endotoxin	LAL test (USP)	<10 EU/mL		X
***In vitro* adventitious virus**	General virus screen	Not detected	X	
***In vivo* adventitious virus**	General virus screen	Not detected	X	
Adeno-associated Viruses	qPCR	Not detected	X	
SV40	qPCR	Not detected	X	
Porcine Virus	9 CFR (GMP)	Not detected	X	
Retroviruses	Fluorescent PCR: Enhanced Reverse Transcriptase (F-PERT) Assay (GLP)	Not detected	X	
	Transmission Electron Microscopy	Report	X	
Cytogenic analysis	Karyotype (g-band)	Normal 46XY/XX		X
Cell Count	NC NC200	Report / ≥$2x10^7$	X	X
Viability	NC NC200	Report / ≥70% viable	X	X
Growth	Cell Expansion	≥10X expansion within 5 days	X	X
Purity / Identity	Markers via Flow Cytometry			
Potency	Multiplex ELISA			
Osteogenic Differentiation	Alzarian Red	Positive		X
Adipogenic Differentiation	Oil Red O	Positive		X
Chondrogenic Differentiation	Toluidine Blue	Positive		X
Inducible IDO Activity	IFN-gamma Induction	Positive		X

All drug products, whether in clinical trial evaluation or commercial production, call for validation of both analytical test methods and the equipment used in characterization and QC release testing using a phase-appropriate approach. Qualification and validation should start as early in the process as possible. Early phase method validation includes accuracy, precision, linearity, specificity, and sensitivity. However, several aspects could change the requirements of the analytical method during process development. For example, synthesis of the product could change as well as the composition, which could then require redevelopment of the test method. If the analytical method has changed, the early phase validation is repeated. Assuming no issues arise during Phase 3, it will be followed up with late-phase validation that includes interference, stability, robustness, selectivity, and system suitability. The analytical method is then ready for lot release testing of the drug product for use in clinical trials or for therapeutics already in production. Analytical test methods for cGMP product characterization and QC release testing of biologic drug substance and drug products are important to ensure the safety, quality, identity, and potency of all biological products including cell gene therapy products, vaccines, therapeutic proteins, and monoclonal antibodies.

FIGURE 4 shows an example of typical characterization and QC release testing required for the release of working cell banks used in the production of a cell therapy product, specifically mesenchymal stromal cells. CDMOs should be able to produce, store, and support cell line characterization. Examples of testing for release of each working cell bank include microbiological safety testing, including sterility, endotoxin, and mycoplasma, as well as adventitious virus testing. This is in addition to the required product-specific testing, such as viability, purity, identity, and potency.

An example of the typical characterization and QC release testing required for a monoclonal antibody is shown in **FIGURE 5**. As in the previous example, safety testing including bioburden/sterility and endotoxin are required along with identification, purity, and potency for protein-based products. Higher order structural characterization is often necessary as

FIGURE 5: Integrated Analytical – Characterization and Lot Release

Attribute	Test Method
Identity / Purity	Peptide Mapping (LC/MS)
	CE-SDS (reduced and non-reduced)
	cIEF
	SE-HPLC
Strength	Total Protein Concentration (A_{280}-A_{320})
Potency	ELISA binding assay
Process Impurities	Host Cell Protein
	Host Cell DNA
	Residual Protein A
	Polysorbate 80
Microbial Contamination	Sterility/Bioburden
	Endotoxin
Additional Testing	Appearance
	pH
	Extractable Volume (DP)
	Osmolality (DP)
	Subvisible Particulates (DP)
Protein Structural Characterization	N-linked oligosaccharide profiling
	N-glycan analysis
	Monosaccharide composition
	Sialic acid content
	N-terminal and C-terminal sequencing
	Methionine oxidation
	Deamidation
	Free thiol assay
	Circular dichroism
	Differential scanning calorimetry

mAb characterization and QC release testing for Bulk Drug Substance

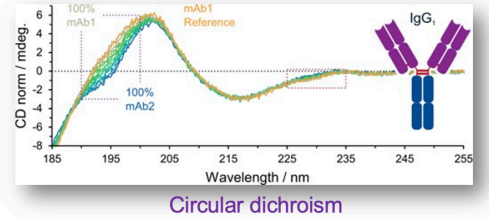
FIGURE 6: Integrated Analytical Services – Stability Studies

Can the CDMO support:

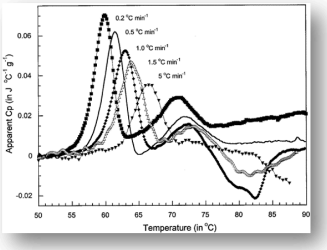
- ICH in-use stability studies
- Accelerated and stressed
- Long-term storage
- Compatibility studies - formulation
- State-of-the-art instrumentation for higher order structure (HOS)

Condition	T_0	1M	3M	6M	9M	12M	18M	24M	36M
Storage (-80°C)	E, S, X	X	X	X, S, E	X	X, S, E	X	X, S, E	X, S, E
Accelerated (2-8°C)		X	X	X, S, E	X	X	NA	NA	NA
Stressed (25°C)		X	X	X, S, E	NA	NA	NA	NA	NA

E = Endotoxin
S = Sterility
X = Appearance, Total Protein, CE-SDS, c-IEF, SE-HPLC, ELISA binding, Osmolality, pH



Circular dichroism



Differential scanning calorimetry

well. Testing may also include the characterization of activity, efficacy, and immunogenicity of the molecule which may be influenced by post translational modifications (PTMs) and alterations. Higher order structure control of these modifications should be demonstrated through the robust characterization and analysis during process development and manufacturing. Understanding all sources of variation, such as oscillation patterns, charge and charge variants, as well as aggregates, is critical to the assessment of product heterogeneity.

Stability testing is an important part of the drug development approval process which determines the safety and integrity of the drug product and how it varies with time under the influence of environmental factors including temperature, humidity, and light. Depicted in **FIGURE 6**, this testing determines whether any physical, chemical, or microbiological changes affect the efficacy and integrity of the final product, thereby ensuring that a pharmaceutical product is safe and effective. It is important that the CDMO knows how to conduct a well-planned study following ICH guidelines. That includes the development and utilization of stability-indicating assays that accurately quantify active ingredients without interference from degradation products, process impurities, and excipients. They should also have an assay that can detect and quantify degradation components as well as one that monitors protein. Higher order structure is important for ensuring the product safety, activity, and efficacy and should be monitored during stability testing, especially under stress conditions. Confidence in the CDMO for accomplishing all the necessary testing throughout the product lifecycle is a critical part of the manufacturing partner selection process.

PREPARING AN EFFECTIVE RFP

Every topic mentioned above provides a good foundation for preparing an effective RFP for candidate CDMO partners. The RFP should be considered a prerequisite for getting an accurate statement of work and budgetary proposal from the CDMO. The process of preparing an RFP starts with identifying the project scope, including needs, expected deliverables, budgetary constraints, and project timeline requirements. This information is compiled and reviewed internally by a multidisciplinary review team including management, scientific staff, clinical staff, and finance. Once a CDMO candidate is identified, an initial meeting is held to assess the technical and operational fit. Typically, a Confidential Disclosure Agreement (CDA) would be executed and then the RFP distributed to the CDMO. Expectations must be clearly communicated. Once the Scope of Work (SOW) and budgetary proposal are received from the CDMO, a customer internal review scores the proposals and selects the top candidate(s). The final selection of a CDMO partner will often require one or more additional meetings to clarify aspects of the SOW and talk in greater detail about the manufacturing process, analytical test methods, project deliverables, and project timeline. The importance of the RFP's quality cannot be overstated, as it directly impacts the relationship between the client and CDMO as well as the outcome of the project.

CONCLUSION

The choice of CDMO for biomanufacturing is crucial to successfully bringing a biologic to clinical trials and the market. Therefore, numerous aspects of the manufacturer's technical and organizational capabilities must be considered. Critical factors include whether the CDMO has the capacity, skills, and innovative technologies to meet the Critical Quality Attributes of the product within the given timeline and budget. In addition to a cGMP-compliant Quality Management System, they should also possess regulatory expertise and a highly responsive program management team. Ideally, the CDMO would offer an integrated "one-stop shop" for the entire process to mitigate risk and streamline the journey from development through commercialization. This would include analytical facilities and expertise for every aspect of the project. Moreover, they should possess extensive process development and optimization capabilities, as well as flexible biomanufacturing capacities and modalities. Scorpius BioManufacturing meets these expectations as a world-class, fully integrated CDMO and CRO using innovative technologies and extensive experience to support their clients every step of the way.