# WHAT THE PROPOSAL PROCESS REVEALS ABOUT A CDMO PARTNER


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**The manner in which a CDMO responds to a request for proposal provides significant insight into how the CDMO will approach a long-term collaboration.**

Receiving a proposal from a CDMO is sort of like a first date: the first impression lingers and the way you're treated often is indicative of how the relationship will go from there. Thus, the proposal process provides a perfect opportunity to learn more about a CDMO before any agreement is signed: the services it can provide, the flexibility it can offer to meet your project's needs, and the responsiveness and enthusiasm with which your project will be managed.

To this end, CDMO appraisal essentially boils down to three metrics: *timing, quality,* and to a lesser extent, *price*. The proposal process gives potential clients insight into how the CDMO measures up in terms of these criteria.

## WHAT ARE YOU LOOKING FOR, AND HOW SOON DO YOU NEED AN ANSWER?

The answer to the second part of that question – How soon do you need an answer? – is easy: "yesterday." In an industry whose clinical trials, regulatory approvals, and manufacturing capacity all have been impacted by the COVID-19 pandemic, biotechs/biopharmas strive to advance products to market faster than ever before.

In vetting CDMOs for "timing," CDMO clients expect responsiveness, a palpable sense of urgency, and painstaking attention to details – particularly those that can accelerate timelines. It is not uncommon for a CDMO client to expect response questions submitted within a week of tendering a request for proposal (RFP). Within one to three weeks, a technical call could be expected to revise the proposal's finer details before a decision must be made whether to move forward (or the client could miss out on a manufacturing slot opening).

Additionally, prospective clients usually review multiple proposals simultaneously. So, ideally, when they submit an RFP, they expect a customized proposal (versus a templatized one) that identifies key points and risks, one that allows for in-depth comparison to competing proposals. However, most CDMOs are content to send a generic proposal – and even that can take a long time.

As clients want to see full details as much as possible, it is better to start with an ambitious proposal and then trim it down than to start with a barebones approach and try to fortify it, which, in our experience, takes a much longer time.

Throughout this process, the CDMO also is deciding whether the prospective client is a good fit as a partner. Organizations seeking a CDMO can make the same determination through observation as well as by asking some questions during master service agreement (MSA) discussions, quality agreement discussions, and the proposal process itself.

## CDMO QUALIFICATIONS REVEALED DURING THE PROPOSAL PROCESS

**Responsiveness** is the first quality to look for in a CDMO, and it starts even before the RFP, at initial contact. Normally, some pre-discussion takes place before the RFP is received, which leads to a confidential disclosure agreement (CDA). Does the CDMO take days to turn around that CDA or weeks? In that same vein, how soon after an RFP is received are questions submitted and a customized proposal provided?

There is a direct correlation between turnaround during the initial proposal process and CDMO responsiveness during an ongoing project. For example, consider that a fast turnaround during the proposal stage (e.g., a day or two) indicates efficient communication and shared urgency between the CDMO's business development (BD) and technical teams. Conversely, a CDMO disinclined to quickly wrangle its technical experts during the proposal process may be just as unlikely to prioritize responsiveness once a deal has been inked.

This can stem from a CDMO's lack of **enthusiasm** for the partnership and the project. Enthusiasm is essential to persevere through a project's difficulties – as well as its routine tasks – while maintaining optimism and momentum. Ostensibly, everyone in this industry chose to pursue innovative medicines out of a commitment to patient well-being. However, a CDMO's technical staff are far removed from the client and even more so from patients.

It is vital that a CDMO draw personnel into the narrative for each client project, sharing its promise to save lives or improve quality of life for patients. A CDMO can stand out by offering clients a platform to share their enthusiasm, dedicating time for the client to address the CDMO's technology team and explain to them the indication/impact of the product.

As these initial steps are occurring, the prospective client also is (and should be) checking the CDMO's **references**. Simply put, to have good references, a CDMO must have a good track record, in addition to being a consistent performer – a CDMO cannot reasonably expect the same references to stump for them repeatedly, and a project completed to customer satisfaction five years ago lacks the impact of a more recent success.

A quality CDMO should have multiple people at its fingertips that prospective clients can contact to glean a good sense of their experience working with that CDMO. References are even more valuable if their project is similar to that of the incoming client. It warrants mention that some great work happens anonymously: some clients decline to be references, often out of a desire to shield their project from a competitor or from public knowledge. If the client is happy with their CDMO, they may consider instead submitting a press release, either individual or joint.

As references are being checked, one or more **technical calls** take place, though the exact timing and the number of calls depends on the project. For example, a standard monoclonal antibody is less likely to necessitate multiple technical calls, while a drug substance intermediate involving multiple stages and materials – received by another of the client's CDMO partners – will add steps and require more extensive discussions. Or, if an RFP lacks detail, a second technical discussion may occur before the proposal is submitted.

In addition to having appropriate personnel on the technical call to facilitate a productive discussion, a CDMO best practice is to meticulously capture information during that call. During the proposal process, no project manager has been assigned, putting the onus on a CDMO's BD representatives to take detailed notes and work to understand the project on a technical level as well as follow up – some might take weeks to finish if they require a conversation with multiple people.

A CDMO's BD rep must be adequately engaged to ensure a successful transition as the client signs an MSA and moves their project forward. BD reps are the first line of information, before a technical call even takes place. By the time an RFP is submitted, the BD reps may already have had multiple engagements with the client regarding risk or processes. For those conversations to be productive, though, **candor** is a must.

A CDMO must be transparent to the entire process it proposes; risks and timelines colored with optimism look good on a proposal but rear their ugly heads in the form of change orders later. All biologic processes carry some inherent risk; they're rarely, if ever, perfect. So, it's a red flag if a CDMO does not list and explain risks during the proposal process.

In that same vein of transparency, pay attention to how a CDMO provides access during the proposal stage. This speaks to the CDMO's adaptability in imagining **creative workarounds**. Site tours are about as transparent as a CDMO can get. Does the CDMO offer physical tours (under COVID-safe protocols)? Are virtual tours an option if an in-person visit is not possible? Is the CDMO's upper management available to speak with the customer?

A CDMO's ability to think on its feet also feeds into its **organizational flexibility** and willingness to negotiate. This is important because projects are messy: something always needs to be explored further, or a surprise may result. For example, some CDMOs will add a fee if you miss your engineering run (booked) slot, even if the delay is explainable, and nothing could have been done. A flexible CDMO may express understanding and work together to reschedule the engineering run absent any penalty. Larger CDMOs tend toward the more rigid end of this spectrum and are less willing to stray from set procedures.

Payment terms provide another example of an opportunity for flexibility: how much money is due up front, how much is due during different stages of work completion, and what is the overall proposal's bottom line? Is the CDMO able to offer any sort of concessions, and do they extend to change orders? As a final example, consider raw materials. If a preferred resin is not available in adequate volumes, is the CDMO willing to discuss different resins? Can the CDMO apply cycling, wherein it uses less resin and reduces costs but changes the process as a result?

Prospective clients ruminate on the above qualifications as the proposal is completed: is it a **generic or a customized proposal?** It takes more work for a CDMO to deliver a custom proposal, but it is necessary to show a clear understanding of a project since each one differs. The RFP is a starting point for any CDMO, but adept organizations distinguish themselves by identifying any gaps up front to fine-tune suggested customization. This allows the client to review CDMO selection with as much information available as possible.

For example, a recent Northway Biotech client had a drug substance intermediary that was to be combined with another product to make their drug substance. The client provided calculations of how much material they needed, and our technical team recalculated the scale to show them we could extrapolate their project/scale-up. Competing CDMOs requested the client perform those calculations.

**Proposal revisions** often result from this deeper analysis of a project: the client wants to know what else the CDMO can do to optimize its project, or the CDMO requires more information to enable workarounds or redundancy measures. In short, proposal revision is the time to advance a proposal from accurate (i.e., outlines basic parameters) to precise (i.e., addresses exact need), before the MSA is executed. This step is critical since, eventually, the proposal is signed as a statement of work and serves as a basis for all later discussions of what was agreed upon — if it is not in the proposal, it will require a change order, accompanied by an unexpected cost increase.

This final round of proposal revisions often addresses **engineering feasibility studies.** A capable CDMO should understand well the types of projects it has completed before as well as its strengths and areas of weakness. Is the project something they have done before, precluding the need for engineering feasibility studies? Or, if it is something totally new to the CDMO, how do they provide expertise for the project?

Engineering feasibility studies can take three to six months and cost upwards of $100,000. Even after the study is complete, a client may not have a solution. Thus, forging ahead without a study is an attractive option, but the CDMO will have to make some educated guesses about the project based on similar projects it has completed. The CDMO should provide the client a good understanding of how its technical team thinks the project will take shape. The client will not have every detail, but they should have enough information to feel comfortable moving forward or canceling the plan.

## CONCLUSIONS

The metrics described above — responsiveness, enthusiasm, notable references, technical call efficiency, candor, creative prowess, organizational flexibility, customized proposals, thorough proposal revision, and a clear understanding of engineering feasibility studies — all can be gauged by prospective CDMO clients during the proposal process. In some cases, the CDMO makes this task easier by taking a proactive approach to the interaction, offering information up front, before (if) it is even requested.

For example, rather than passively asking a potential client, "What do you want us to do?" a proactive CDMO will meet the expectation that it should weigh in early and often. Its representatives may provide suggestions regarding a certain formulation or additional services. They may also share solutions to perceived issues or rationale that their program is a good fit for your project. Like gifted athletes, they strive to anticipate the play before it happens, rather than react as it passes by them.

Northway Biotech embraces this mindset: active engagement versus passive, and forward-thinking action versus reactive. We prioritize responsiveness such that we can turn around a CDA in 24 to 36 hours as well as compress projects on ambitious timelines (i.e., other CDMOs might require an MSA in place before any activities begin, versus maybe using a terms and conditions document until cGMP activities kick off). Further, our technical and BD teams are among the most knowledgeable in the industry and are available to respond to queries quickly.

We conduct technical calls with all necessary parties on the line and no extraneous voices to dilute the conversation, taking detailed notes to drive speedy responses to client queries and a smooth transition once a deal is signed. Clients are welcome to visit us on-site, through virtual tours, or even via a prerecorded tour that appropriately represents all equipment and offers opportunities to submit questions.

Finally, Northway Biotech offers the experience, flexibility, and creative approach to overcome whatever challenges your project presents. If a client needs to reach our platform process' end point in a few short months, we cannot gather all the stability data we normally would. However, we can conduct some accelerated tests (i.e., a reduced stability study) with just a few time points to acquire quick data that supports better decision-making. This is just one of many workarounds we can execute to meet client needs, based on the time and the resources available.

To learn more, contact the authors or visit Northway Biotech at https://www.northwaybiotech.com/.

## ABOUT THE AUTHORS

Vladas Algirdas Bumelis, Prof., is the Founder and CEO of Northway Biotech. He holds PhDs in both chemistry and biotechnology from Vilnius University and is a full member of the Lithuanian Academy of Sciences. Prof. V. Bumelis has extensive experience in the pharmaceutical and biotech industries, having previously served in senior management positions at international companies in the biopharma industry such as Teva Pharmaceuticals, Sicor Inc., Biofa, and Biotechna. His illustrious career has been recognized many times. In 2004, Prof. V. Bumelis received the Science Award of Lithuania in recognition of his achievements in the development and production of recombinant proteins, while in 2012, he was named CEO of the year in Lithuania. Vladas can be contacted at vladas.bumelis@northwaybiotech.com.

Rose Rhomberg is a Director of Business Development for Northway Biotech. Rose has more than 20 years of sales experience in highly technical fields including electro-optics, acoustics, and biologics. Her contract development and manufacturing experience is in mammalian cell culture. Rose understands the voice of the customer and is focused on building relationships with companies that will benefit from Northway Biotech's services. Rose graduated with an economics degree from Claremont McKenna College (CA) and earned her MBA at the Eberly College of Business, Indiana University of Pennsylvania, as a Delta Epsilon Iota member. She can be contacted at rose.rhomberg@northwaybiotech.com.

Stephen Wang is a Senior Director of Business Development at Northway Biotech. Stephen has around a decade of experience in the pharma and biotech industry. He has been responsible for account management and business development for companies including Sanofi and Catalent Biologics. Stephen is focused on providing the best service to Northway's partners as they advance their pipeline through the clinic and beyond. Stephen has a Bachelor's in biology from UC Berkeley. He can be contacted at stephen.wang@northwaybiotech.com.

## ABOUT NORTHWAY BIOTECH

Northway Biotech is a leading CDMO supporting customers worldwide. Its highly experienced, professional team executes projects at any stage, from cell line construction and process development to cGMP manufacturing of biopharmaceutical products. The company's wide-ranging expertise and vertically integrated service offering translate to the ability to rapidly execute multiple projects from its state-of-the-art GMP facilities while ensuring full process and product compliance at all stages of research, development, and commercial manufacturing. Northway Biotech is a privately owned company founded in 2004 and located in Vilnius (Lithuania) and Waltham, MA (USA).

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