

CREATING A STREAMLINED PROCESS FOR ESTABLISHING MUTUAL CONFIDENTIALITY DISCLOSURE AGREEMENTS WITH CDMOS

Source: Singota Solutions

Singota® Solutions is a CDMO located in Bloomington, Indiana, USA that specializes in Parenteral, Early Phase Drug Development and Aseptic Filling projects.

A confidentiality disclosure agreement (CDA) is necessary to facilitate a confidential framework between a client and CDMO, allowing a free exchange of information to evaluate potential fit between client needs and CDMO capabilities. Putting such an agreement in place quickly while ensuring careful, thorough language and mutual understanding can be challenging.

Disparities in CDA templates, out-of-date language, agreements involving more than two parties, and difficulty in gathering necessary signatures all can derail a process which, ideally, can be completed within 24-48 hours. Accordingly, Singota Solutions utilizes the combination of a somewhat universal and adaptable template, a dedicated and experienced contract administrator, a responsive and knowledgeable legal counsel, and a process informed by years of experience to complete CDAs rapidly.

Typical CDA Challenges

The CDA is a standard document used by every CDMO to protect both its information and a potential clients' information, so most — if not all — organizations maintain a “templated” version of this document. The key shortcoming in many such templates is a lack of updated language. For example, in today's world, contract information is backed up on in-house computer systems, so language in the CDA should expressly state that specific type of information also is protected.

Or, it may be assumed the agreement is “mutual,” but the CDA should explicitly state as much to provide surety for both parties. The overarching goal is to eliminate any ambiguity from the agreement.

Considering the sheer number of biopharmaceutical companies and CDMOs across the globe, one might assume there would exist significant variation in verbiage, but most companies, from international drug developers to emerging contract manufacturers, use a similar CDA form. Variation more commonly takes place in the level of detail some organizations demand from a CDA and the processes by which they complete CDAs.

Companies in the process of exploring needs for formulation development, for example, try to be extremely precise with language protecting their technical details. Meanwhile, a CDA typically is intended to be more generalized due to its purpose, which is to protect information exchanged while exploring a potential working relationship. Often, drug formulation is so specific to a given client, there can be a tendency to focus on that one aspect, which could potentially extend the time it takes to implement the CDA.

To execute the contract expeditiously and ensure its proper execution, it is very beneficial to have someone in a role overseeing those contracts. CDMOs usually deal with multiple clients and need to maintain an up-to-date file on each, facilitating quick and efficient contract completion. Having a dedicated resource also helps prevent one's legal counsel from being overwhelmed. Some contracts are complicated and can take a long time to review. Having a point person to review contracts before they cross the legal counsel's desk preserves the latter's time and expertise.

This approach also serves biopharma clients, who have confidence all aspects of their contracts are in place. They know the status of all their contracts: that everything is on file, up-to-date, and that they can follow up with a single contact on any contract to make sure it's still active months or years later.

How Singota Expedites Contract Execution

At Singota, a contract administrator handles all CDAs (and MSAs), editing the documents and gaining approval from our legal team before following up with each client: talking them through the contract and explaining any edits made, as well as addressing any concerns they may have. The contract administrator then routes all the contracts for signature, both internally and with the client. By way of this process, we typically can complete a CDA in 24-48 hours, depending on how quickly the client responds.

Key to this process is our in-house CDA “checklist” (template) — simply a list of all high-priority CDA sections to check against client CDA templates for alignment on language, definitions, terms, etc. This exercise sets the standard and creates uniformity in regard to the CDAs being signed. Below is an overview of common sections included in this CDA checklist to expedite the review process:

- The CDA title should include the word “mutual.”
- Make sure that your company's listed name and address are correct.
- Confirm that the purpose listed is accurate.
- Make sure all defined terms are accurate and, if any are missing, add them.
- Verify that the definition of confidential information includes everything your company needs.
- Make sure all information transmitted orally, electronically, in writing, or by visual inspection is stated and included.
- Assert that all related persons are held to the same confidentiality standards listed in the CDA. Stipulate that you can disclose information to permitted recipients as long as they are bound to the same confidentiality standards listed in the CDA.

- An explicit term for the CDA needs to be stated. While term length varies by company, Singota tries to standardize contract terms to five or 10 years to simplify tracking, versus renegotiating new CDAs every year.
- If no language exists surrounding the retainment of a legal copy, as well as information contained in backup operations, add it.
- This information will be held to the same confidentiality standards of the CDA.
- Governing law should be set in a mutual venue. In the U.S., Singota prefers to use Delaware while, for international clients, Switzerland and England both provide viable options. In the U.S., Delaware is advantageous for dispute resolution because its law is structured to work for the benefit of both parties. It has a well-developed legal framework and its court system is focused on helping to rule on business disputes. While our aim is to work with clients without ever having to go to court, having governing law set to a neutral venue can be more conducive to dispute resolution.
- Assignment should be allowed as long as the other parties' consent is given, and such consent shall not be unreasonably withheld.
- No amendment or modification is binding unless all involved parties agree in writing. Sometimes, CDAs envelop several different parties on a single project. In these scenarios, some language is changed to be more generalized, so all of the parties are included, but little else is altered.

The greater challenge with CDAs involving more than two parties is getting each entity's approval. This also entails finding out whether each partner has edits to the agreement, and then sending revised versions of the document to each of the other partners for approval — a process that continues until consensus is achieved.



Regardless of the number of parties involved, signature/approval completion can be problematic if mishandled. Some people or organizations simply prefer an actual physical document to sign, which can take longer, as the CDA then must be scanned into a computer system or mailed to other parties. Singota generally uses DocuSign to complete contract signatures, but we are able to work with clients who prefer other means.

Final Thoughts

Ensuring a CDA process that is efficient, straightforward, expeditious, and comprehensive requires making sure your organization's CDA template is always kept up-to-date. At minimum, this exercise should be completed annually. Our templates constantly are reviewed by our team and our legal counsel to ensure they are as up-to-date as possible for the following year.

Singota Solutions is a US based CDMO in Bloomington, Indiana. Singota specializes in formulation development and aseptic fill finish for injectable projects. Once a formulation is established, Singota utilizes state of the art robotic filling technology and focuses on smaller batch size requirements. For more information, visit Singota.com to explore how Singota has established itself as a one-stop solution for all your developmental needs.

Contact solutions@singota.com to schedule a meeting with our business development team to further discuss your current or future projects.