

5 KEYS TO AVOID DRUG DEVELOPMENT DELAYS WHEN USING 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.

Dealing with contract development and manufacturing organizations (CDMOs) can be a nightmare for some drug developers. You may be a start-up pharmaceutical company with one molecule and you now need to hand over your baby to a cold and unfamiliar group of people who haven't been nurturing this project for years. Maybe you are in academia and this is your first big chance to spin off your own company and you need a partner to help you with development. Whoever you are and whatever your situation; it can be daunting to select and partner with a CDMO. Here are five key factors to keep in mind when trying to troubleshoot drug development delays by selecting the right CDMO.

1. Communication It seems so simple, but have you recently tried to get a living human being on the telephone when you need a quick answer or update? CDMOs with project managers who work directly with clients and directly with the laboratory provide multiple benefits through communication. Weekly or biweekly phone conversations to provide updates, clarification, and prevent small issues from turning into large problems is just one example of how excellent communication can help keep your project on track.

2. Trust I need to trust you to provide me with the correct specifications or the latest revision of your protocol and you need to trust that my team and I will execute on our project plan to the agreed specifications and timeline. Without trust, there can be unreasonable demands or stresses placed onto a project that will jeopardize its success. Trust is not given, it is earned; this may be the hardest of the five keys to perfect. However, when you have it, interacting with each other should be seamless.

3. Expertise (in the field) All CDMOs should be able to give you references on recent projects. Take the time to ask and learn about similar projects that your prospective CDMO has completed in the last three calendar years. Learning about a CDMO's expertise is a great way to see how closely their recent projects match with your project, but also to see their presentation skills. Professional PowerPoint slides, project plans, and redacted reports will provide insight into the professionalism and expertise of the CDMO.

4. Flexibility Nothing is going to go 100% according to plan. As a result, having flexibility should be an essential characteristic of your CDMO. Think about how nimble is the team you have selected; can they halt a development batch during the run, reformulate with a new excipient, update the batch record, and get back on track within a couple of days? How quickly do they respond when you have a change? How willing are they to work with your SOPs or rewrite their own? How often does your CDMO say "no"?

5. Transparency Your project or product is of the utmost importance to you and your company. You should want your CDMO to feel the same way. You want them to feel like "the lab down the hall" because they are your partner, not your vendor. This last key of transparency is especially important for us; at Singota we have our E-Transparency system® which allows you to log into our system and see your inventory in our warehouse. Your CDMO's systems should be as transparent as possible; if they are transparent then it will help you to trust them, give them an opportunity to demonstrate their expertise, allow both parties to communicate solutions that are both creative and flexible, in order to ultimately avoid as many drug development delays as possible

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.