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5 things to consider when choosing your DRUG PRODUCT CDMO

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HOW TO MAKE AN INFORMED CHOICE

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Fill finish can be a high-risk process. It is a specialist process requiring high levels of knowledge, understanding, expertise and quality compliance. From initial R&D to clinical trial, in most cases the drug development journey is long. Aseptic manufacturing is near the end of this long and complex pathway, it is almost the final processing step before for clinical studies. Your compound may be in short supply and highly valuable, so trusting an outsourced partner could be a necessary decision but is one that should not be taken lightly.

There are practical elements of your decision:

- **Do you need a vendor who can provide development on the formulation or process?**
- **Would your timelines favour in-house analytical capabilities?**
- **Do you need lyophilisation expertise or optimization?**
- **Does the geographic location of the drug product CDMO fit with your clinical trial strategy?**

Whilst these are important points to consider there are also less tangible reasons you should apply to your choice, which are arguably as, if not more, important than the practical reasons. In this article we address some of these and why they are important.

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1 Culture

You wouldn't choose a minder for your child without taking in to account if the person you are trusting is someone who's morals and outlook on life align with yours, as well as checking what the day to day feel of the 'day care' looked like?

So make those same checks with your CDMO:

- **Are they a good size fit with your company and your team?** There is no 'one size fits all' approach when it comes to this decision. You'll want to make sure that you and your business will make a difference to the CDMO, the same way that the drug product CDMO will make a difference to yours.
- **Aim for Win / Win.** Will there be an opportunity to achieve this utopian state where each of the parties involved gain from the collaboration and not just transactionally or financially?
- **Culture.** There are telling signs that can appear early in discussions that will give a clue as to what the culture is like at the CDMO. Are the CDMO team collaborative, positive and forthcoming with information? Do they want to make a difference? Are they empowered and do they feel like they have a voice? Do they want a strategic relationship and not just a signed proposal? The importance of a strong culture that aligns with your business is imperative because if things go wrong, it is culture and relationships that will enable a solid plan to pave the way forwards to success.
- **Relationship.** What is the approach of the CDMO to this? We know that long-term, strategic and tactical is best, but what are they like as people? Do they want to help you? Do they pick up on the small things (that can make the biggest difference)? Are they genuinely interested in helping you and are your two companies aligned? Early indicators of this can be as simple as how they approach your due diligence visit to site. Do they make suggestions and help your travel plans? Are they open with the agenda and willing to make accommodations and changes? A good partner would be keen to make things as easy as possible as early as possible.

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2 Flexability, capacity and scalability

In my experience, these three go hand in hand. You can't be rewarded with flexibility if the CDMO has no capacity – similarly, you can be offered all the capacity you require but if there is no flexibility at critical times then it's redundant. Then when scaling up to commercial supply, to successfully execute validation batches, regulatory inspections and submissions, arguably both flexibility and capacity are required. Therefore, choosing a CDMO who ticks all these boxes is an ideal situation.

A note on flexibility: I write this as Head of Business Development for a CDMO, so I should be highlighting the risk to business if a manufacturing slot is left vacant, but let's strive for that abovementioned win/win. Cancellation charges are the last thing that I want to talk to my clients about, at best they harm a relationship and at worst they lose the relationship entirely. I'd much rather have constructive conversations about how best to utilise the capacity within my organisation.

Booking manufacturing slots 12+ months out is not always possible for early phase drug development companies, find a CMO who has shorter term capacity as well as the 'can do' attitude and flexible mentality. Rigid manufacturing plans have a place in drug product manufacture (Media Fill Tests being on critical timelines and of course commercial supply) but there are ways a CDMO can create capacity and flexibility as long as they have internal and external relationships and the right attitude.

Looking to the future is essential. You won't want to have to transfer your project to another CDMO as this comes with a cost (time and financial). Do you feel reassured that the CDMO has the capability and experience to successfully execute PPQ batches and can the CDMO scale up with you and cope with your future supply demands?

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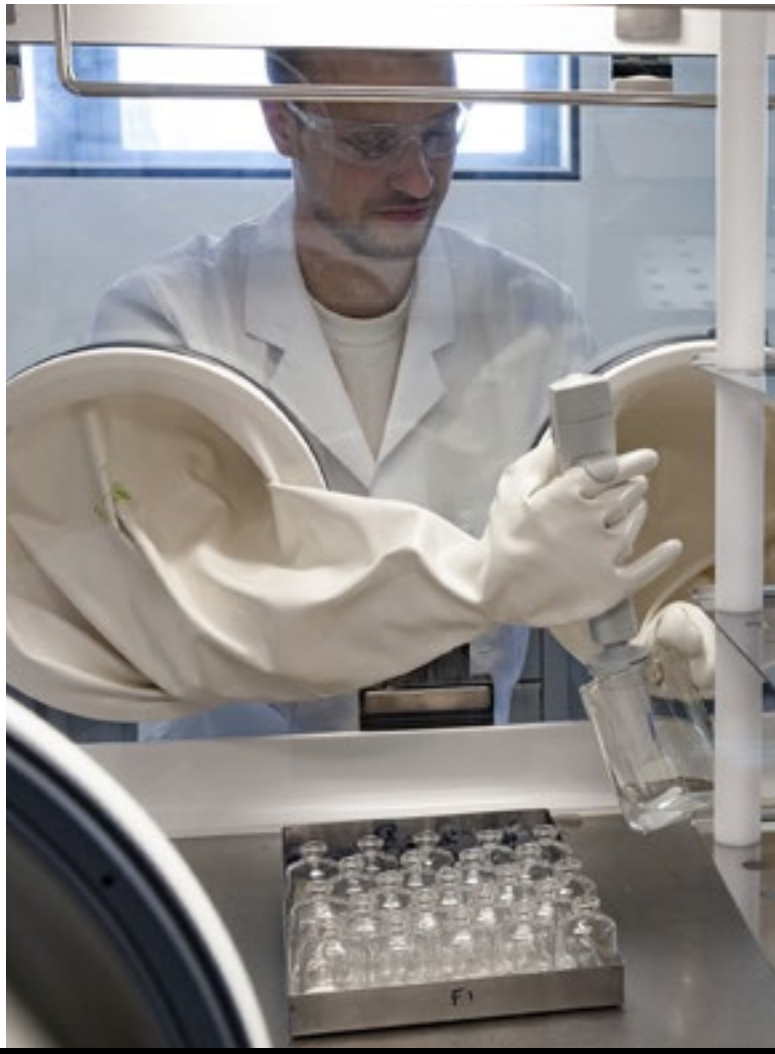
3 Capability, which ties in nicely with experience

Whether your compound is highly potent, an antibody-drug conjugate (ADC) or a toxin, or if there is a compounding or filling step that is a little different (light or heat sensitivity, high viscosity, nitrogen overlay) or you require a lyophilization formulation to be developed or optimized; you need to be sure that the CDMO you choose is able to confidently work with your process to achieve the best possible results for you.

When speaking to your CDMO partner you should be reassured not only of their experience and expertise in fill finish but in the specific or niche area that you require. Always check for experience and that the team members have specific expertise, this will allow for conversations to be progressive and constructive from the start. With the right experience and knowledge, a CDMO will be able to bring added value to your project straight away.

Additionally, if your team of experts can discuss specific details with a CDMO who understands, will really help the project to flow and could be instrumental in overcoming issues and avoiding delays. The added value of experience should never be underestimated.



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4 Quality: regulatory and annex 1 compliance

Within this heavily regulated industry it is critical to choose a partner who has a proven track record of cGMP compliance, has a strong audit history and a deep understanding of the latest regulatory updates and requirements. Check the size and experience within the Quality Department. Do they have the required skills and knowledge to fully support your project? If you're heading to the commercial market, you will need a CDMO who has a quality team experienced in doing this. You don't want to be left worrying about the details when making your submission.

Annex 1 compliance. The latest EU GMP Annex 1 revision (effective from August 2023) provided updated guidance on the manufacture of sterile drug products. It was published with new and specific guidance and contained a strong focus on risk management and having a contamination control strategy and cross contamination control strategy. If your current or chosen vendor is Annex 1 compliant they will have a deep understanding of the regulations and what is required.

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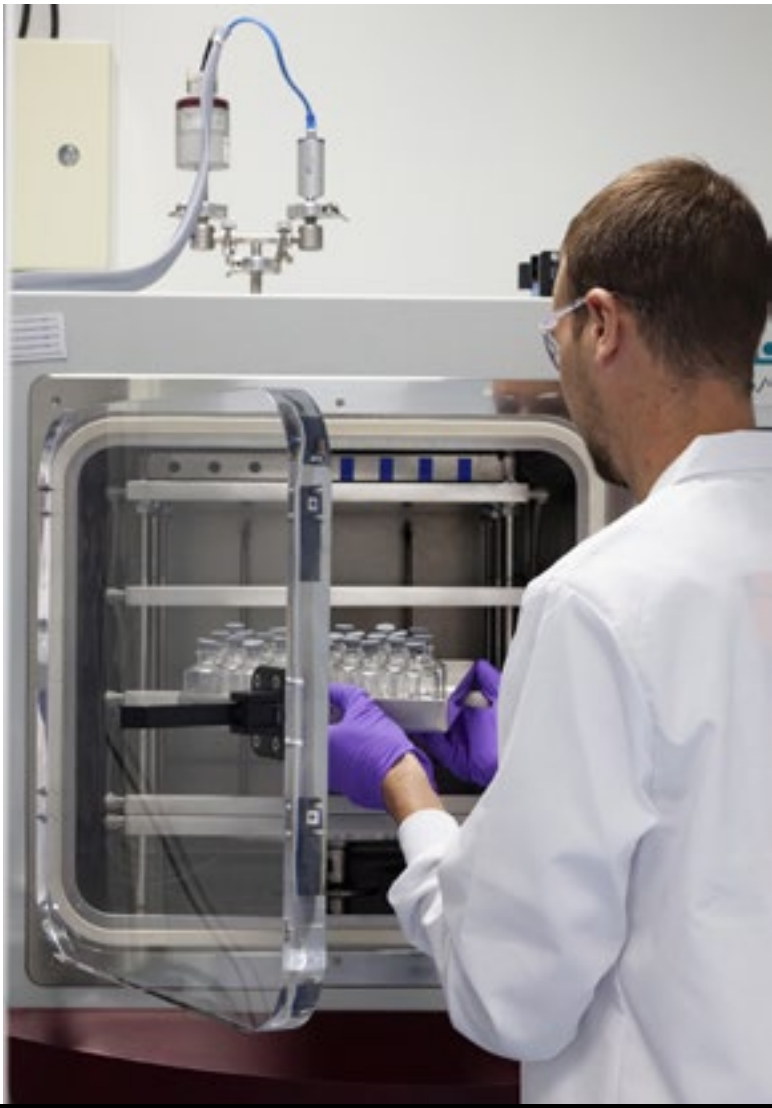
5 Details & collaboration

An early indication of how the collaboration could progress is how the CDMO works with you and your team to fully assess your needs and requirements for the project. The drug product CDMO should have their subject matter experts on hand to ask questions and ensure that a Proposal accurately reflects the scope of the project you have. If this stage has been carried out correctly then the level of detail in the Proposal should be high and give you confidence that the CDMO not only understands your needs but can fully address them.



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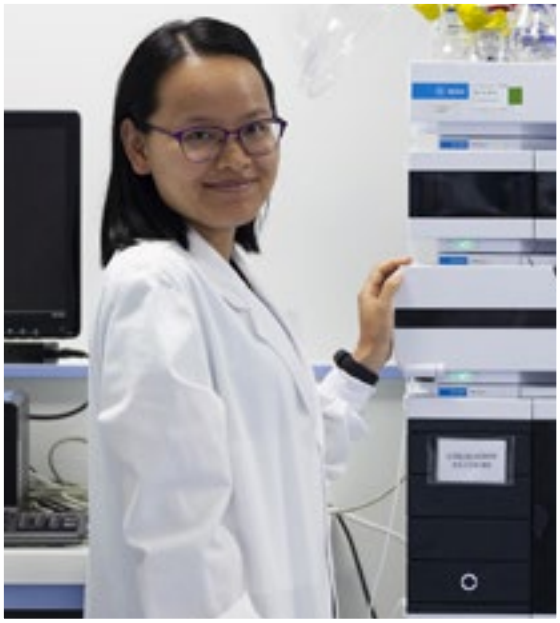
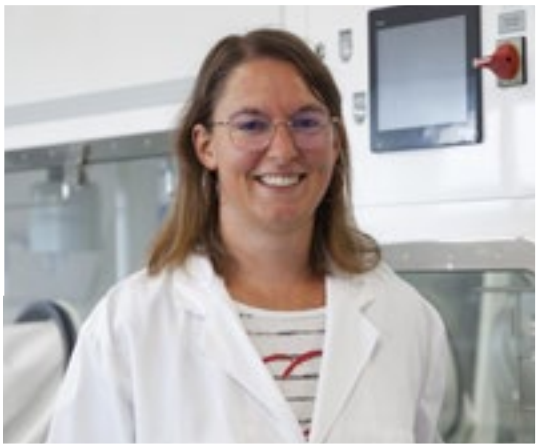
bonus and finally...

Can you work with the team? Do you get along and can you have fun whilst you work. This point may not make the top of the list but it's certainly a factor to consider. This collaboration will last for a long time, let's ensure that we share some smiles and laughs throughout this journey and make it not only successful but enjoyable and memorable as well.





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SOME ILLUMINATING STATISTICS

THE GLOBAL PHARMACEUTICAL CDMO MARKET OUTLOOK (2023-2030):

$181288 million

was the size of the worldwide Pharmaceutical CDMO market in 2022.

6.74%

is the anticipated future expansion as projected by the Compound Annual Growth Rate (CAGR).

$268091.1 million

is the value the global Pharmaceutical CDMO market is poised to attain during the forecast period.

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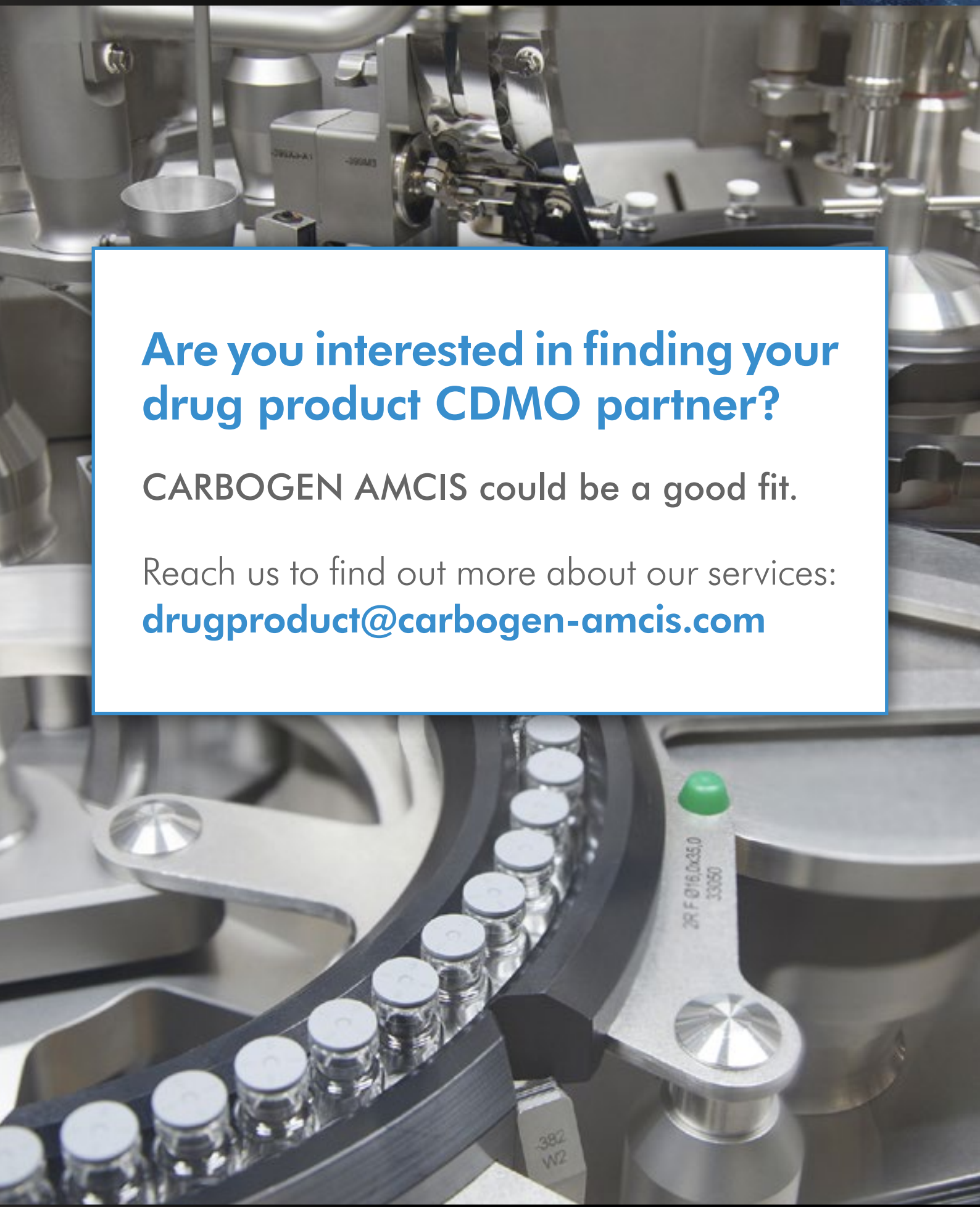

Are you interested in finding your drug product CDMO partner?

CARBOGEN AMCIS could be a good fit.

Reach us to find out more about our services:
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