

Your CDMO is your partner; Strategies for success

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Why am I qualified to discuss this topic?

35 years in Clinical and Biotech Operations

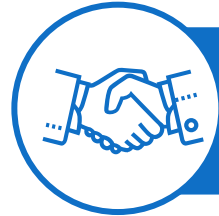
- Clinical, QA, and Analytical Labs
- Purification Process Development
- Manufacturing DS and DP Operations
- MSAT
- Business Development



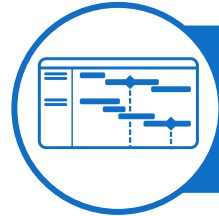
A robust list of companies who work with clients and CDMOS'

- **Genetics Institute** (early days of biotech) now Pfizer, Andover MA
- **Lonza** (CDMO)
- **Human Genome Sciences** (innovator and CDMO) now GSK, Rockville MD
- **Laureate** (CDMO) was Thermo Fisher, site now closed
- **MedImmune AZ** (Innovator)
- **BPTC** (Consulting)
- **Ridgeback** (innovator and BARDA)
- **Tunnell** (consulting and staffing firm supporting the full spectrum of drug development)

Discussion Highlights



Why the partnership matters



Approaches for a good partnership



Frequent Events and Solutions



Q&A

Why does the partnership matter?

- A CDMO is part of the process and your product, an extension of the sponsor company
- The sponsor is not in control of what happens at the CDMO and the CDMO can not control the sponsor
- Both parties must have the non-zero sum game approach because if one party loses, it will impact the other
- There will be many times that your plans are derailed. A good partnership will explore and implement solutions that may require either party to act outside of normal operating procedures



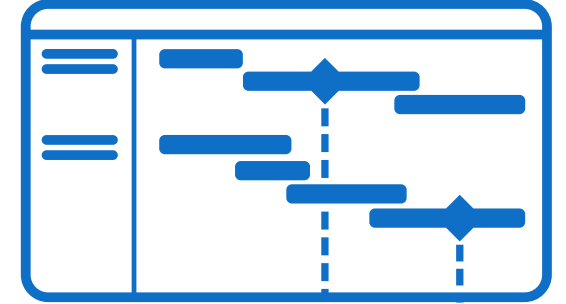
- And many more...



Set up a good partnership

Strategic priorities listed in RFP

- Build provisions that allow both parties to have flexibility in solving problems
- The Quality Agreement should define response times that are reasonable and enforceable
- Define options for upside opportunities when partner goes above and beyond
- Beware of organizational misalignment; build and effective communication channels
- Plan for failures and delays – this is critical
- Plan for over promising and under delivering, and how to mitigate
- CDMO carries most of risk of costs, sponsor carries risk of delays to program and costs – plan for it
- Build provisions for keeping relationship “warm” while waiting for clinical data or other delays
- Define exit strategies, including cancelations provisions and wind down processes



Specific Examples

The following are examples of frequent events based on experience

Common Events

Documentation required for cGMP activities not prepared in time, causing a last-minute rush and untrained staff. Result: deviations

- Example of overpromising timelines and lack of operational experience on the floor.

Budget and timelines are often skewed to be “best case” to appease investors and clients’ clinical needs. Result: Missed targets/budgets

- This practice fails to account for the inevitable human performance challenges.



Helpful Solutions

- During Quality agreement negotiations, be aware of the limits. Sponsor will often need at least 2 often 3 rounds of review. The CDMO, facing competing priorities, may not have the resources to manage extra rounds of review, resulting in mistakes. Make sure to put a high time value on this exercise. It can not be rushed.
- Understand your process risks – these include process maturity, CDMO staff experience, equipment performance history, historical failure rates – then make sure to factor those into the timeline and budget before you share with investors/leaders/other decision makes.

Specific Examples

If you are a small or emerging company working with a much larger one or vice versa, be prepared for organizational misalignment in the areas of leadership, IT systems, finance, logistics, technical and other SME support, and governance.

- Set up communication channels and steering committees up front and make sure you have access to the senior leadership at least twice a year
- Build process flow maps that help both parties understand how work is done and by whom, in advance
- Consider thinking about “best practice” when determining which systems or processes are best

Final thoughts

- There will always be challenges in a partnership – the sooner you face them together, the better
- Remember what each party needs while dealing with opportunities and challenges
- Remember why you chose to work with each other. If key staff leave and relationships change, invest in those new ones to ensure a smooth transition
- There should always be an exit strategy



Q&A

