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Top 10 traits to look for in a CDMO partner for cell, gene, or advanced therapy medicinal products

Exploring partnerships with contract development and manufacturing organizations (CDMOs) for investigational products or approved drugs can be challenging, even in the case of traditional small molecule drug development. When outsourcing cell and gene therapy (CGT) or advanced therapy medicinal product (ATMP) manufacturing, the need to understand potential risks and choose a partner carefully is amplified.

This guide can help ease the CDMO selection process by identifying key areas of conflict and uncertainty in the partnership and production process. By proactively asking questions and addressing concerns with CDMO candidates, pharmaceutical companies can minimize conflicts down the line and ensure they have selected a partner that maximizes their chance of success.

Top traits for CDMO partners fall into three main categories:

The quality of the relationship the CDMO offers

Credentials and capabilities

Foresight and flexibility

If your selected CDMO ticks these boxes, you can rest assured that your product is in capable hands.

RELATIONSHIP MATTERS

- [ ] Select a CDMO that offers a robust, evolving, communicative experience.
- [ ] Discuss the level of risk-sharing and responsibilities.

CREDENTIALS AND CAPABILITIES

- [ ] Verify the CDMO's approved licenses and ability to obtain licensing for new products.
- [ ] Explore compliance records and the CDMO's history of regulatory relationships.
- [ ] Examine the network and management of vendors and suppliers.
- [ ] Discuss the opportunity for closed production lines or dedicated line capacity.

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FORESIGHT AND ADAPTABILITY

- [ ] **Demand face time with the subject matter experts who will help guide decision-making.**
- [ ] **Look for a positive track record in the production of multiple types of biologics.**
- [ ] **Explore the potential for modular configurations to adapt to changes in production needs.**
- [ ] **Discuss preparedness plans and capabilities.**

By selecting the right partner from the start, process changes and production headaches can be minimized. This reduction in hassle and risk often outweighs the short-term financial benefits of trusting a less expensive but less experienced CDMO. An experienced, quality CDMO will be prepared and pleased to discuss these topics with informed clients like you.

About advanced therapies at Thermo Fisher Scientific

Advanced therapeutics, including cell and gene therapies, have the potential to revolutionize healthcare, and speed is of the essence. Knowing your CDMO partner has expertise, capacity, and a global supply network is critical to transitioning seamlessly from clinic to commercial with confidence. Patheon pharma services offers the confidence of partnering with an experienced CDMO, combining scale with breadth of services and a support network to meet your critical timelines.

20+ years

More than two decades of cGMP advanced therapeutics manufacturing experience, making us a trusted partner

500+

We have manufactured more than 500 viral vector cGMP clinical and commercial lots

130+

We have a proven track record and have produced more than 130 viral vector products globally

45

Flexible network of 45 drug substance suites worldwide

Ready to discuss your next project? Connect with us

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