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Delivering the ADC Promise

What challenges do CDMOs face when manufacturing antibody-drug conjugates?

Maryam Mahdi | 10/22/2019 | Quick Read

With companies seeking external support for antibody-drug conjugate development and manufacturing, CDMOs are playing an increasingly integral role in their success story. Piramal Pharma Solutions – an early adopter of ADC manufacturing capabilities – is one such actor. Here, John Fowler, COO at Piramal Pharma Solutions, discusses the promise – and the challenges – of ADCs.

“With 40 ADCs in clinical trials, there’s a great deal to be excited about when it comes to this class of drugs,” says Fowler. “They have the potential to change not only the way we treat cancer, but a variety of disease indications. And that’s why three of our clients have been able to skip phase III and are ready to apply for INDs.”

Five ADCs have now been approved – certainly “wins” for the field, but what challenges do CDMOs specifically encounter when it comes to ADCs?

- **Scale up.** “The sticking point for companies is that an ADC has three elements: antibody, linker and a cytotoxic agent. All three pose different challenges and linkers can have varying levels of sophistication, so developing expertise to handle these challenges is essential,” says Fowler.
- **Cost.** A single batch of product may cost “several million dollars” according to Fowler. But he argues that the cost burden is outweighed by the market potential of ADCs.
- **Supply chain.** Dealing with multiple vendors and quality systems can often slow down the development cycle of ADCs. Fowler, therefore, recommends that suppliers adopt an integrated approach to enhance their capability for managing the production of high potent APIs, payloads and linkers to help “de-risk” the process. Fowler explains that having direct control of an entire supply chain brings adds value to a company as they are able to prioritize and control timelines to include accelerated quality release under a common system.



John Fowler, COO at Piramal Pharma Solutions.

Despite the development and manufacturing challenges presented by ADCs, Fowler is optimistic about the future – with the approvals to date proving the concept. “ADCs are improving clinical outcomes for cancer, and so we’re seeing the field open up. I expect to see more companies pursuing innovative solutions for patients – and, therefore, a diverse range of products entering the market. Ultimately, we cannot ignore the therapeutic benefits offered by ADCs – they more than make up for the challenges of their manufacture.”



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About the Author

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After finishing my degree, I envisioned a career in science communications. However, life took an unexpected turn and I ended up teaching abroad. Though the experience was amazing and I learned a great deal from it, I jumped at the opportunity to work for Texere. I'm excited to see where this new journey takes me!

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