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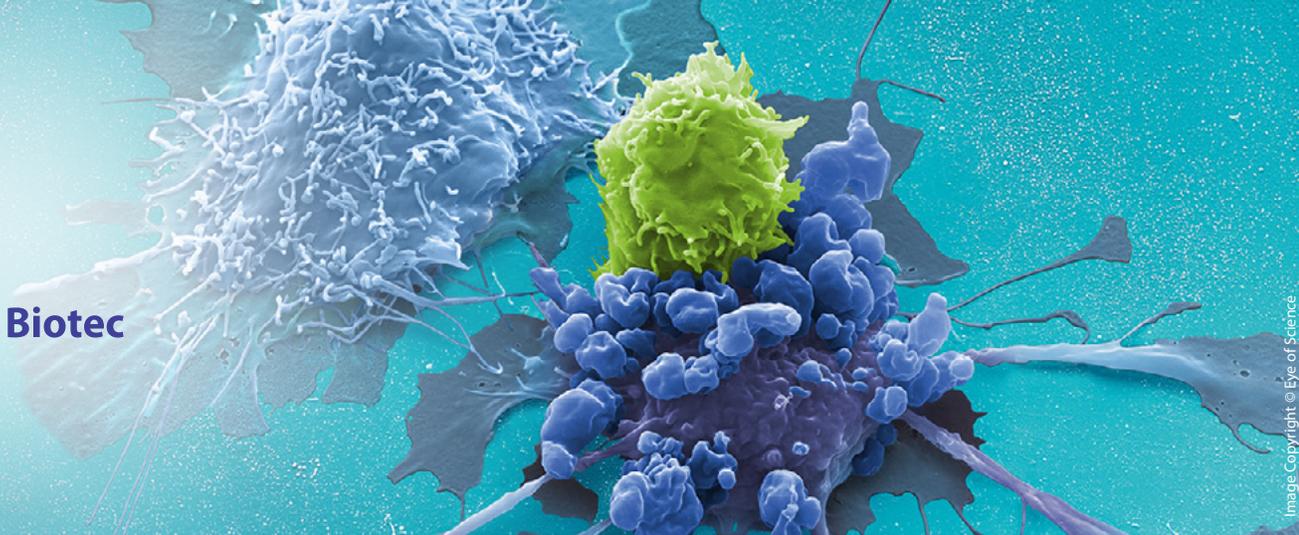


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# Novel Complex Cell Manufacturing

by Scott D. Hanton, PhD

**Ian Gaudet, PhD**, has been with Miltenyi Biotec since 2016, currently as the site head at Miltenyi's cutting-edge contract development and manufacturing organization (CDMO) in San Jose, CA, leading a team focused on rapid translation of novel cell-based therapies from bench to bedside while enabling long-term commercial feasibility. He studied bioengineering at the University of California, San Diego, and received his doctorate in biomedical engineering jointly from Rutgers University and the University of Medicine and Dentistry of New Jersey.

**Q: What are some challenges and critical considerations for the manufacturing of cellular therapies?**

**A:** Historically, new cellular products originated from academic environments, developed in basic research using extremely welltrained scientists. Translating this into commercial manufacturing environments was difficult. Scale up of manual, complex procedures required human perfection. The goal is to remove the need for human operator excellence. The translation to automated workflows increased productivity enormously. The paradigm shift is to integrate, automate, and de-risk the process.

**Q: How does your approach to T cell manufacturing address these challenges?**

**A:** We have what the field has been looking for—a standardized platform for CAR T cell therapy production. The Miltenyi platform, including [CliniMACS Prodigy®](#), [lentiviral vector manufacturing](#), and [analytics with MACSQuant®](#) is a complete manufacturing process. The goal is to provide plug and play for new developers to minimize the time and cost to clinical, and ultimately commercial, success. The platform has the complete integrated collection of components to produce CAR T cell therapies: [culture medium](#), [cytokines](#), [activation reagents](#), [single use disposable units](#), and [no open culture manipulations](#). New developers can come to Miltenyi and know that all of the key pieces are provided—it's a one stop approach for manufacturing CAR T cells. All the raw materials, the right platform, and the expertise to transfer new products from bench to bedside.



The old ways led to an inability to change the process without answering critical questions about how that change impacted the process, and thus the product. The process is now robust, which enables the understanding of the critical quality attributes of the product. The Prodigy platform's process is vetted enabling users to enrich clinical programs for their customers.

**Q: What advice would you give to an organization that wants to conduct a cell and gene therapy project?**

**A:** Collaborate with the right partner that has the key expertise to guide that journey to an investigational new drug and eventual commercialization. The FDA expects a high level of understanding around chemistry, manufacturing, and controls to commercialize a new product. This deep understanding is lacking in manual

manufacturing processes that have historically comprised pre-clinical and early-phase production. On the other hand, we have a well-characterized platform, have demonstrated fundamental understanding, and have a successful history demonstrating control in manufacturing. Our mitigation strategies have been accepted. Partnering with a contract development and manufacturing organization who interacts regularly with the agency makes the development process more efficient for the customer.

**Q: What are some clinical applications for your cell manufacturing capabilities?**

**A:** The most common product is CAR T cells. It's our most successful area and includes most of our current client pipeline. We also currently support other cell-based therapies, including our platforms for hematopoietic stem cells for gene therapy, and adherent cells, such as iPSC, NK, and NK-CAR therapies. We have also developed custom processes for a broad range of immunological cell types including regulatory T cells and myeloid cells.

**Q: What else would you like to tell me?**

**A:** A key piece of our success, that is often understated, is that the analytical methods are an integrated part of the platform and competencies. Manufacturing is only half of the story. The testing shows that the manufactured product is suitable for clinical infusion. The testing is often the more complicated part to getting to clinical readiness. The analytical platform is a huge part of why people come to us. If you have the right analytical methods, you can separate the product from the process.

Scott D. Hanton, PhD, is the editorial director of *Clinical Lab Manager* and *Lab Manager*.

Article originally published in *Clinical Lab Manager* May 2021, volume 11. Re-printed with permission.



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