

Cell and gene therapy**Expanding the cell and gene therapy manufacturing workflow****A collaboration between Northeastern University's BATL and Thermo Fisher Scientific****The challenge**

To bolster its hands-on education for academics, industry researchers, and regulators, the Biopharmaceutical Analysis Training Laboratory (BATL) at Northeastern University sought to expand its cell and gene therapy offerings. Previously, BATL had attempted coordination with multiple solutions providers; but with the lab's focus on improving analytical methods, it needed a single collaborative partner to integrate the manufacturing workflow.

Background

Scientific advances during the past 25 years have vastly improved clinicians' ability to diagnose and treat patients. Yet despite rapid expansion of cell and gene therapies, manufacturing inefficiencies and regulatory issues hinder broad access to these potentially life-saving therapies.

To address these challenges, Thermo Fisher has developed a portfolio of integrated solutions and services to support cell and gene therapy developers from clinical research to commercial manufacturing. As part of the company's commitment to continued innovation, Thermo Fisher also collaborates with academic institutions such as the Biopharmaceutical Analysis

The solution

BATL partnered with Thermo Fisher to address operational challenges and create efficiencies in cell and gene therapy manufacturing. With a breadth of solutions to cover all stages of the workflow and extensive in-house competence, Thermo Fisher could readily support BATL's mission of enabling biopharmaceutical education, global regulatory convergence, industry partnerships, and use-inspired research for the benefit of patients worldwide.

Training Laboratory (BATL) at Northeastern University to optimize workflows and field-test new technologies.

BATL was established in 2014 to address the most pressing needs of the global bioanalytical and biomanufacturing community, through offerings such as experiential training and regulatory education. With a background in biotechnology and biomedical science, Dr. Jared Auclair, Director of BATL, understands the importance of preparing the next generation of scientists to lead industrial research, particularly in cGMP labs, and places a heavy emphasis on use-inspired education and research.

“ We have barely scratched the surface of what biotech companies can do with these life-changing therapies. Traditional therapies can prevent and treat a number of life-threatening diseases, but we have never truly cured a disease. The cell and gene therapy space offers this opportunity to cure diseases—if we can figure out how to make these therapies accessible to patients more broadly.

Dr. Jared Auclair, Director of BATL

Situation: Equipping an educational lab to inform real-world cell and gene therapy development

In a mock cGMP lab at BATL, researchers and students test various methodologies to address quality and process challenges in cell and gene therapy, ultimately delivering these learnings back to the industry. To ensure these insights are applicable in real-world settings, Dr. Auclair needed the right partner to equip the lab with the same solutions and experience available in manufacturers' own labs. Because BATL's focus is on finding reproducible ways to improve the production process itself, the lab needed more than a technology and instrument provider; it needed a true partner to enable its mission.

Based on his experience coordinating with multiple vendors during his graduate and doctoral studies, Dr. Auclair knew that finding state-of-the-art technologies and integrating them to work together would be a challenge. However, he was able to eliminate this bottleneck by partnering with Thermo Fisher. The organization stood out as a single entity that could meet all of BATL's needs with their end-to-end solutions across full cell and gene manufacturing workflows.

Response: Partnering with Thermo Fisher for full workflow support

Partnering with Thermo Fisher, BATL has access to some of the most advanced solutions available, from fit-for-purpose cell culture media to state-of-the-art bioprocess manufacturing equipment, enabling the lab to identify ways to transform biomanufacturing. For example, BATL adopted the Gibco™ CTS™ Rotea™ Counterflow Centrifugation System, which offers the flexibility of a modular, closed platform for cell processing and is currently used by cell and gene therapy developers to scale manufacturing processes cost-effectively.

BATL also invested in single-use bioreactors in lieu of traditional steel tanks, enabling production of smaller batch therapies that are critical in cell and gene therapy applications. Automating the manufacturing process reduces BATL's need for full-time staff, delivering value back to academic and industry partners by leaving more resources for equipment and training.

Thermo Fisher not only supplies the lab with innovative technology solutions, but also supports BATL through continuous collaboration. Leveraging their internal competence and portfolio

of equipment and technology has allowed BATL to build their cell and gene therapy manufacturing capabilities while leaning on external experienced professionals to strengthen their educational offerings.

Value delivered: Accelerating science

By finding the right strategic partner, the BATL team was able to streamline internal processes and spend more time focusing on science. The lab has adopted solutions from across the full Thermo Fisher portfolio, making it easy to receive rapid support when needed. In addition, the sales and support teams of Thermo Fisher are able to provide guidance for any issues BATL encounters across the manufacturing workflow, including how to integrate products to enable process efficiencies. The partnership has enabled BATL to offer extended resources to their students and regulatory partners without having to hire in-house experienced professionals in cell and gene therapy.

Supported by leading technology, customized service programs, and competent professionals of Thermo Fisher, BATL is creating a bridge between industry and regulatory stakeholders to help accelerate drug development and approvals for the benefit of patients worldwide.

When I have worked with multiple vendors in the past, I felt like I spent most of my time chasing them for support or updates. As BATL is integrating a complete cell and gene therapy manufacturing workflow, I didn't want to spend my days figuring out why solutions weren't talking to each other. I'd rather focus on the science and working with Thermo Fisher lets me do that.

Dr. Jared Auclair, Director of BATL

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