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Thermo Fisher to open new cGMP plasmid DNA manufacturing facility in US

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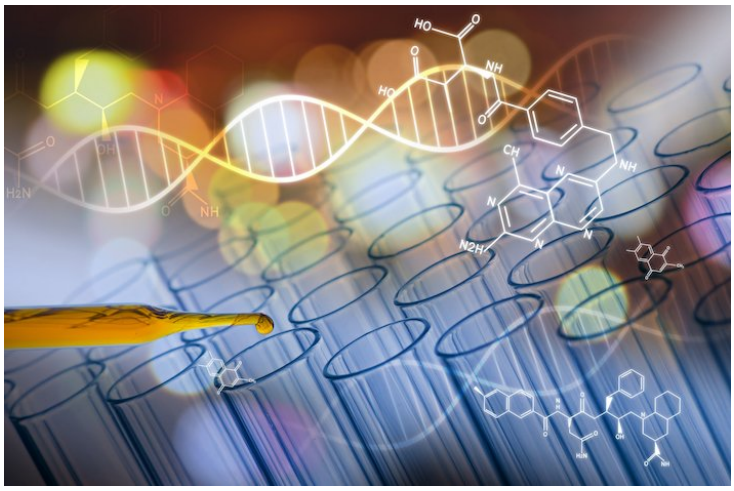
The 67,000-square-foot facility is expected to be completed in the first half of 2021



Thermo Fisher Scientific has announced the construction of a new cGMP plasmid DNA manufacturing facility in Carlsbad, Calif. The site will expand the company's clinical and commercial capabilities for cGMP plasmid DNA used as a critical raw material to develop and manufacture cell and gene-based therapies including life-saving cancer treatments as well as mRNA vaccines. In addition, the site will have the capability to produce large-scale plasmid DNA as a primary drug substance for DNA therapies.

As the global plasmid market continues to grow rapidly, the global supply cannot meet the current and projected demand. The 67,000-square-foot facility, expected to be completed in the first half of 2021, will feature advanced technologies, including single use equipment with up to 1,000L scale, digital connectivity and data visibility to enable operational efficiencies and operator training.

"The race to develop new transformative cell and gene therapies and vaccines is outpacing supply of commercial-quality plasmid DNA that can be produced at scale," said Mike Shafer, Senior Vice President and President, Pharma Services, Thermo Fisher. "Our new state-of-the-art site will not only tackle the supply bottleneck for our customers, but also uniquely positions us to deliver robust, end-to-end cell and gene therapy capabilities. Our customers can leverage our deep industry knowledge and expertise in the complexities of cell and gene therapy at all points along the pathway to commercialisation – from research and preclinical development to clinical and now expanded commercial and supply chain services."

This expansion builds on the company's continued investment in cell and gene therapy services. Customers can leverage its fully integrated development and manufacturing capabilities, including viral vector services in Cambridge, Lexington and Plainville, Mass, and Alachua, Fla; a new cell therapy manufacturing facility in Princeton, NJ and, a new dedicated cryocenter in Weil am Rhein, Germany to provide specialised cryogenic and cold chain supply chain services to support clinical trials across Europe and globally.

Located on the Carlsbad campus of Thermo Fisher's center of excellence for life sciences solutions, the new commercial facility will add approximately 150 jobs over the next 12 months.