

The Berke Report CDM0 & Manufacturing The First Week of May 2023

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- 05.02.23 Fusion Pharmaceuticals Opens Radiopharmaceutical Manufacturing Facility (contractpharma)
 - The 27,000 sq.-ft. GMP compliant facility, located adjacent to the company's R&D labs, has clinical and commercial manufacturing scale capabilities designed to support the Company's growing pipeline of targeted alpha therapies (TATs). The new manufacturing facility, part of a 15-year lease agreement with Hamilton, Ontario-based McMaster University, was built by McMaster and equipped and validated by Fusion. At full capacity, it is expected to produce more than 100,000 doses of TATs per year.
- 05.02.23 CordenPharma Announces Entry Into Oligonucleotide API Manufacturing (outsourcedpharma)
- CordenPharma Announces Entry into Oligonucleotide Manufacturing with Two-phase Investment at CordenPharma Colorado. Phase One is the reconditioning of existing laboratory space, purchase of development equipment, and hiring of an expert team to set up process and analytical development capabilities, with a target completion in Q4 2023. Phase Two, which is being initiated at the same time as Phase One, includes the redesign of existing manufacturing space to create a fully GMP compliant manufacturing area housing synthesis, cleavage, downstream processing and lyophilization at 10-100 mmol scale. These manufacturing assets provide early to mid-phase clinical trial supply for customer demands, with the benefit of being fully-integrated with Italian facility CordenPharma Caponago for Lipid NanoParticle (LNP) formulation service offerings and sterile filling capability, as well as with multiple CordenPharma sites for the supply of standard and custom Lipid synthesis capabilities.
- 04.28.23 Alcami Completes Expansion of cGMP Biostorage Facility in Amherst, NH (contractpharma)
 - Alcami Corp., a CDMO, has completed the Phase III expansion of its cGMP biostorage facility in Amherst, NH, creating a total of 160,000 ft² of ambient cGMP biostorage capacity with 21,000 pallet locations. It is now fully operational to support a variety of cGMP client storage needs. Alcami has also added nearly 10,000 ft³ of -20 °C cold storage capacity and over 12,000 ft³ of ICH stability storage in Massachusetts.