

The Berke Report CDMO & Manufacturing The Third Week of April 2023

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- 04.19.23 Ajinomoto Bio-Pharma Services Receives FDA Approval for High Potency Fill Line (PR)
 - Aji Bio-Pharma has six fill finish lines located in San Diego, including a new line that offers a range of configurations, including prefilled syringes, cartridges and vials. The high-speed process is rated to move up to 22,000 syringes per hour through the line, with a batch capacity of over 200 thousand syringes. This multi-purpose fill line has been designed to meet FDA and EMEA commercial compliance.
- 04.19.23 Roquette Opens \$25 Million Pharmaceutical Innovation Center (contactpharma)
 - Roquette, a company involved in plant-based ingredients and a leading provider of pharmaceutical and nutraceutical excipients, opened its new pharmaceutical innovation center near Philadelphia. Staffed with a team of highly skilled research, application and formulation experts, the new \$25 million center will be an advanced training and collaboration hub for pharmaceutical and nutraceutical manufacturers around the world. With a focus on optimizing patient experience with next-generation oral dosage forms, the U.S. facility complements the cutting-edge research activities of Roquette's existing pharma innovation centers in France and Singapore.
- 04.18.23 Sterling Pharma Solutions Granted MIA (IMP) License by MHRA for cGMP Antibody-Drug Conjugate Manufacturing at its Facility in Deeside, UK (Iskh)
 - Sterling acquired the 6,500 square-metre site as part of its purchase of ADC Biotechnology in April 2021, and has since gone on to invest in expanding the facility to develop its scientific and analytical teams, install a new water for injection (WFI) plant, and establish bioconjugation and ADC manufacturing capabilities. The license allows for GMP bulk drug substance manufacture to support all phases of clinical studies, GMP release testing, and supporting stability studies. The site will work in parallel with Sterling's facility in Germantown, Wisconsin, which provides services to develop and manufacture highly potent small molecules that make up part of an ADC drug molecule.
- 04.18.23 Lipella Pharmaceuticals Enters Manufacturing Collaboration Agreement with Cook MyoSite (medtechalert)
 - Lipella Pharmaceuticals, a clinical-stage biotechnology company addressing serious diseases with significant unmet need, has entered into a manufacturing collaboration agreement with Cook MyoSite to facilitate Chemistry, Manufacturing, and Control documentation for Lipella's drug candidate LP-10 (liposomal tacrolimus), aimed at treating hemorrhagic cystitis. LP-10 has been granted Orphan Drug Designation by the FDA.
- 04.18.23 PCI Pharma Services Announces New Sterile Fill-Finish Capabilities Now Available in Melbourne and San Diego (PR)
 - three new state-of-the-art automated sterile fill-finish machines at its San Diego and Melbourne facilities are now fully operational. The innovative machinery from Cytiva can be used to fill various sterile medications into vials and syringes for small-to-mid scale client needs. The Microcell Vial Filler and SA25 Aseptic Filling Workcell at PCI's San Diego facility ensures the delivery of medicines from phase I through phase III, supporting local and global Clinical client needs. Additionally, a Microcell Vial Filler at Melbourne further enhances the early-stage services offered and brings additional capacity to Australia—the world's leading phase I environment. These advanced machines expedite the filling process with automation and remove the need for human intervention in a sterile environment, creating compliance advantages over standard equipment.
- 04.17.23 Meridian sets down \$100m for US manufacturing facility (<u>outsourcingpharma</u>)
 - Only a few months after being bought out, the CDMO is building a \$100M facility in Bridgeton, Missouri. The facility will cover 155,000sf and be used to increase the production capacity of drug-device combination products, and sterile-finish capabilities. The exact number of new employees was not disclosed, but it noted that it employs approximately 300 employees in St Louis, with a total headcount of 900 in the metro area.