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Media Contact:

Abby Ryan
(512)-686-2146
aryan@AustinPx.com

AustinPx's KinetiSol™ Technology Receives FDA Advanced Manufacturing Technology Designation

Designation supports earlier FDA engagement and greater regulatory predictability for pharma and biotech sponsors using formulation and manufacturing technology to enable their drug candidates

GEORGETOWN, TX., September 15, 2026 — AustinPx, a contract development and manufacturing organization (CDMO), today announced that the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER) has granted Advanced Manufacturing Technology (AMT) designation to KinetiSol™ Technology.

KinetiSol is a solvent-free technology for producing amorphous solid dispersions of poorly soluble oral drug candidates. It can be used from early development through commercial manufacturing and expands the options available for molecules that can be difficult to address with conventional ASD technologies.

The FDA created the AMT Designation Program to encourage the early adoption of innovative manufacturing methods that can enhance product quality, reduce drug development time, strengthen supply reliability and help prevent or address critical drug shortages.

"Drug developers shouldn't have to choose between the manufacturing technology that best fits the molecule and the one with the most familiar regulatory path," said Elizabeth Hickman, CEO of AustinPx. "Awarded based on the FDA's comprehensive review of the KinetiSol Technology, the AMT designation provides our clients with greater confidence in the regulatory path to commercializing their KinetiSol-enabled drug candidates."

For sponsors using KinetiSol as the amorphous dispersion manufacturing process for clinical candidates, the designation provides opportunities for earlier FDA engagement and additional communication during drug development and application assessment. This can help sponsors

address Chemistry, Manufacturing and Controls (CMC) questions sooner, reduce regulatory uncertainty and plan more efficiently as their programs move toward commercial manufacturing.

“After more than 15 years of developing KinetiSol and applying it to over 70 poorly soluble molecules, we are honored to receive this designation,” said Chris Brough, Ph.D., Chief Technology Officer and co-inventor of KinetiSol. “As more of our clients advance their KinetiSol-formulated candidates into late-phase development and toward commercialization, the FDA’s recognition reinforces KinetiSol’s value as a commercial manufacturing technology.”

To learn more about KinetiSol and the AMT designation, visit www.austinpx.com/amt-designation.

About AustinPx

AustinPx is a contract development and manufacturing organization (CDMO) providing analytical and formulation development services and cGMP manufacturing for small molecule drugs. The company specializes in phase-appropriate development strategies, speed to clinic and speed to market strategies, and bioavailability enhancement of poorly soluble molecules, including its next-generation amorphous dispersion platform, KinetiSol™ Technology. For more information, visit www.AustinPx.com.