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Kindeva Drug Delivery Launches New Analytical Services Global Business Unit

WOODBURY, Minn. and ST. LOUIS, Mo.; Jan. 31, 2024 (Business Wire) – Kindeva Drug Delivery (Kindeva), a global leader in drug-device combination products, announced the expansion of its analytical services capabilities — launching a new global business unit offering integrated and stand-alone analytical support to the wider pharmaceutical, biopharmaceutical, and medical device sector. For more than half a century, Kindeva has developed significant knowledge, experience, and expertise working on inhaled, injectable, and transdermal drug delivery development programs and cGMP commercial supply. Additionally, Kindeva has built deep expertise and capability in cGMP analytical services supporting its product development and supply partners.

In addition to increasing Kindeva's global analytical footprint, Kindeva's recently opened 32,000-square-foot state-of-the-art laboratories in Woodbury, Minnesota, will serve as the central hub for its expanded suite of stand-alone analytical services. Kindeva's Global Chief Commercial Officer Dave Stevens added: "Offering considerable analytical testing capabilities on a stand-alone basis to the wider pharmaceutical and device industry is an important step for Kindeva's growing role as a global contract analytical, development, and manufacturing organization. 2024 is an exciting year for bringing many areas of needed industry solutions to fruition with the opening of a brand new world-class, state-of-the-art sterile injectable facility in Bridgeton, Missouri — capable of manufacturing more than 100M vials, cartridges, and syringes — as well

as the operationalization of our first 152a green propellant-capable GMP capacity in Loughborough, U.K. Expanding the analytical suite of capabilities and capacity reflects our ambition to be a true full-service partner and market leader in the CRO/CDMO industry and further accelerate the safety and efficacy objectives of innovators."

Kindeva will offer extractables and leachables, elemental impurities, medical device, and container closure integrity testing. Kindeva's new container closure integrity testing to USP <1207> will be led by newly appointed Manager of Container Closure Integrity (CCI) and Medical Device Testing, Michael Dominguez, who recently joined Kindeva from DDL Testing. Dominguez brings deep expertise spanning a wide range of performance and functional medical device testing standards in deterministic CCI methods, including high voltage leak detection, vacuum decay, laser headspace analysis, and residual seal force testing. Kindeva's extractables and leachables testing, and elemental impurities testing to ensure products comply with the ICH Q3D Guideline for Elemental Impurities, are led by Dan Dohmeier. Dohmeier's team brings more than 60 years of extractables and leachables method development, validation, testing, and compound identification experience to address customer testing needs. Kindeva, including Dominguez and Dohmeier, will be available to meet in Anaheim, California, at the upcoming MD&M West on Feb. 6-8, 2024, in Booth #972. For a complete listing of Kindeva's analytical services, visit https://www.kindevadd.com/analytical-services/.

About Kindeva Drug Delivery

Kindeva Drug Delivery is a global contract development and manufacturing organization focused on drug-device combination products. We develop and manufacture products across a broad range of drug-delivery formats, including pulmonary & nasal, injectable, and transdermal. Our service offerings span early-stage feasibility through commercial scale drug product fill-finish, container closure system manufacturing, and drug-device product assembly. Kindeva serves a global client base from our state-of-the-art manufacturing, research, and development facilities located across the U.S. and U.K.

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