Kindeva: A Historic CDMO, Reborn

Our name has changed, but Kindeva remains the world’s foremost CDMO in guiding customers through complex drug formulation and delivery, from product development to manufacturing.
Trust is the foundation of any organization’s relationship with a contract development and manufacturing organization — trust in that CDMO’s capability, its ability to function efficiently while maintaining high quality and, perhaps most of all, trust it will know what to do when issues arise.

Many large organizations rightfully ask, couldn’t we handle this work in-house? Indeed, most companies beyond a certain size have the in-house expertise to guide a product through development and commercialization. A more crucial question might be whether those in-house teams can draw upon deep experience to address unforeseen challenges — perhaps in a formulation or delivery method that is novel to them?

Smaller companies have a different set of concerns. Maybe their in-house capability is limited. They need to find a partner with a more holistic understanding of the process, from start to finish, of formulating, developing, and manufacturing complex drug products.

Kindeva Drug Delivery (“Kindeva”) is able to provide CDMO solutions for companies of all sizes. While the name and brand launched in 2020, the company’s legacy spans decades, bolstered by the expertise and capability that longevity provides. This article details Kindeva’s unmatched capabilities in complex drug products — from formulation and product development to scale-up and commercial manufacturing.

Who is Kindeva?

Kindeva is a privately held company owned by Altaris Capital Partners, LLC. It was formed when 3M sold its drug delivery systems business to Altaris in 2020. Kindeva can trace its origins back to Riker Labs, founded in the mid-19th century, which invented the world’s first metered-dose inhaler in 1956 before being bought by 3M in 1970. Now, Kindeva has grown to be a global organization with a manufacturing and R&D footprint in both the US and the UK.

The name Kindeva (kin-DEV-uh) is a combination of “kinetic” and “development” — representative of the company’s expertise in using a delivery device to move drugs across or through a complex set of layers or surfaces. In short, “Kindeva“ helps to personify the team’s capability.

While M&A activity can be interpreted as negative in some cases, Kindeva’s formation as a stand-alone entity has instead empowered the company. As a stand-alone company, Kindeva focuses exclusively on solving customers’ toughest problems — and is able to accelerate decision-making and responsiveness.

What hasn’t changed at Kindeva is the team with whom customers work, their commitment to delivering quality, and their expertise in drug formulation, delivery, and production. We are invigorated by the opportunities this shift creates, both in-house and for customers.

What Kindeva Does...

All pharmaceuticals are inherently complex. Careful consideration must inform how that product is manufactured, at the desired scale, to ensure its consistent safety and efficacy — as well as how the drug will be formulated in conjunction with its intended delivery system.

Complex drug formulations are at the heart of Kindeva’s operation. The team works to ensure complex molecules are as effective in the clinic as in the lab. Any formulation
conceived is weighed against the feasibility of manufacturing that drug at scale, and at a cost profile consistent with what the customer seeks.

Further, Kindeva develops each drug formulation parallel to its delivery system, so the latter’s feasibility of successfully delivering the drug can be determined and adapted, as the delivery system is inextricably intertwined with the underlying drug’s effectiveness.

An excellent example of this concept in action is microneedles – more appropriately referred to as microsystems – which deliver drugs to a part of the body just below the skin (not deep enough to pierce subcutaneous tissue, muscle, or the nerve layer). Injections at this depth can trigger a robust immune response from a patient. This response is desirable if you’re delivering a vaccine (e.g., immune-oncology assets), in no small part because it means you need relatively less of the underlying drug to trigger the targeted response.

Microsystems, while not intended solely for self-administration, nonetheless provide value in that arena. In a situation like the COVID-19 pandemic, where one may need to distribute a vaccine across a very large population, the response would be limited if the model followed was that of the flu vaccine (i.e., typically, a standard syringe that must be refrigerated, as well as administered by a physician to achieve intramuscular delivery).

Metered-dose inhalers (MDI) provide another relevant example. Developers must think about valve design, the actuator, the propellant, the excipient — all the elements affecting how the drug is expressed into the lungs, how the body metabolizes it, and how the patient is impacted.

Finally, consider transdermal patches — critical choices include the patch adhesive, liner, and backing. Again, the whole system impact must be examined: how the drug gets across the skin into the body, how it wears, the length of its wear period (e.g., a few hours, a few days), patch geometry, and patient skin sensitivity and irritation.

... and How We Do It

Kindeva nurtures the entire complex drug/delivery device life cycle alongside its customers, from product development through to commercial manufacturing. This total package approach offers a holistic alternative to partners who technically develop a product but leave it to others to carry across the finish line.

Dating back well before its brand/name change, Kindeva has the longest track record of innovation and industry leadership among CDMOs of complex drug programs — proving its mettle through success with novel, think-on-your-feet regulatory and approval challenges.

Kindeva has completed more than 20 drug master files (DMFs), more than 20 new drug applications (NDAs), and more than 30 abbreviated new drug applications (ANDAs). Our customers have launched more than 20 products. Kindeva has navigated metered-dose inhalers and the first seven-day drug-and-adhesive patch through strict formulation requirements, as well as clinical and regulatory efforts.

Kindeva also is differentiated by its track record in developing and maintaining intellectual property (IP). The company’s robust patent library and in-house know-how are tangible proof that there is no substitute for experience.

The same is true of Kindeva’s manufacturing expertise. Kindeva supports clinical and regulatory trials, as well as validates the manufacturing process. Our team can create initial product prototypes, manufacture small runs, and scale up production. Kindeva has exhibited continuous excellence in this respect, making numerous products and guiding them through regulatory approval before transitioning into commercial manufacturing and packaging for distribution to 60+ countries, factoring in all the varying requirements.

Once a product is ready to transition to commercial manufacturing, Kindeva can devise a launch control strategy for that product, bolstered by quality agreements our team develops with customers. Upon this foundation, Kindeva builds a manufacturing operation that adheres to agreed-upon specifications while maintaining compliance to evolving regulatory standards.
Kindeva's expertise is invaluable in terms of time and cost savings, considering some countries accept FDA approval for product registration on their soil, while others don’t. Labeling and packaging must be well-understood and meticulously applied to pass muster. Language and translation issues also may be part of this equation. Additionally, Kindeva maintains a keen awareness of shifting regulatory standards. For example, some markets may have serialization requirements whose processes must be understood. In these scenarios, Kindeva will work very closely with our customers to file appropriate updates and manage change carefully.

**Conclusions**

Whatever healthcare challenge a company is attempting to overcome, the drug delivery system and the underlying molecule become deeply integrated. Whether it’s a viscous biologic, a complex inhaled therapy for novel diseases, or a high-value vaccine, the delivery approach is vital to achieving the appropriate pharmacokinetic profile you’re targeting. Thus, the earlier in the process you make decisions around integrating drug and device, the better. Whether your company is a startup with big new ideas or a corporate giant with design and formulation tweaks, Kindeva can help you to achieve them — start to finish.

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**About The Author**

*Aaron Mann* is the CEO of Kindeva Drug Delivery. Previous industry roles include leading 3M’s Drug Delivery Business, and leading strategy and business development for 3M’s Healthcare Business Group. After beginning his career with Bain & Company, focused on healthcare and performance improvement practices, Aaron served as an executive at Phillips-Medisize (Corporate Development and Marketing) and Remedi SeniorCare (Operations). He holds a B.A. from Carleton College and an MBA from the Harvard Business School.

**About Kindeva Drug Delivery**

Headquartered outside St. Paul, Minnesota, *Kindeva Drug Delivery* is a leading global contract development and manufacturing organization (CDMO) in the pharmaceutical industry. Kindeva provides unique technologies and quality services to its customers, ranging from formulation and product development to commercial manufacturing. Kindeva focuses on complex drug programs, and its current offering spans inhalation drug delivery, transdermal drug delivery, microstructured transdermal systems (microsystems), and connected drug delivery. Kindeva employs approximately 900 people at six facilities worldwide.