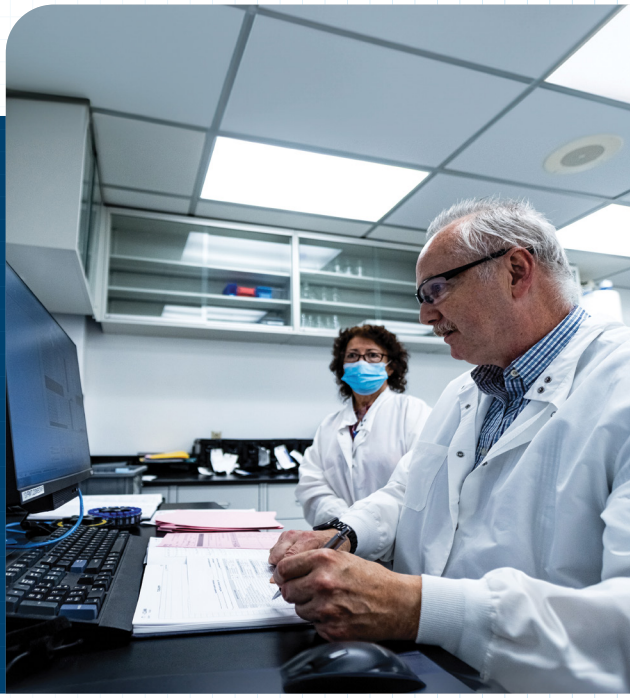
Kindeva
DRUG DELIVERY
Manufacturing More Tomorrows™



Analytical Services

Ensure your product's quality & reliability

Your therapy is a force for good. Kindeva Drug Delivery can support its regulatory compliance. Working with an experienced partner from the beginning streamlines timelines and accelerates your path to market, while delivering the quality patients expect and require. We provide unrivaled support across drug-delivery formats, backed by state-of-the-art facilities and an industry-leading, service-focused team.

Over a century of analytical experience

With more than 100 years of experience and a demonstrated track record of compliance with regulatory bodies worldwide, we are a global force in combination product development and manufacturing. We have an extensive history of providing analytical services, backed by industry-leading capabilities and unrivaled know-how.

How we safeguard your product's quality

Kindeva provides a wide range of analytical services, each tailored to your unique needs.

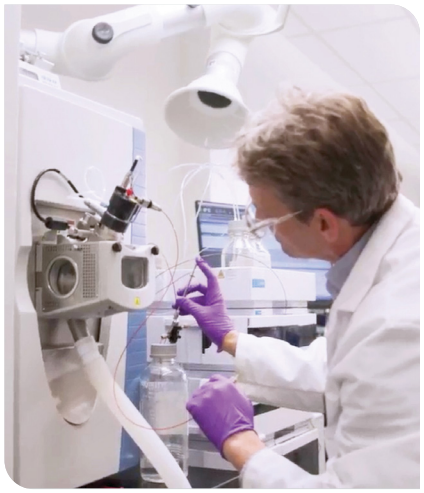
Analytical method development & validation

- Up to date with USP, ICH, and ASTM guidance
- Risk-based approach to analytical method development
- Rapid response time and expert guidance to support products in clinical stage development
- Long-term support across your product's life cycle, alongside method verification and method transfer options

Stability testing & storage

- Custom stability protocol development following ICH guidelines
- ICH storage condition testing: -20°C, 5°C, 25°C/60% RH, 25°C/75% RH, 30°C/65% RH, 30°C/75% RH, and 40°C/75% RH (Other conditions available upon request)
- Temperature cycling
- Continuous monitoring & real-time data, utilizing the latest technology

Extractables and leachables testing



- Extensive analytical capabilites for your combination product's container closure system, delivery system, containment system, and packaging — in extreme and standard conditions
- Wide range of analytical equipment: GC, GC/MS, headspace GC/MS, UPLC, and high-resolution accurate mass (HRAM) LC/MS/MS
- Best practices and guidance as outlined in USP <1663>, PQRI guidance, and ISO 10993
- Extractable/leachable compound identification

Medical device testing

- Optimize performance and safety testing by ensuring consistent device functionality and precise dosage delivery, meeting ISO and FDA guidelines for needle-based injection systems and combination products
- Incorporate key aspects of device testing, such as delivery accuracy, device actuation, and mechanical functionality, as well as stability and quality testing with both the drug and device components

Container closure integrity testing

Coming Q2, 2024

- 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

Elemental impurity testing

Coming Q2, 2024

- Demonstrate control of elemental impurities in compliance with ICH Q3D guideline for elemental impurities

Contact us to explore our analytical and testing services.

COMBINE FORCES WITH KINDEVA

cGMP-Compliant, FDA-Registered Laboratory

Kindeva performs our analytical and testing services in our Woodbury, MN, laboratory. This FDA-registered facility operates in accordance with cGMP standards, with Quality by Design (QbD) principles at the center of all our processes.

Capabilities spanning delivery formats

Kindeva has a rich history of excellence and innovation across pulmonary & nasal, injectable, and transdermal drug-delivery formats. This expertise forms the bedrock of our analytical chemistry and testing services, allowing us to provide unmatched support for your combination product across all stages of development and manufacturing.

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.