Kindeva

Why Kindeva

Analytical and regulatory services: Exceptional by design

Why fast-track healthier tomorrows with Kindeva?

We are a drug delivery CDMO dedicated to supporting you in transforming tomorrow for patients, through expert analytical and regulatory support.

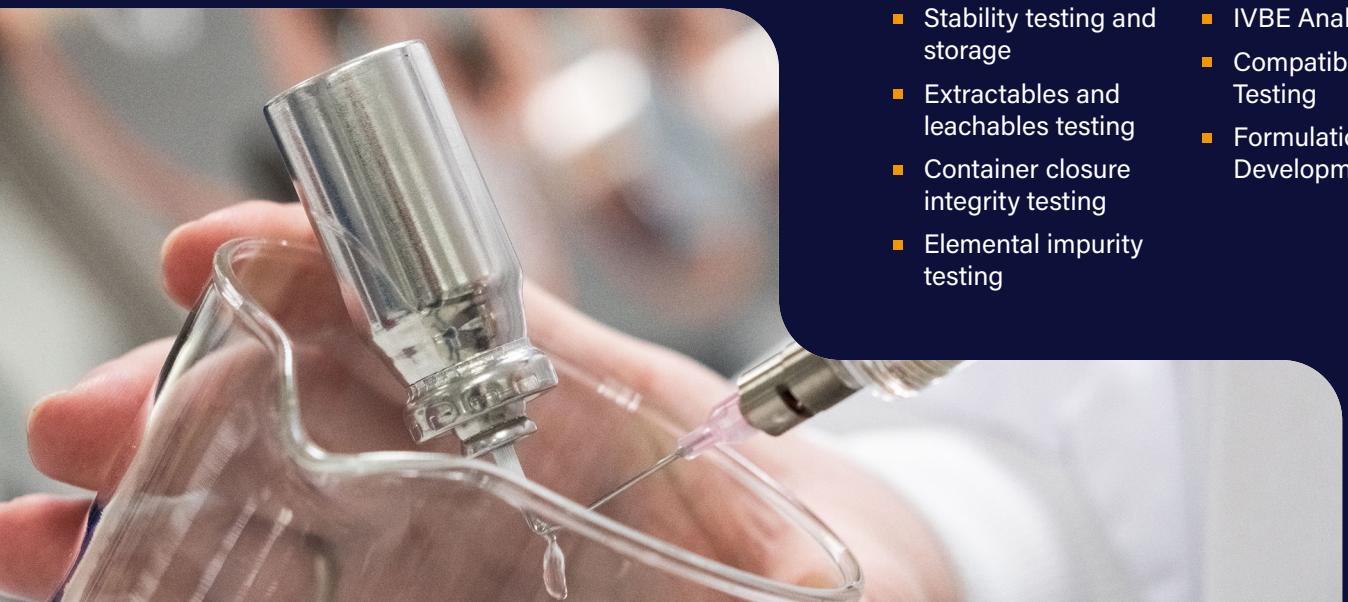
Leveraging specialist injectable, pulmonary, nasal and dermal expertise, our team can help you overcome testing and compliance, as well as quality challenges, and advance your project, your ambitions and the future of drug delivery.

Analytical capabilities: Specialist expertise

Our analytical team is dedicated to your lasting legacy. We invest in the highest quality facilities and phase-appropriate analytical capabilities to provide strategic value throughout the development and commercialization of your drug product, turning your analytical obstacles into long-term successes.

Services

- Analytical method development and validation
- Raw material testing
- Stability testing and storage
- Extractables and leachables testing
- Container closure integrity testing
- Elemental impurity testing
- Performance and Functional Analysis
- Device Design and testing services
- IVBE Analysis
- Compatibility Testing
- Formulation Development



Regulatory support
A strategically minded approach

Our team has a rich regulatory heritage of obtaining and maintaining IMPD/IND, DMF and Marketing Authorisation approvals, as well as in-depth knowledge of global legislation, regulations and guidelines, helping you to meet the demands of today and deliver the possibilities of tomorrow.

Services

Regulatory operations

- Preparation of eCTD-ready submission documents
- Regulatory intelligence monitoring
- Document management and archiving
- Management of publishing vendors
- Drug and establishment listing

Regulatory strategy

- Initial product development strategies
- Pre-submission support
- Expedited approval pathways
- Health authority interactions
- Product labeling
- Combination products and human factors studies
- Post-marketing maintenance

Regulatory compliance

- Annual and periodic reporting (PADER / DMF / IND / NDA)
- Internal/external audit support and CAPAs
- Advertising and promotional material reviews
- Packaging artwork updates
- Drug shortage notifications
- Regulatory change management

Quality built in

We operate within Quality by Design (QbD) principles, ensuring that quality is embedded in every stage of the development and manufacturing process to amplify the impact of your product. With extensive experience in meeting both medical device and pharmaceutical requirements from regulatory bodies worldwide, our experts can help you:

- Streamline timelines and accelerate your path to market
- Deliver the quality patients expect, while complying with the latest global regulations
- Leverage a risk-based approach that encompasses the life cycle of your product and intended use
- Establish development and manufacturing methods that are sustainable from batch release throughout your stability programs

Our commitment to quality

1. **Customer**
   - Alignment to customer expectation
2. **Leadership**
   - cGMP and compliance focus
   - Quality 1st behaviors
3. **People**
   - Data integrity and right-the-first-time
4. **Process**
   - State-of-the-art processes
   - Real time continuous process
5. **Improvement**
   - Proactive signal management
6. **Evidence-based decision making**
   - Risk based CQV driven
7. **Relationship management**
   - Proactive communication
   - Transparency
   - Partnership

Manufacturing More Tomorrows™

As your strategically-minded analytical, regulatory and quality partner, we help the pharmaceutical industry manufacture and deliver over 150 million products annually, accelerating the global reach of essential therapies.

You dream it, we deliver it. Let's make your future.

Let's transform tomorrow together. **Contact us**