DataRevive
A VALIDANT COMPANY

CORPORATE PROFILE

Expert Guidance for a **Faster Path to Drug Product Approval**

Specializing In:

- Regulatory Strategy
- CMC
- Preclinical
- Clinical

For Product Including:

- Small Molecule Drugs
- Biological Products including Biosimilars
- Vaccines
- Gene & Cell Therapies

In Global Markets:

- USA
- Europe
- Asia
- ROW

DataRevive delivers deep real-world regulatory, CMC, preclinical, clinical, and GxP expertise to pharmaceutical and biotech innovators seeking product approvals in major global markets.

Our team includes a truly one-of-a-kind roster of former FDA CMC and clinical professionals and industry operators who specialize in critical regulatory pathways globally.

Helping You Navigate Development End-to-End

DataRevive's experts aren't just consultants but hands-on partners in your success, working alongside you to accelerate time-to-market while upholding high quality from the earliest stages on.

Strategic Consulting

Including therapeutic regulatory strategy and planning for CMC, preclinical and clinical study design, and more.

Execution Services

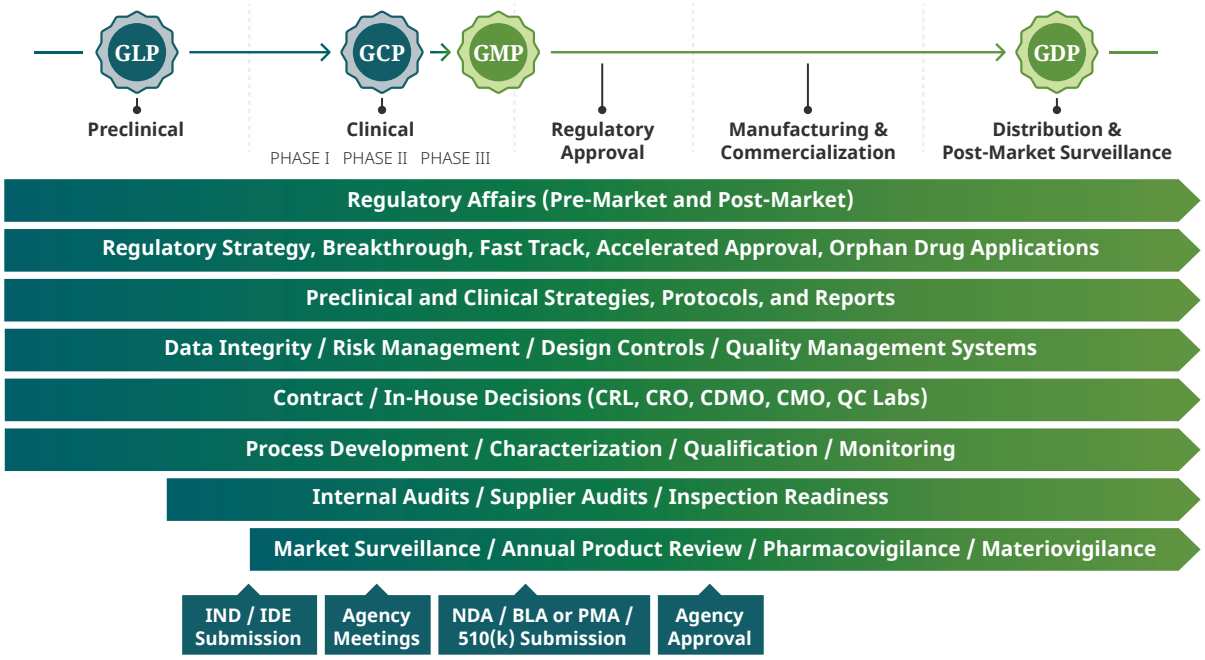
Handling dossier writing, filings, and maintenance for INDs, BLAs, and NDAs, as well as representing you at agency meetings.

Ongoing Support

Providing post-approval regulatory support services such as GMP mock inspections and regulatory agent services.

Specialized Regulatory Focus, **Proven Results**

No other consulting firm maintains the depth and breadth of expertise that DataRevive has in-house to support drug products through the entire regulatory approval lifecycle.



IND Packages Optimized for Approval

DataRevive upholds an exceptional track record for having IND applications accepted on first submission.

Streamlining Time to BLA/NDA Submission

We will help you prepare for pre-BLA meetings, compile clinical trial study summaries, conduct GMP pre-approval mock inspections, and write and submit your final marketing application.

Lifecycle Strategies to Approval and Beyond

DataRevive is your one-stop-shop for regulatory strategy but we also extend support post-approval. As a Validant company, we are part of a team specializing in every facet of the GxP product lifecycle.

Get and keep your global approvals on track with DataRevive.

Start today by visiting **www.data-revive.com.**

DataRevive
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US Headquarters
Rockville, MD

Asia Headquarters
Beijing, China