



## Regulatory Strategies

### Get to Market Faster with Robust Regulatory Strategies

Even with positive results and solid data, your submissions to regulatory agencies can still be met with questions and requests for additional data and trials.

These costly delays can often be avoided with the right regulatory strategy.

### Our Experts Can Help You...

- ✓ Navigate the complex global regulatory arena with clear strategic objectives and planning
- ✓ Meet the requirements of global regulatory affairs and compliance to balance risk (de-risk assessment)
- ✓ Develop, refine and validate PBPK and PBBM models to support biowaivers
- ✓ Develop and validate IVIVC/IVIVR to support clinical relevant drug product specifications
- ✓ Establish safe space to gain flexibility in regulatory assessment
- ✓ Integrate support and training for your R&D teams
- ✓ Decrease the cost and time required to develop detailed reports
- ✓ Facilitate interactions with regulatory agencies, from meetings and conference calls to answering regulatory questions
- ✓ Ensure patient-centric drug product development/quality and reduce the number of information requests