

Recent IND Enabling Support

- IND enabling Tox and CMC execution team for a biologic
- IND enabling development planning, execution of DS development and Manufacturing at a Chinese CMO, and formulation problem solving for an injectable oncology product
- CMC and Clinical strategy support for a depot delivery for a metabolic disease, submission publishing
- Planning and support of DS, DP, Analytical, Tox, Regulatory for 1 preclinical and 1 clinical stage CNS asset
- DS, DP, Analytical planning and oversight with CMOs, , QA function, writing and publishing support for 3 INDs, DS, DP, Analytical , validation and writing of 2 NDA programs
- Tech Ops, NDA writing and tox support of a drug device combination in pain management
- Support of CMC NDA writing and regulatory operations, technical support of DS manufacturing, delivery device design verification