

Recent NDA-Enabling Support

- DS, DP, Analytical planning and oversite 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