Consultancy

Regulatory Strategy

Scientific Input

IND for Novel First-in-Class Small Molecule Drugs

NEED

- US biotech company required integrated program management including IND-enabling preclinical studies and writing of First-In-Human study
- Support for the organization, storage, planning and scheduling of IND
- Short time frame for filing of IND to meet financial milestones

APPROACH

- Integrated project team led by Celerion program director
- Collaborated with the client on drug development program plan and site management
- Consistent communications plans including teleconferences and team meetings
- Detailed tracking of required deliverables to meet milestones
- Supported chemistry completion and outsourcing of synthesis to a GMP facility
- Audited non-Celerion vendor sites on behalf of client
- Oversaw development of bioanalytical assays
- Provided regulatory guidance with the FDA, and prepared IND documentation

BENEFITS

- Completed Chemistry and Manufacturing Controls (CMC) and preclinical work and IND submitted within challenging investor-driven timelines
- Managed a complex program with numerous vendors, client representatives and external consultants, to ensure program remained on track
- Supported the alignment of the operational team and client management enabling the senior management to focus on investor activities following review of IND, FDA allowed initiation of FIH study with patient arm
- Exceeded client expectations and began additional program for second generation compound