Regulatory Strategy

Scientific Input

Regulatory Operations

EU Biotech Needs First-in-Human FDA Support

NEED

- European biotechnology company with lead recombinant biotechnology product intended to treat inflammatory diseases seeking First-In-Human (FIH) US clinical study required assistance in communicating with FDA
- Required experienced regulatory affairs team to better understand FDA perspective and requirements
- Required meaningful interaction with FDA to enable on-time clinical start-up for drug development program

APPROACH

- Reviewed non-clinical data and non-clinical development program
- Reviewed manufacturing data from third-party contract manufacturers
- Prepared preIND debriefing package
- Authored all non-clinical and manufacturing sections of the IND with continuous input and collaboration from initial client, subsequent major pharmaceutical licensee, toxicology experts, and contract manufacturers
- Published complete IND with protocol provided by new Investigational New Drug (IND) client, a major pharmaceutical company

BENEFITS

- Obtained on-time and effective FDA input during and throughout the IND pre-filing phase even with unexpected non-clinical results subsequent to filing of pre-IND meeting debriefing package
- On-time and effective clearance of IND allowed clinical trial start-up as per client's requirements

See Other Case Studies

Semen Clinical Studies

Difficult to Recruit Population

Bioanalytical Support of Oncology Studies