DESCRIPTION OF Clinical & Regulatory Support

Include as requested (but are not limited to the following activities):

- Clinical and Regulatory strategy support
- FDA negotiations and interactions (Q-sub meetings, IDE submissions)
- Interaction with company personnel on device design changes and implications to clinical and regulatory strategy
- Clinical protocol design and development
- All phases of clinical study execution and project management
- Reporting (FDA and IRB submissions, IDE submissions, amendments, annual reports)
- Key opinion leader and medical advisor management
- Steering Committee, DSMB, CEC and CRO selection and management
- Development and creation of protocol/CRFs, consent, DSMB/CEC Charters
- Study related materials (training, site selection, site qualification
- Development of process documents (SOPs, work instructions)
- Site selection, management and start-up
- Site agreements negotiations and contracts
- CRO management and interaction