

Project Case Summary

Global Regulatory Support for I.V. and I.M. Formulations

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Client:	<i>Small U.S. company</i>
FDA Reviewing Division:	<i>Division of Antiviral Products</i>
Project Profile:	<i>I.V. and I.M. Formulations</i>

Beckloff Associates was engaged in the project after the client had inactivated their IND.

1. Planned global drug development strategy with client, including indications, CMC, nonclinical, and clinical development plans for U.S. and ex-U.S. countries for I.V. and I.M. formulations
2. Provided guidance and training regarding GMP manufacturing guidelines
3. Reviewed and evaluated drug product and drug substance CMC data, including stability studies, packaging, manufacturing methods, and Certificates of Analyses
4. Managed all regulatory affairs activities, and interacted with the FDA on the client's behalf
5. Led meetings with FDA, prepared Meeting Request and Information Package, and prepared the client for the meeting
6. Submitted two INDs to the FDA (electronic submission in CTD format)
7. Prepared, reviewed, and submitted documentation to FDA including IND Information Amendments, Protocol Amendments, Safety Reports, Annual Reports, and General Correspondence
8. Reviewed, evaluated, and revised Investigator's Brochure (IB) on annual basis
9. Reviewed, evaluated, and revised new protocols and protocol amendments
10. Reviewed regulatory documents and approval of study drug shipment
11. Prepared, reviewed, and evaluated clinical study documents and reports
12. Prepared U.S. Fast Track Designation request (approved)

13. Reviewed and evaluated documentation to ex-U.S. regulatory authorities, Requests for Scientific Advice, and General Correspondence
14. Prepared CTAs with IMPDs for ex-U.S. regulatory/ethics commissions
15. Maintained file of ex-U.S. regulatory documentation

Outcome:	<i>2 INDs submitted, U.S. Fast Track Designation approved, CTAs submitted, Phase 2 trials underway</i>
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