

# **Alters Bioscience Consulting**

## **Pre-Clinical Development, Due-Diligence, Scientific Writing**

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**I am an independent consultant working with biotech companies to advance the development of therapeutic agents for oncology, autoimmune and inflammatory disease. My expertise spans basic research through Phase I and includes IND-enabling pharmacology, efficacy and mechanistic studies.**

## **Consulting Services**

- Identifying client needs, developing and implementing pre-clinical/translational R&D strategy, compiling and adhering to project plans and budgets.
- Performing literature-based project assessments, designing and implementing study protocols and integrating study results into ongoing development plans.
- Evaluating, selecting and managing appropriate contract research organizations (CROs) and academic collaborators.
- Performing scientific and intellectual property due-diligence on new corporate ventures and product in-licensing opportunities.
- Writing relevant sections of INDs, business plans, reports, manuscripts and other scientific and corporate documents.

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## **Summary of Qualifications**

Fifteen years of broad and extensive experience in the biopharmaceutical industry. Expertise spans all phases of drug development from basic research through Phase I clinical study, and multiple therapeutic areas including oncology, autoimmune disease, transplantation and asthma/allergy. Experience with a wide range of therapeutics including proteins, small molecules, cell-based vaccines, nanoparticles and antibodies and major technology areas including targeted therapeutics, immunology, drug delivery, biomarker identification and cell and gene therapy.

Excellent collaborative skills gained by serving as liaison between industry, CROs, government agencies and thought leaders in academia and industry. Proven analytical, writing and presentation skills as evidenced by reports, IND submissions, publications and presentations to external experts in the field. Extensive management experience including scientists with diverse educational backgrounds, project teams composed of cross-functional contributors and external collaborators.

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## Representative Consulting Projects

### Pre-clinical development

- Designed and implemented IND-enabling pre-clinical strategy for oncology therapeutic now in Phase II. Evaluated and directed CROs to perform a series of studies including mechanism of action, efficacy in a variety of orthotopic and metastatic xenograft models, pharmacokinetic and biodistribution studies. The data were used to support the IND filing.
- Developed and implemented pre clinical strategy for a series of biologics, one of which is now in Phase I. Strategy included literature-based assessments of several novel therapeutic agents for rheumatoid arthritis, multiple sclerosis and transplantation, followed by immunoassay development, *in vitro* mechanism studies and autoimmunity model efficacy experiments performed by CROs.
- Designed and implemented pre clinical studies to document the *in vitro* activity and *in vivo* efficacy and toxicity of a targeted oncology therapeutic both as a single agent and in combination with standard cytotoxic drugs.

### Due-diligence

- Provided scientific evaluation of new corporate ventures including in-licensing new product opportunities and research feasibility proposals. Analyzed scientific data and evaluated input from thought leaders in the field. Proposed internal development strategy for chosen corporate ventures.
- Evaluated intellectual property position of a variety of therapeutic and diagnostic approaches for potential new partnership opportunities.

### Scientific Writing

- Worked with team to write and submit IND including obtaining, analyzing and graphing data from IND enabling studies and writing a series of internal reports.
- Wrote corporate documents including business plans, annual reports, INDs, Investigator Brochures, grants and manuscripts.
- Represented company at scientific meetings, presented findings and initiated collaborations with industrial, academic and government institutions.

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## Education

- Ph.D. Cancer Biology, Stanford University, Stanford, CA.
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