Vice President, Biologics Development

AREAS OF EXPERTISE

- **GMP**
- **R&D**
- **Regulatory Compliance**
- **Biochemistry**
- **Analytics**
- **Quality Control**
- **Regulatory Affairs**
- **CMC**

INTRODUCTION

Consultant is a senior biotechnology manager with extensive experience in the analysis and production of biopharmaceuticals. Experienced in both therapeutics and diagnostics ranging from discovery research to cGMP manufacturing. A comprehensive background in biologics analytical and process development, and implementing strategies for regulatory approval. An accomplished, goal oriented technical manager skilled at building and directing cross-functional product development teams.

WORK EXPERIENCE

2007 – Present
Industry Consultant
Example Engagements:

- Developmental planning and management of the production and characterization of biologics to meet regulatory expectations, management of outsourced activities and preparation of CMC documents for regulatory submissions.
- Technical guidance provided on analytical test method development and validation, product characterization, specifications, downstream process development and issues related to comparability and biosimilarity.

2006 – 2007
Biovest International, Worcester, MA
Vice President, Biologics Development
Duties:

- Directed analytical, process development and immunology departments for cancer vaccine and cell culture instrumentation divisions.
- Responsible for CMC activities related to product development of an autologous, antibody conjugate vaccine for Follicular Lymphoma.
- Defined and implemented an analytical strategy for the analysis and QC release of drug product and process intermediates. Methods ranged from physicochemical (mass spec, HPLC, light scattering) to bioanalytical (ELISA, SDS-PAGE, IEF) and potency assays.
- Developed ELISA and PCR based methods to monitor patient antibody responses and minimal residual disease to support secondary endpoints in a Phase III clinical trial.
- Developed and optimized protein purification and vaccine manufacturing processes.

1998 – 2005
Antigenics Inc., Lexington, MA
Senior Director, Scientific Affairs (2005)
Duties:

- Strategic planning and coordination of project activities between Development, Operations and R&D from discovery through commercialization.
- Provided guidance to regulatory affairs on scientific and CMC issues.
- Responsible for portfolio management and due diligence for business development activities.
- Primary author of key components of the CMC sections for regulatory filings including INDs, amendments and a BLA.
- Prepared detailed product development plans for new and existing programs.

Senior Director of Pharmaceutical Technologies (2001 – 2004)
Duties:

- Managed all aspects of analytical and process development, formulation, product characterization and discovery research for novel cancer vaccines.
- Developed, qualified and validated a broad range of physicochemical and biological methods for the characterization and quality control of biological products.
- Devised and implemented an analytical approach, involving in vitro cell-based and enzymatic assays, to fulfill the potency assay requirement for a complex biologic.
- Thought leader in defining creative strategies to meet the unique regulatory challenges for an unprecedented, patient-specific autologous immunotherapy.
- Developed manufacturing processes for autologous and recombinant products. Optimized conventional and affinity chromatographic and other protein separation methods to improve efficiency, robustness, and cGMP compliance.
- Developed a new formulation to enhance drug product stability and deliverability.
- Built and directed a discovery research function focused on developing new products based on core technology platforms.

Director of Analytical and Process Development (1998 – 2001)
Duties:

- Directed analytical and process development for protein-based immunotherapies for cancer and infectious diseases.
- Built a multi-disciplinary team which developed analytical methods for the characterization and analysis of protein and small molecule therapeutics.
- Developed purification procedures for autologous and recombinant proteins.

1996 – 1998
Autoimmune Inc., Lexington, MA
Associate Director of Biochemistry
Duties:

- Directed a team responsible for the characterization of proteins and protein-lipid mixtures for the treatment of autoimmune disorders.
- Developed a novel, FDA accepted approach to defining potency of a complex biologic.
- Developed immunoassays for drug product characterization and to support clinical programs.
- Used a variety of methods including chromatography, SDS-PAGE, ELISA, immunoblots, mass spec, CE, DSC and others to characterize complex protein mixtures.
- Completed comprehensive analysis of the lipid composition of a complex product derived from neuronal membranes.

- Authored and reviewed CMC sections for a BLA.
- Devised viral and microbial validation program to ensure regulatory compliance.
- Developed and qualified analytical test methods and implemented them in QC.
- Directed manufacturing process and analytical test method validation efforts.
- Established, managed and audited programs with external contractors.

1989 – 1996
Oncogene Science, Inc., Cambridge, MA
Principal Investigator, Diagnostic Research (1994 – 1996)
Duties:
- Managed the research and development program for cancer diagnostics.
- Developed antibodies and ELISAs to novel cancer markers for their detection in blood and tumor extracts. Targets included oncogenes, tumor suppressor genes, and steroid hormone receptors.
- Identified new diagnostic products based on the role of proteinases in cancer.
- Developed over 40 commercially available products for the research product and clinical diagnostic market.
- Oversaw all aspects of protein chemistry, hybridoma development and mammalian cell culture for the cancer diagnostics and AIDS vaccine programs
- Obtained SBIR grant support for new research programs.

Program Manager – Tumor Markers and Protein Chemistry (1993 – 1994)
Manager of Protein Chemistry (1989 – 1992)

1984 – 1988
Integrated Genetics, Inc., Framingham, MA
Staff Scientist
Duties:
- Responsible for the development of purification strategies and the characterization of proteins from natural and recombinant sources, including hCG, LH, FSH, erythropoietin and GM-CSF.
- Managed the exploratory research program investigating therapeutic applications of the Scavenger receptor, NMDA receptor and Na+, K+ ATPase.

EDUCATION

1977 – 1981
California Institute of Technology, Pasadena, CA
Postdoctoral Fellow

1972 - 1977
University of California, Berkeley, CA
Ph.D.: Biochemistry

Indiana University, Bloomington, IN
Bachelor of Science: Chemistry