Vice President, Pharmaceutical Development

AREAS OF EXPERTISE

- **Technology Transfer**
- **Regulatory Affairs**
- **Quality Assurance**
- **Biochemistry**
- **Quality Control, Biologics**
- **Analytical Method and Process Validation**
- **Regulatory Submissions**
- **Deviations/CAPA/Change Control**
- **Supply of Clinical Trial Material**
- **GxP, GMP**
- **21 CFR 210, 212**
- **SOPs**

INTRODUCTION

Consultant has been involved in several projects in either start up, early production or remediation (due to 483) for the creation, documentation, production of and shipping and storage of cell banks (bacterial and mammalian, non-recombinant and recombinant), raw material programs, in-process testing for PCS and drug substance and drug product testing programs and specifications. Working increasingly in the cell line creation, cell banking area as it has become apparent that the agencies (FDA and EU) are requiring more vigilance in this area.

Consultant has most recently undertaken projects in assisting in the modification of Quality Systems in a company producing radio chemical drugs, currently in compliance with 21 CFR part 212, to provide guidance for satisfaction of 21 CFR 211 requirements, specializing in raw material selection and acceptance systems, deviations, CAPA and Change Control. In addition, performed due diligence for an allogenic project to provide both review and advice for selection of raw materials and an assessment of the process and the CMO to be used.

Consultant continues to perform regular audits of biological production projects from raw material selection and testing through to drug product testing for both production originators and contract manufacturing/testing organizations.

WORK EXPERIENCE

09/1999 – Present
Industry Consultant
Duties:

- Audit of new facility from selection and receipt of raw materials, definition of critical raw materials and production in a new facility employing single use technology.
- Due diligence for development of CART program from selection of target, raw materials to interim use of CMO and CMO assessment.
- Audit of Global Cell Banking functions.
- Project to examine the development function and technology transfer for a biosimilar product produced in CHO cells. Emphasized cell line development, selection and banking in addition to method validation and method transfer.

- 4- month assignment to assist in developing Quality Systems for a 21 CFR part 212: radiolabeled product intended for 21 CFR 211 application.
- Assumed project manager role for tech transfer of biosimilar (mammalian cell lines) processes from contractor to in-house production assuring the transfer of full documentation of vector and cell line as well as master and working cell banks and analytical methods for comparability analysis for EU and US submissions.
- Working in India to perform project for review, revision and addition of appropriate documentation of raw material, cell line generation and banking, method and process validation and QC release testing program documentation for bacterially produced biosimilars in preparation for US IND submission.
- Provided regulatory guidance concerning production of bacterial cell banks, characterization and audit of several facilities to determine suitability of contracted or an in-house developed facility. Authored complete 483 response for client,
- Project manager for test methods project (chemical and physical methods, including Elemental analyses, IOQ of new equipment, plan for not qualified current equipment, re-write of 144 methods for EP, USP and in-house developed analyses, plus determination and execution of verification/validation of these same methods. Assisted in the search for and hiring of my replacement.
- Completed assessment of project for isolating neural stem cells (patient specific) for propagation and reinsertion into spinal cord. Provided testing regimens and advice concerning production rooms to assure sterility of drug product- cells.
- Completing project to advise client on the design, installation and validation of cleanroom facilities using qualified subcontractors.
- Completed analysis and assessment of product release method validations for compliance to current USP, EP, ICH guidelines (50 products) for a generic small molecule sterile manufacturing facility for updating CMC filings and response to FDA, EMA.
- Audit of contract laboratories, contract manufacturing facilities, parts suppliers, raw material API suppliers and compounding facilities as well as microbiology/ technology transfer support for several product development programs.
- Co-writing of eCTD for a new biologic entity, monitoring of outsourced production, development of analytical profile of drug, analytical assessment of formulation, auditing of raw material, analytical result and production vendors.
- Scale up activities for production of a cell-based cancer vaccine, coordinated with clinical development.
- Complete editing and addition of regulatory strategy to file a BMF for a cell line to produce viral vaccines
- Stability studies, vendor outsourcing selection and qualification for submission of a medical device PMA and Pre-Approval Inspection. Development and execution of assay validations as well as reports for submission for this PMA (HPV analysis).
- Assisted in development of testing program and pre-IND meeting documentation for gene therapy cell-based device
- Development of outsourcing production plans, preparation of FDA IND documentation for cell based toxicology testing program.
- Assessment and recommendations for improvement for both protein and small molecule products with respect to analytical method validation and current compliance with USP, EP and ICH Guidelines. As well as the design and execution of process validation to support a process control strategy (PCS)Gathering and organizing data for cell banks to provide historical documentation in electronic form. Review of all cell banking processes in two organizations and 4 European countries for compliance to FDA requirements and client requirement for security and assurance for process control strategies.
- Completed assessment and wrote response for 483 citation regarding cell banks (bacterial). Stated requirements for production rooms design required to assure sterility for preparation of cell banks, audited cell banking facilities as a potential solution other than building a new facility.

- Reviewing cell bank assurance and process validation documentation to satisfy Phase 4 requirements established by FDA prior to product approval and launch.
- Quality Systems Assessments for Stability, Technology Transfer, Annual Product Review, and Process Validation for major biotechnology firm under consent decree. Continued working as team lead for analytical and process investigations for three years.
- Writing and reviewing CMC and Facilities documentation in CTD format for vaccine products in Italy
- Writing and reviewing cell line master and working cell bank documentation, process development data, manufacturing development data and stability data for inclusion in a BLA for a multivalent vaccine.
- For Schering Consent Decree project: assisted with Regulatory Affairs documentation development and writing and developing standards and processes for the microbiology groups in Puerto Rico and NJ. Assisted the Quality Assurance group in selecting and auditing vendors for analytical and microbiological services.
- As Team Lead in Puerto Rico, responsibilities included interaction with senior management of major pharma company, assigning review, as well as reviewing, laboratory and manufacturing investigations, validation protocols for equipment and processes and batch records. Mentoring was performed for the investigations group during the project.
- Auditing and suggestions for improvement in sterile compounding facilities. Oversaw outsourcing and performance of ELISA assay to solve monitoring problem.
- Review of documentation for development and validation of test methods for compliance to current QSR, cGMP, US and European regulatory requirements.
- Assisted with writing of test methods, test method development reports, test method validation protocols and reports. Responsible for advising on process validation, quality assurance systems, reference standards and raw materials.

08/1998 – 2010
Copernicus Therapeutics, Inc.
Vice President, Pharmaceutical Development, (06/1999 – 2010)
Duties:
- Supervision of clean room preparation of compacted DNA for collaborative efforts. Implemented a quality systems program, batch records and testing plans for clinical product. Supervised animal testing program for toxicology. Supervised outsourced testing and production programs.

Director, Pharmaceutical Development, (08/1998 – 06/1999)
Duties:
- Supervision of clean room preparation of compacted DNA for collaborative efforts. Implemented a quality systems program, batch records and testing plans for clinical product. Supervised animal testing program for toxicology. Supervised outsourced testing and production programs.

03/1996 – 08/1998
SmithKline Beecham
Manager, Quality Control, Biochemistry, World Wide Supply Organization
Duties:
- Hiring and training staff to equip laboratories and implement a full program of biochemical and chemical analyses including: raw materials analysis, raw materials stability, vendor qualification, chemical water testing, in-process protein characterization, bulk drug substance and drug product analyses and stability programs for both drug substance and drug product.
- Design of the analytical comparability program for the scaled up manufacturing process.
- Coordination of technology transfer for three monoclonal antibody products from four user groups in Research and Development.

- Support of validation of the facility for water systems, cleaning and process validation as well as assisting in implementation of a LIMS data system.

03/1991 – 03/1996
Hoffmann-La Roche, Nutley, NJ
Associate Research Investigator, Pharmaceutical Analysis Research and Development (Quality Control), Research Investigator, Analytical Research and Development
Duties:
- Hired and trained staff and implemented methods for interferon and pipeline products (monoclonal antibodies, fusion proteins and new cytokines) for clinical and marketed product distribution.
- Implemented a revision of the Quality Control testing program for the new pipeline projects with respect to characterization for equivalency/comparability, in-process characterization and validation.
- Designed viral validation program for two products.
- Developed and coordinated release/acceptance testing program for two contract organizations under shared manufacturing arrangement.
- Devised protocols for and coordinated all testing of Roche/contractor information for IND, CTX and PLA/ELA submissions and clinical documentation worldwide for three recombinant (mammalian cell culture) projects.
- Assumed responsibility of CMC leader for a monoclonal antibody project and prepared and presented dossiers to US and MCA regulatory agencies for Roche.
- Attended all contractor FDA/EMEA meetings as Roche representative.
- Designed and executed comparability program for a monoclonal antibody in order to accomplish a cell line, media, culture method, purification and site of manufacture switch.
- Led project sub-teams for clinical manufacture and design of protocols for validation of the fill/finish and worldwide shipping for a protein dosage forms.
- Supervised generation of analytical method documents, set release and in process specifications and reviewed batch records for in-house production of a mammalian cell culture product.

12/1983 – 01/1991
BioResponse, Inc.
Research Scientist, Manager Special Projects, Manager Quality Control
Manager, Protein Chemistry and Molecular Biology
Duties:
- Equipped laboratories and hired and trained technical staff for small-scale purification (up to 100 grams antibody) and protein characterization assays.
- Supplied all protein characterization data to Quality Control.
- Equipped laboratory and hired and trained technical staff to generate recombinantly modified cell lines (plasmid generation, cell line transfection, selection and characterization).
- Assumed full responsibility for Quality Control and integrated protein characterization analyses with raw material release, water testing and environmental monitoring and microbiological testing, cell line characterization (master and working cell banks) and product quality for client submissions.
- Designed and documented analyses for regulatory submissions including in-process and bulk product consistency and contaminant profiles.
- Implemented new technology through collaboration PCR, viral assays.
- Administrative responsibilities included bath record review, assembly of lot files, generation of Certificates of Analysis, and release of bulk drug substance.
- Assisted marketing and business development groups with client interaction for Quality Control and troubleshooting issues.
- Radiation safety officer for seven years developed licensing program and maintained all records.

- Responsible party during state inspections.

02/1979 – 11/1983
Stanford University, Department of Pharmacology
Postdoctoral Fellow
Duties:
- Projects included isolation of glucocorticoid receptors, protein purification and characterization, plasmid construction and cell line transfection and cloning.

EDUCATION

Cornell Graduate School of Medical Sciences
Ph.D.: Anatomy and Cell Biology, minor in Biochemistry and Pharmacology

PROFESSIONAL AFFILIATIONS

- AAPS
- Drug Information Association
- Parenteral Drug Association
- California Separation Science Society (CASSS)
- Editor: BioProcessing
- Regulatory Affairs Professional Society