Curriculum Vitae

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CORE COMPETENCIES

Professional	Relationships	Areas
▪ CMC	▪ Coaching/development	▪ Biopharmaceuticals
▪ Contract organizations	▪ Business development	▪ Diagnostic/devices
▪ Business acumen	▪ Partners	▪ Quality
▪ Management	▪ Regulatory agencies	▪ Manufacturing
▪ Technology transfers	▪ Cross-functional teams	▪ Biotechnology

SYNOPSIS

My experience ranges from research and development through manufacture, testing, quality assurance and regulatory submissions. Strong background in CMC for biotechnology products and have served as co-chair plenary and workshop sessions at international meetings. I have had ongoing participation in CASSS as Associate Director, member of WCBP organizing committee (past), and current member of CMC Forum organizing committee. Recently co-chaired CMC Forum "Effective Management of Contract Organizations: Sponsors, Contract Organizations, Health Authorities and Patients: Keeping the Product Pipeline Moving, Compliant and Available". I led a team in the re-launching of HIV immunoassays while comprehending international regulatory requirements. Diagnostic Quality Control responsibilities have included establishing the first GMP analytical biochemistry laboratory at Abbott Laboratories with responsibilities eventually growing to head a group of 70 individuals overseeing blood-screening products, gene-probe assays, therapeutic and drugs of abuse assays and the development of a multi-channel blood-screening instrument. Quality Assurance responsibilities have included CAPAS, deviations, investigations, evaluation of manufacturing/testing of reagents and products at a European site, establishing Quality agreements with U. S. and international partners and working with teams in writing submissions, inserts and responses to regulatory questions. I have a strong record in successfully coaching/developing coworkers and people in my group.

PROFESSIONAL EXPERIENCE

2012 to Present Genzyme, Boston, MA

Associate Director of Validation Support

Scope: Responsible for validation life-cycle management for instruments, microbiological methods, and chemistry methods and CMC support for a legacy product under FDA Consent Decree.

Accomplishments:

- Successfully led group to install technology transfer, method development/validation, and instrument qualification Quality System under tight consent decree timeline.
- Established a group of 17 people (FTE and contractors) with responsibility of life-cycle management for a legacy biopharmaceutical.
- Successfully led group through a regulatory audit (no observations).
- Brought broader perspective of industry CMC practices into consent decree quality strategy.
- Initiated successful company-wide implementation of a method validation report template.
- Led qualification of initial product Working Reference Standard and was responsible for drafting FDA submissions for material. Member of team to extend site WRS strategy globally.
- Led effort to install single vendor instrument service program
- Established independent teams within group balancing efficiency and flexibility.
- Led effort to revise suite of validation SOPs to increase efficiency.
- Member of global Analytical Life Cycle Management team for analytical methods.

2010 to 2012 PPD cGMP Labs, Wayne, PA

Associate Director of Operations

Scope: Site head, responsible for all aspects of this small and large-molecule contract-testing laboratory established to attract business from East Coast clients. Successful operations required client contract management and efficiently performing time-sensitive work while meeting financial objectives.

Accomplishments:

- Development, validation, and QC testing established for small and large molecules drugs through Phase III.
- Implemented a large registration program for 2 small molecule drugs.
- Hosted 20-plus client audits with no significant findings.
- Supported business goals by growing the group from 5 to 24 employees.
- Doubled commissioned lab space to support potential future growth of business.
- Supported method development, qualification, validation and forced degradation for a hydrophobic protein used in a vaccine.
- Panel discussion member for 2012 CMC Forum "Applying Better Science to Reduce Drug Development Time".

2007 to 2010 PPD cGMP Labs, Middleton, WI

Lab Manager, Biopharmaceutical Testing

Scope: Manager of a Biopharmaceutical Testing group that tripled in size to support business growth. Responsibilities included stability; method development/validation and GMP support functions to ensure compliance to the company SOP's, ICH guidelines, FDA requirements and contractual obligations while adhering to client timelines. I provided coaching and technical guidance for method and instrumentation troubleshooting, laboratory investigations and internal and external conflict resolutions.

Accomplishments:

- Worked with approximately 30 different clients supporting large molecule analytical needs from first in human through approval and release.
- Work included development, validation, and QC testing for all phases including commercial drugs.
- Provided guidance to clients covering comparability, trending, method transfer, forced degradation, aggregation, reference characterization/qualification, method robustness, activity assays, and host cell protein analysis needs.
- Led group that validated methods for four products subsequently approved by the FDA.
- Led forced comparability and forced degradation studies for product subsequently approved by FDA.
- Invited by a client to attend teleconferences with the FDA regarding product analytical needs.
- Co-chaired 2010 WCBP plenary session "Protein Particle Analysis and Immunogenicity Risk Assessment".
- Co-chaired 2011 WCBP workshop "Small Company Key Issues – It's a Risky Business…Or Is It? Managing Risk Associated with Early Product Development".

2003 to 2007 Beckman Coulter, Chaska, MN

Staff Scientist (Research & Development and Quality)
Developmental Center Manager
Senior Quality Scientist

Scope: Primary responsibilities included immunoassay introduction, product improvement and support and responsibility for Developmental Quality Assurance in working with European and U. S. partner companies during product development. Traveled extensively to work with European partner regarding development, support and manufacture of blood virus assays.

Accomplishments:

- Developmental QA lead for multiple products being developed by U.S. and European partner companies.
- Led product and process risk assessments (FMEA and FTA)
- Participated in determining whether customer complaint qualified as a MDR reportable event.
- Participated in teams establishing clinical needs for products under development.
- Wrote sections of package inserts for products.
- Led a cross-functional team to return an HIV combination product to market on random-access instrument. Met tight timeline, resulting in double-digit sales growth outside of the U. S. Challenges to project included:
    - Timeline pressures because planned international sales growth goals required assay to be returned to the market.
    - Modifying software to increase sensitivity to HIV-2 within constraints or other assays.
    - Validated over 50 other assays for changes in software made to improve HIV assay
- Evaluated foreign manufacturers of diagnostic products for compliance to FDA expectations for hepatitis and HIV diagnostic assays.
- Led a risk-assessment effort to evaluate cross-contamination with a developmental project close to market launch.
- Led and participated in failure investigations.
- Implemented enduring Quality Agreements with outside companies, requiring negotiation and persuasion internally, as well as with domestic and international partner companies.

1989 to 1998 Abbott Laboratories, Abbott Park, IL

DNA Probe-Focused Factory Manager
Quality Assurance Manager
Assistant Research Biochemist, Hepatitis/Retrovirus Rare-Reagent, R & D

Scope: Supported immunoassay business through product development, rare reagent production and operation support, and assumed responsibility for DNA Product Business. Exceeded budget and financial goals over a seven-year period while managing QC groups comprised of over 70 individuals with budgets as large as $8 million. Led resolution of CAPAs and addressing customer complaints.

Accomplishments:

- Developed analytical methods and scaled-up purification processes for HIV and hepatitis blood-screening assays.
- Met financial goals through managing salaries, expenses, equipment purchases, lab footprint, over-time, efficiency and multi-shift work.
- Recruited internally to set up a new department for analytical biochemistry testing under drug GMPs.
- Reduced customer complaints from 175 to less than 25 complaints/million tests for DNA probe products.
- Worked across functional areas to implement novel planning approach that saved $400K per year.
- During a time period in which the company received numerous “observations” from the FDA, led Pre-PMA FDA inspection for DNA probe assay that resulted in no observations.
- Recruited by a vice-president to be a member of a team to rapidly respond to Division needs to establish method and process validation policies for the Diagnostic Division.
- Determined the potential costs to the company of a court ruling at the request from Director of Quality.

EDUCATION

Post-Doctoral Studies, Howard Hughes Medical Institute at Vanderbilt University, Nashville, TN
Ph. D. Oncology, McArdle Lab for Cancer Research at the University of Wisconsin, Madison, WS
B. S. Biology, Illinois State University, Bloomington, IL