Anil M. Dwivedi, Ph. D.

19207 Tattershall Drive
Germantown, MD 20874

Home: 301-540-8541
Cell: 484-889-2459

AMDwivedi@gmail.com

BACKGROUND SUMMARY

Experienced pharmaceutical/biotech professional; quality control, analytical method development and validation, lab operations, Lab information management system (LIMS), quality and regulatory compliance

- Proven leadership in quality control (QC) and Analytical development
- Recognized as a strong leader; focused, goal oriented, achiever and team player, always aligns departmental goals with company goals
- Extensive experience in managing and directing testing of pharmaceutical, water and environmental samples in various laboratories, collecting data and preparing reports for the clients
- Selection of suitable labs, cost negotiation, ensuring that labs have qualified personnel, equipment, facility and quality systems, periodic auditing of laboratories for the compliance with federal and local regulations (FDA, ICH, cGMP, EPA etc.)
- Established several SOPs: Sample Management, Change Control, Laboratory Investigations
    - Strong background in technology transfer, change control, protocol development, review and approval, execution of protocols in support of method validation for testing at in-house lab and external lab, OOS investigations, CAPA, cGMP compliant QC lab operations including equipment, standards and procedures
- Strong focus on efficiency and quality
- A strong hands on technical leader, troubleshoot, guidance and quick resolution of the issues
- Strong background in a variety of analytical techniques, e.g., HPLC, GC, MS, several spectroscopic techniques (FTIR, Raman, AA, ICP, ICP-MS)
- 1 US Patent and 41 Research Publications

PROFESSIONAL EXPERIENCE

Norwich Pharmaceuticals, Norwich, NY (March 2012 – September 2013)
Director of Quality Control

I joined Norwich to establish a quality control lab in support of company's new efforts for developing biological drugs, especially, bio-generics. In addition to developing the QC lab for biological testing, I also led and managed quality control activities in support of commercial manufacturing of small molecule drugs (solid dosages) that is the core business of the company. I directed a group of 45 employees, 35 in small molecule and 10 in biological areas. I provided oversight on environmental monitoring, raw materials qualification and testing, finished product release and stability testing in compliance with cGMP and ICH regulations. I also managed the tests outsourced to other laboratories, coordinating testing, collecting data and compiling reports for senior management.

- Acquired and validated a data acquisition and processing system for GC and LC
- Reviewed and approved SOPs, protocols, and technical reports
- Developed metrics for the lab performance
- Hired several new staff
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United States Pharmacopeia, Rockville, MD (June 2010 – August 2011)
Manager, Standards

I managed quality control activities in support of qualifying reference standard materials in biological, antibiotics, antiviral and antifungal areas. My group's activities included development of test protocols, selection of testing labs, coordination of the lab work performed laboratories all over the world,

including management of deviations, OOS and associated CAPA, analyzing data and preparing the final report for the reference standard certification and approval. I also managed customer complaints related to marketed reference standards. 5 Ph.D. scientists reported to me.

- Established new processes for development, review and approval of test protocols and final reports to be submitted to an executive committee for reference approval
- Qualified a lab in Indiana for testing protein reference standards
- Managed and directed qualification of 160 reference standards (10 biological and 150 others) in one year coordinating QC/analytical activities at USP, contract and volunteer labs

PharmAthene, Inc., Annapolis, MD (July 2009 - June 2010)
Senior Director, Analytical Sciences

Head of analytical science group; I was responsible for managing analytical activities to support PharmAthene's anthrax vaccine development program, including technology transfer for bulk drug substance (*Bacillus anthracis* preventive antigen, a protein recombinantly produced from *E. Coli)* manufacturing from PharmAthene UK to a CMO in USA; analytical methods transfer, new methods development and validation for protein analysis (HPLC, SDS-PAGE, peptide mapping, western blot, Elisa, LC/MS, IEF, circular dirchroism and fluorescence etc) and leading a CMC team. I managed the testing of drug substance and finished vaccine dosages at contract laboratories.

- Started an analytical science group
- Developed strategies for transferring analytical methods to contract laboratories
- Developed an overarching analytical plan for the vaccine development
- Got several analytical methods validated in a timely fashion prior to the start of manufacturing process validation for the bulk drug substance at a contract manufacturing facility
- Submitted a proposal to Biomedical Advanced Research and Development Authority (BARDA) for forced degradation studies of the API and development of stability indicating analytical methods. BARDA agreed with my proposal and funded it with 1 million dollar

Amylin Pharmaceuticals, San Diego, CA (2008 - 2009)
Senior Director, Quality Control

I Joined Amylin Pharmaceuticals to support outsourced manufacturing and managing quality control testing of commercial products at several contracted facilities; raw materials, drug substance (large peptides) and finished products (parenteral) release and stability testing including deviations, change control and OOSs and CAPA.
In addition I had responsibilities for starting an in-house QC lab, hiring staff, procurement and management of lab equipment, establishment of quality systems for lab operations such as, IQ/OQ/PQ of instruments, standards and reagents management, data documentation, review and approval, analysts training, change control, OOS, deviation and CAPA in compliance with cGMP. On a regular basis I was also involved in; review and approval of SOPs and GMP/GCP/GLP protocols, review and approval of deviations and OOS and review of batch records.
I managed a group of 35 staff member (budget, hiring, training and performance management, etc.). I provided technical direction on a variety of analytical techniques: HPLC, GC, LC/MS, ICP, SDS-PAGE, Peptide Mapping, CD, Fluorescence, etc.

- Managed development and validation of a cell based functional bioassay for a drug product (large peptide), very critical for a timely NDA submission
- Managed transfer and validation of several analytical methods to the new QC lab
- Submitted two sNDAs (reports) to FDA for Qualifying the new QC lab for API and finished product release and stability testing
- Hosted FDA-PAI of the QC lab; inspection ended without any 483's.
- Led a team for establishing specifications for a phase 3 development drug product

Cephalon, Inc., West Chester, PA (2005 – 2008)
Senior Director of Worldwide Quality Control

I was responsible for a QC group (15 staff) supporting late phase drug development and marketed products (parenteral and solid dosages). I supported both small and biological molecules.

Responsibilities included; ensuring QC strategies and plans for all Cephalon sites, auditing and qualifying CMOs and CROs, stability and release testing of raw materials and finished products, reviewing and approving change control, deviations and OOS investigations and ensuring that CAPA was in place in compliance with cGMP and ICH regulations. I reviewed and approved process validation protocols for API and finished product manufacturing, and approved batch records. My group was responsible for annual product review and trending. I provided technical direction on a variety of analytical techniques: HPLC, GC, LC/MS, ICP, SDS-PAGE, Peptide Mapping, CD, Fluorescence, etc. I hosted and led regulatory inspections and was a key member of a CMC team.

- A key team member of a CMC team for two NDAS that got approved and the products are in market. Prepared several CMC sections
- Led two successful PAI FDA inspections of CMOs
- Managed validation and transfer of a reversed phase HPLC method to a contract lab within 3 months. This was very critical for a timely NDA submission
- Worked closely with a European Contract lab to resolve several GMP and technical issues without which it was not possible to start the stability studies of the registration batches
- Prepared reports based on data collected at contract lab for submission to FDA

West Pharmaceutical Services, Lionville, PA (2000 - 2005)

Senior Director of Quality Laboratory Operations, (February 2005-August 2005)
Director of Analytical Laboratories, Americas (January 2003- February 2005)
Director of Contract Lab Services (September 2001– January 2003)
Associate Director of Contract Lab Service (May 2000-Sept 2001

As in-charge of laboratory operations, I was responsible for both analytical and quality control activities in support commercial products of the company and providing analytical and QC support to pharmaceutical and biopharmaceutical clients who contracted West's analytical lab services. Managed 4 analytical laboratories (AR&D and QC, staff of about 100) with two major functions:

-Full analytical and QC support to West's all North American manufacturing sites including method development/validation, OOS investigations, trouble shooting, Stability studies, raw material and finished product testing using both in-house methods and USP/EP/JP pharmacopeial methods. Manage annual product quality reviews and resolve product complaints.

-Contract lab service business provided analytical development and QC support to major pharmaceutical and biotech companies: method development and validation, API and finished drug product (solid and parenterals) testing including stability studies, methods transfer, and extractable and leachable testing under cGMP. Both biologics and small molecules were tested in the lab.

- Developed a state of art full CGMP contract lab service group. Two FDA inspections approved the lab without any 483's
- Purchased, validated and implemented a LIMS for the lab
- Timely resolution of manufacturing issues and customer product complaints.
- Developed capabilities for handling class I –V controlled drug substances (DEA License)
- Implemented OSHA policies. Got built a contained area for toxic drugs.
- Several SOP's and Quality Systems for a CGMP compliant lab operation.
- Submitted analytical methods in DMF with FDA
- Reduced turn around time of routine raw material compendial testing from 25 days to 10 days.
- Established lab metrics for monitoring, turn around time, quality and client-satisfaction.
- Established computer system validation program in compliance with 21 CFR part 11
- Contract lab business grew by 400% in 5 years

Lancaster Laboratories, Lancaster, PA (1996 – 2000)

Manager, Analytical Chemistry

Managed Analytical/QC department (35 staff members) that was responsible for analytical methods development and validation, method transfers and testing of stability samples of finished drug products and drug substances. Performed several compendial (USP, EP and JP) testing of raw materials, water, and finished products. Developed and validated methods for analyzing cleaning

validation studies. Responsibilities also included several quality functions, budgeting, staffing and P/L of the departments.

- Instituted several quality systems for many successful client audits and two FDA inspections.
- Lab doubled in staff with several new instrumentations. Business grew about 300%.
- Reduced turn-around time by 60%.
- Organized the lab for enhancing efficiency and defined roles and responsibilities.

R. W. Johnson Pharmaceutical Research Institute (A Johnson and Johnson Company), Raritan, NJ (1994 – 1996)

Principal Scientist, Analytical Research and Development

Managed a group of analysts (15 staff members) responsible for methods development and testing of API, finished drug products, and excipients. In addition, the group was responsible for releasing all clinical trial supplies and for managing reference standards program for the entire company.

- Established a program for managing and dispensing analytical reference standards in compliance with GMP.
- Set up a sample scheduling and tracking system that reduced the turn around time by 25% in the first six months.
- Set up a near infrared lab. Various applications of NIR, such as, identification and characterization of tablets, capsules and raw materials were explored.

DuPont Merck Pharmaceuticals, Wilmington, Delaware (1988-94)

Principal Research Scientist, Analytical R&D (1991-1994)
Senior Research Scientist, Analytical Research and Development (1988-91)

In charge of an analytical lab that supported drug development in various phases; developed assays and techniques for several INDs. Most of the work was directed to biological molecules, proteins, peptides and nucleic acid therapeutics.

- First one to structurally characterize human recombinant plasminogen activator inhibitor-1 in its active and latent forms using IEHPLC, and spectroscopic methods. The study led to the development of a stabilizer to stop the conversion of the active form into a latent form.
- Introduced near infrared (NIR) technology to the company and proved its worth through devising an analytical method for quantitating the amount of an insoluble polymeric drug in animal feeds for safety assessment studies. Without this method the IND filing would have been delayed.
- Performed circular dichroism (CD) and FTIR studies of the interaction of bis-naphthalimides with DNA to understand the mechanism of anti-tumor activities. The data was used in IND filing.
- Headed several task force, and organized a symposium on Analytical Techniques during a DuPont Merck Science Conference.
- Received Commitment to Excellence Awards from Cardiovascular and Cancer Divisions, and two R&D Team Awards.

EDUCATIONAL TRAINING

BS (Chemistry), Banaras Hindu University, Varanasi, India
MS (Physics), Indian Institute of Technology, Kanpur, India
Ph.D. Physics (Spectroscopic studies of biomolecules), Lucknow University, Lucknow, India

MEMBERSHIP IN PROFESSIONAL SOCIETIES

Member of American Chemical Society
Member of American Association of Pharmaceutical Scientists (AAPS)
Member of PDA