Nirmal Paliwal

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#### **CMC, Analytical and Formulation development leader**

#### CMC, Analytical and Formulation development leader with 12 plus years of bio-pharma industrial experience involving CMC analytical method development & extended analytical characterization for DSI, DS and DP, stability analysis (GMP and non-GMP) and formulation development. Strong ability to develop and manage internal as well as external (CDMO/CRO) analytical development teams. Hands-on experience with multiple analytical methods for Biologics (Mab’s, recombinant proteins, ADC’s, Bispecific’s and Vaccines) as well as small molecules, like Liquid Chromatography and Mass Spectrometry (intact mass, subunit assay, peptide mapping, PTM analysis), HPLC/UPLC (RP, NP, IEX, SEC, Affinity, HIC, HILIC), GC, Capillary electrophoresis (CGE and icIEF), Residual impurities (HCP, leachable Protein A, rDNA), DDPCR, RTPCR, NGS, Cell based potency & viral infectivity assays, Flow cytometry, enzyme digests, CD, DLS, DSC, ITC, UV/VIS/Fluorescence spectroscopy, SPR, Octet and Elisa. Excellent people management, data interpretation, and technical writing skills (Module 2 and 3 for eCTD, IND, IMPD, BLA etc.). Strong experience with QBD, Process characterization (PC) and PPQ studies.

**Areas of Strengths & Competencies:**

People management• CDMO/CRO management • CMC project management • Analytical method development for batch release and extended characterization • Qualification and Validation • Formulation development • QBD • PPQ planning & execution • CQA assessment and specification setting • Developability assessment • cGMP • Clinical & toxicology material supply for early and late phase clinical trials.

**Professional Experience**

**BeiGene Inc. (Consultant through Alku), Pennington, NJ, USA 10/2024 – Present**

***QC, AD and Formulation Development Consultant for new GMP site***

* Support establishments of new QC , Formulation and Analytical Development labs at a new R&D facility in North America
* Support instrument CQV (Commissioning, qualification, and validation), SOP generation and revision, testing record keeping, etc.
* Establish protocols for managing inventory and supplies for the laboratory.
* Guide assay validation and technology transfer activities, including testing (e.g., DS, DP release and stability testing) in support of GMP manufacturing operations.
* Serve as subject matter expert for residual DNA by qPCR, host cell protein ELISA, Residual Protein A ELISA, binding activity ELISA, HPLC/UPLC, Capillary Electrophoresis (CE), and capillary isoelectric focusing electrophoresis(cIEF), including qualification, assay validation and transfer activities.
* Train other junior-level analysts and new hires.

**Icosavax Inc. (Acquired by AstraZeneca), Princeton, NJ, USA 06/2022 – 08/2023**

***Director of CMC Analytical and Formulation Development***

* CMC Development of Virus-Like Particle (VLP) technology-based vaccines against various infectious diseases, with multiple self-assembling protein components & small molecule adjuvants.
* As a CMC team member collaborate across all disciplines within the company as well as manage external vendors/CDMO's/CTL's to progress early and late-stage CMC analytical method development, method qualification and technology transfer.
* Technical review and approval of internal and external CMC and analytical documentation.
* Analytical technology transfer for 10X scale up (200-2000L), analytical method establishment, method troubleshooting & method qualification for DSI, DS & DP (release as well as extended characterization methods).
* CMC platform development and release of GMP clinical trial and toxicology material in a time and cost-effective manner.
* Process optimization and troubleshooting of analytical methods at CDMO’s & CRO’s, delivery of CMC sections for CTD documents.
* Make critical decisions and trade-offs that improve resource utilization and ensure program success while maintaining phase appropriate risk profile.

**National Resilience Inc., Princeton, NJ, USA July 2021 – Feb 2022**

***Head of Analytical Development***

* Hired and training an Analytical Development group & building state-of-the-art lab infrastructure.
* Mentoring and coaching Scientists and Research Associates.
* Representing analytical department in client facing meetings.
* Providing Process Analytical Technology assistance for GMP manufacturing as well as non-GMP pilot plants.
* Ensuring timely delivery of analytical testing and reports.

**Thermo Fisher Scientific (*Patheon Biologics)*, Princeton, NJ, USA Apr 2019 – June 2021**

***Group Leader, Analytical Development***

* Managed an analytical group responsible for establishing, developing, qualifying, and transferring analytical methods for Biologics. Worked with Quality Control and other groups to troubleshoot and improve existing analytical methods.
* Designed experimental plans based on the defined deliverables, planning the activities to meet the project timelines.
* Support routine sample analysis towards process development. Work with Process Development and Manufacturing groups to troubleshoot process development and characterization challenges.
* Prepare protocols, reports and test methods as needed.
* Present and discuss data at project and department meetings.
* Ensure high performance with cross training and productive functioning of my group.

**Sciex Separations, Brea, CA, USA Jun 2017– Jun 2018**

***Biopharma Development Scientist***

* Analytical workflow development involving Capillary Electrophoresis, HPLC, DLS and Mass Spectrometry of large molecules.
* Qualification and validation of novel kits for analysis of biologics.
* Method qualification, writing application notes and technical reports.

**National Institute of Allergy and Infectious Diseases (NIAID), MD, USA Oct 2016 – May 2017**

***Scientist (Consultant through MSC LLC), Analytical Development***

* Analytical method development involving Capillary Electrophoresis, HPLC, MS, Octet, etc.
* Protein characterization and formulation development support (Monoclonal Antibody based vaccines, Viral nano-particles based vaccine’s, Fusion proteins, etc.).
* Method qualification and transfer
* Technical reports (SOP’s, Qualification reports, Analytical reports for IND filings, etc.).

**Abbvie Inc., Greater Boston, MA, USA Apr 2015 – May 2016**

***Scientist (Contract position through US tech solutions), Protein Analysis***

* HPLC method development, qualification, and transfer.
* Performed intact mass and subunit mass analysis using Q-TOF mass spectrometers.
* Performed peptide mapping and CHO cell proteomics using Orbitrap MS.
* Developed charge heterogeneity assays (icIEF) to compare process consistency.
* Analytical lead for Phase 3 project, ensuring completion of assays in time and primary author of technical reports for the same.

**Goodwin Biotechnology Inc., USA Oct 2014 – Feb 2015**

***Contract Scientist, Method development and Protein characterization***

* Provided analytical support by conducting characterization assays to upstream processing, downstream processing, and bio-conjugation groups.
* Performed protein characterization and in-process assays, such as HPLC, MS, ELISA, SDS PAGE, IEF, capillary electrophoresis, cell-based assays, binding affinity (Octet), Spectro-fluorometric, etc.
* Provided support and technical expertise to assay qualification and validation group to develop, verify and qualify assays in a cGMP environment.

**Biogen Idec Inc., Cambridge, MA July 2013 – Mar 2014**

***Scientist (Contract position through Hays Life sciences), Analytical Development***

* Primary responsibilities included bio-analytical method development, characterization of biologics and method qualifications.
* Use of analytical techniques like Capillary western electrophoresis, SDS-PAGE, HPLC/UPLC and mass spectrometry (MS).
* Worked simultaneously on multiple projects, both as a part of a team and independently and drafted technical development method protocols and qualification reports.

**Education**

**Ph.D. in Biochemistry • University of Massachusetts Lowell, MA • Sep 2010 – May 2013**

**M.S. in Biotechnology • University of Massachusetts Lowell, MA • Sep 2006-Dec 2008**

**B.S. in Pharmaceutical Technology • Marathwada University, Aurangabad, India • 2002**