VISHWAS KUMAR

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SUMMARY

Clinical Professional with Clinical Development/ Analytical and R&D with over 18+ years' experience relating to biotech, clinical development, immunology, microbiology, media optimization, quality, and purification principles. Utilizes strong Pharma and Biotech industry qualifications and extensive experience in molecular biology, in vitro cell based assay, immunoassays, and quality analysis to lead project management, product development/ improvement, process engineering, ingredients application and cost savings from concept to commercialization. Experience in preparing and conducting large international clinical studies, including preparing multiple study budgets. In-depth knowledge of FDA laws, GCP and ICH guidelines. Solid mentoring and managerial experience. Collaborates and communicates with cross-functional teams and departments to design and execute experiments and carry out projects.

Areas of Expertise

Clinical Development~ Pharmaceutical ~Regulatory Submissions ~ Drug Development ~Therapeutics Areas ~ ICH-GCP ~ FDA~ SOPs~ IBs/ CRFs / CSRs ~ Protocols~ Product Development & Improvement ~ Analysis & Evaluation ~ Innovative Methodologies ~ Technical Communication ~ Project Leadership ~ Documentation & Reporting ~ Ingredient Application Technology ~ Process Engineering & Operations ~ Quality Assurance & Safety ~ Regulatory Compliance ~ Design & Statistical Data Analysis ~ Training & Professional Development

Professional Highlights

- ✓ Broad experience in Translation. From discovery to Clinical Phase I/II/III in Immuno-Oncology, Vaccines, monoclonal antibodies and cell & gene therapy programs
- ✓ Experience in multiple stages of drug development including target discovery/validation, mechanism of action and large molecule drug discovery. Specifically, lead full drug discovery efforts on two targets and developed pre-clinical drugs
- ✓ Strategized, developed & executed Clinical trials plans for four assets in Vaccines, NeoCart, Ocular disease to Phase I/II/III and from discovery to IND submission and BLA filing (US, Canada & Mexico)
- ✓ Leading multiple matrix teams comprising of biomarker, diagnostics, bio-analytical sciences, discovery biology, clinical sciences and clinical pharmacology to achieve Translational R&D objectives
- ✓ Successfully identified and implemented characterization of new molecule and DoE for leading candidate for drug discovery
- ✓ Expertise in identifying and engaging thought leaders to gain insights on scientific issues to align and optimize clinical development plans and translational strategies
- ✓ Strong project management skills, formulation (DS&DP) engaged clinical-trial sites, central labs, commercial vendors and academic vendors, and achieved time sensitive goals
- ✓ Experience in authoring clinical protocols, Investigator brochures
- ✓ Expertise in analysis of multivariate data, correlation with clinical endpoints, PK-PD correlation & data visualization to drive dose selection and evaluate patient safety
- ✓ Excellent writing and presentations skills evident from peer-reviewed publications, numerous presentations in international congresses and invited talks

OCUGEN, MALVERN,PA — OCT 2021- PRESENT

DIRECTOR (ANALYTICAL RESEARCH & DEVELOPMENT)

• Led CMC teams (upstream, downstream, analytical, and manufacturing) to support the key deliverables for phase III/commercial supply. Managed cross-functional teams in developing comprehensive integrated development and supply plans for the commercial product. Prepared and managed timelines for process development, manufacturing, quality, regulatory strategies in readiness for BLA submission.

•Process optimization and troubleshooting of analytical methods at CDMO's & CRO's, delivery of CMC sections for CTD documents

• Supported key regulatory submissions (IND amendments, BLAs, briefing books) and authority interactions in F2F meetings, provide leadership in supporting key technical reports and documents required for regulatory submission.
•Provided leadership in resolving program and cross-functional challenges with internal and external teams demonstrating negotiation and resource management skills. Reporting directly to the CEO and President of Ocugen.
• CMC Development of Virus-Like Particle (VLP) technology-based vaccines against various infectious diseases, with multiple self-assembling protein components as well as adjuvants
• Responsible for active oversight of all data monitoring programs and initiatives, including creating the PPA program and managing the CPV program for DS and DP.

THERMO FISHER SCIENTIFIC, PRINCETON NJ 2019- 2021
SENIOR SCIENTIST, LEAD (ANALYTICAL DEVELOPMENT)

• Manage an analytical group responsible for establishing, developing, qualifying, and transferring analytical methods (Potency, Binding Elisa, Infectivity etc) for monoclonal antibodies and other biologics (Bispecific antibodies, Fusion proteins, enzymes, etc). Work with Quality Control and other Operations groups to troubleshoot and improve existing analytical methods.
• Characterization RLD, API, excipient, packing material and finished product using relevant pre-formulation instrument/techniques independently
• Design Upstream (CHO and E Coli.), Downstream (CHO and E Coli.) and Analytical technology transfer for scale up (500L), establishment, qualification, and validation for DSI, DS and DP (Biologics)
• Support routine sample analysis towards process development. Work with Process Development and Manufacturing groups to troubleshoot process challenges.
• Led/Supported technology transfer activities and oversight at CDMOs/CROs, prepare protocols, reports and test methods as needed.
• Execute all aspects of drug substance development for Thermofisher portfolio of assets ranging from preclinical to Phase III/validation across diverse modalities including small molecules, peptides, biologics, cellular products, and ADCs
• Vendor management, including CROs, CDMOs, instrument/equipment manufactures for DS development, regulatory strategy, analytical testing, tech transfers, and procurement, installation, and qualification of equipment, manufactured CAR-T cells

UNIQURE, BOSTON, MA
SENIOR SCIENTIST (ANALYTICAL R & D) 2018- 2019

- Responsible for Process Development, Analytical Development, Drug Product Development, Formulation, Manufacturing Sciences and Technical Supports, CMC
- Worked late stage Pharmaceutical Development and Technical Support functions for adeno-associated virus (AAV)-based gene therapy products
- CMC platform development and delivery of GMP clinical trial and toxicology material in a time and cost-effective manner
- Responsible for process development (including Upstream cell culture, virus vector productions and Downstream purification), analytical development, drug product development, process scale-up, technology transfer, method transfer and GMP manufacturing supports
- Development, Qualification and Transfer Cell Based Potency Assays for relative potency in parallel line analysis, Receptor Binding ELISAs

CREAFILL FIBERS, CHESTERTOWN, MD
MANAGER, CLINICAL OPERATIONS (CLINICAL DIVISION) 2015-2018

- Wrote medical investigational brochures/protocols and regulatory procedural/guidance documents and reports.
- Clinical data management, clinical research protocols, CRF and clinical training.
- Worked with subject matter experts or KOLs in cervical cancer, gastroenterology and endocrinology to deliver training to clinical coordinators and doctors.
- Medical device product support for cervical cancer device including language translation management with third parties.

- Assisted and oversaw writing and documentation of the new product feasibility and system development process cycles while adhering to quality control, GMP regulatory requirements, CE marking, CE conformity assessment including Clinical Evaluation Reports (CER) as per Medical Device Directive (93/42/EEC), maintained FDA quality systems and ISO 13485 regulated environments.
- 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 development
- Led a research and development team for an interstitial fluid (ISF)-based, minimally invasive, novel biosensor system to measure cortisol, alcohol, and glucose in bodily fluids.
- Mentored and worked with ISF team responsible for mechanical design, research, and fabrication of a prototype system.
- Participated in all aspects of small-scale clinical studies including data analysis, reporting and presentations.
- Was accountable for R&D federal funding opportunities plus generated international joint ventures and partnerships.

CREAFILL FIBERS, CHESTERTOWN, MD
SENIOR RESEARCH SCIENTIST (ANALYTICAL AND R&D DIVISION) **2009 – 2014**

- Direct planning and execution of development, qualification and validation of cell-based bioassays and immunoassays for biosimilar therapeutics.
- Serve as Project Manager for multiple projects, guiding scope, timeline and budget to ensure an on-time delivery.
- Downstream process/ purification of monospecific monoclonal antibodies and bispecific monoclonal antibody. Strong hands-on experience in AKTA Avant purification system.
- Create reporting detailing the bioassay section for regulatory submission, standard operating procedures (SOPs) and technical reports.
- Developed and implemented high-throughput whole blood flow cytometry (FACS) based assays to measure receptor occupancy to support drug safety studies.
- Develop colorimetric and chemiluminescent ELISAs, as well as bead-based immunoassays on Bio Scale's AMMP Platform (using the ViBE Technology), through best-pair analysis and optimization of assay diluents, reagent formulation, and incubation times.
- Perform NativePAGE and Western Blots to qualify and characterize proteins and monitor expression of phospho-proteins in different cell lines, respectively.
- DNA extraction & purification pathological organisms for PCR validation.
- Strong Experience with human blood, plasma separation, cell activation, isolation & detection nucleic acids, protein & small molecules; immunoconjugate synthesis.
- Oversees the specimen processing the integrity and GMP/GLP compliant documentation.

Position Accomplishments:

- Cell culture (maintenance of primary cells and cell lines), B and T cell purification via magnetic beads, Transfection experiments for siRNA and shRNA (via electroporation and lipofection), Quantitative Real Time PCR (ddPCR-qRT-PCR), Luminex and ELISA assay (for chemokine and cytokinequantification), Biomark/Fluidigm, Immunohistofluorescence staining, Confocal microscopy.
- Development & Validation HPLC methods protein structure & characterization via high resolution mass spectrometry.
- Perform maintenance of laboratory equipment, schedule and assist in the performance of check essential equipment/controllers and software, maintained Lab Vantage's Sapphire LIMS System, built all test methods, work items & specifications.

RANBAXY PVT. LTD., MOHALI, INDIA
SCIENTIST (RESEARCH & DEVELOPMENT DIVISION) **2006 – 2007**

- Supported discovery of therapeutic monoclonal antibodies by delivering highly purified protein, carbohydrate antigens & screening in cell-based assays.
- Generated technical reporting, communicating identified trends and analysis with leadership teams and cross-functional departments.
- Perform and analyzes various clinical assay such as real time PCR, quality-by-design (QbD) approaches to drug product development
- Developed purification method programs using Unicorn software, maintained & troubleshot AKTA instrument.

- Conducted microbiological and biochemical safety and stability analyses of samples and starter cultures.
- Strategic design of ion channel receptors, soluble human proteins & toxin for optimal functional expression & purification.
- Evaluated assay results of biologics, drugs and pharmaceutical samples.

Position Accomplishments:

- Assay development, HTS, Enzyme Kinetics: Km, IC50 determination. ELISA, RID, Cell based assays.
- Western Blot, SDS-PAGE, HPLC, ITC, DSF, Protein refolding, Tangential flow filtration (TFF).

NATIONAL INSTITUTE OF PHARMACEUTICAL RESEARCH & EDUCATION (NIPER), MOHALI, INDIA
RESEARCH ASSOCIATE R&D 2005 – 2006

- Focused on isolation of probiotic from two type patients cancer and tuberculosis, checking their acid and bile tolerance.
- Develop and improve purification processes for monoclonal antibodies
- Purification, characterization, and quality control of products by using HPLC, LC-MS and NMR.
- Cloned & expressed 100 putative caner biomarkers used for monoclonal antibody development.
  Performed analysis of blood & body fluids for diagnostic purposes: Hematology, Coagulation, Urinalysis .

Position Accomplishments:

- Successfully extracted DNA from samples and performed real time PCR.
- Fermented and harvested more than 5L of yeast culture, study protein expression in different yeast cells, column chromatography, FPLC, Western Blot, Bradford Assay, BCA Assay, Diafiltration, UV-spectroscopy, ultrasonic cell disruptor, pH meter.

MUKAT HOSPITAL, CHANDIGARH, INDIA
QUALITY RESEARCH TECHNICIAN 2004 - 2005

Education & Certifications

PhD. Biotechnology, CMJ University India
M.S. in Management Information Systems, Stratford University Virginia
M.S. in Biotechnology, Molecular Biology, Immunology & Genetics, Punjabi University
B.S. in Biochemistry, Microbiology & Cell Biology, D.A.V Collage
Certified Internal Auditor ISO 9001:2008, University of Maryland

Awards& Recognition

Best poster presentation INDO-US Symposium 'Stem Cell Identification and Characterization; Role of Molecular Marker', Punjab University
Best Oral presentation symposium 'Fermentation Technology', Punjabi University
Best Oral presentation symposium 'Med Biotech', Punjabi University

Publications

Screening, Isolation, Microbiological and Biochemical Characterization of Lactobacillusfrom Human Faecal Sample (Tuberculosis & Cancer Patients)

Immunomodulatory and other health effects of a new Faecal Isolate

Professional Affiliations

Indian Science Congress – Lifetime Member
Indian Peptide Society - Member
American Association of Pharmaceutical Scientists (AAPS) – Member