

COVER-LETTER

SHRISH CHANDRA PANDEY

M.TECH.(BIOTECHNOLOGY)

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CAREER SUMMARY:

Seasoned Scientist with 9+ Years of Cross-disciplinary research experience covering Regulatory Audits and Compliances (WHO, US-FDA, EU-GMP, S-FDA, TGA, ANVISA, NPRA, CDSCO & GLP) with wide experience for Technology Transfer to International Clients (Germany, Russia, Egypt, Malaysia, Saudi-Arabia, Iran, Cuba & China) and Quality Management System on vaccines/Pharmaceuticals/Biologics Vaccine industry.

Conceptualize and design affordable, scalable, and robust processes for high-quality vaccine development including **COVID-19, Pneumococcal (PCV), Meningococcal (MCV), H1N1, H5N1, Haemophilus-Influenzae B, Tetanus-Toxoid & Hepatitis-B** while also overseeing **Cell & Gene Therapy (CAR-T)** initiatives managing **AAV** and **LVV** process development, analytical methods, and QMS compliance. covering both under-utilized as well as new therapies and vaccines of public health importance. Experienced in promoting vaccine regulation and pharmacovigilance, quality assurance and quality monitoring systems. Collaborate for development and use of guidelines on vaccine regulation, quality control/quality assurance of vaccines, Good Manufacturing Practices and laboratory quality control of vaccines e.g. Licensing and Marketing Authorization (MA), Emergency Use Authorization (**EUA**), Good Regulatory Practices (GRPs), Quality Management Systems and Quality Risks Management. Experienced of Large-scale manufacturing of Bulk drug substance with Support functions, Trainings and handling of Quality Management system in vaccine industry. Expertise in *in-silico* design and development, ELISA and other analytical assays for Infectious Diseases. Strong professional with a Master's Degree (M.Tech) Research focused in Medicine and Biotechnology.

CURRICULUM VITAE

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OBJECTIVE:

To work in a stimulating and challenging organization where there is a good work culture and that would facilitate the maximum utilization and application of my Cross-Disciplinary skills and expertise in making a potential impact to the organization. Skilled in the design and development of Microbiological Assays, Molecular Biology Techniques.

PROFESSIONAL EXPERIENCE:

(A) Invigorate Biotechnologies LLP, PBTI, Mohali, Punjab

- **Deputy Manager, Process Development (R&D- QC)** (Oct' 2024 Onwards)
- **Assistant Manager, Process Development (R&D- QC)** (Feb' 2023 to Sep' 2024)

JOB RESPONSIBILITIES:

- **Leading** process development, analytical testing, and QMS activities for **Cell & Gene Therapy (CAR-T) AAV/LVV platforms**.
- Technology development, Process development and scale up for Hepatitis B Vaccine, HIB PRP and conjugate vaccine, Pneumococcal polysaccharides and Respective conjugate vaccine, meningococcal polysaccharides and respective conjugate vaccine, DPT group and Pentavalent vaccine.
- Technology transfer to clients in Russia, Iran, Turkey, Egypt.
- GMP, QMS and technical training for clients.
- Technical support to clients on qualification and installations of equipment & systems, validation support and process and equipment/system.
- Prepared documents pertaining to product and technology development.

(B) BioBridge Healthcare Solutions Pvt. Ltd, Chandigarh

- **Senior Executive, Quality Control (R&D)** (Jul' 2021 to Feb' 2023)

JOB RESPONSIBILITIES:

- Diligently performed QC testing for Bivalent **Covid Vaccine**, Pneumococcal polysaccharides (PS) and other relevant PS-conjugate vaccine.
- Analytical Methods (SDS-PAGE, Western Blot, ELISA, Total Protein Estimation) Development and Validations for **S1** and **N** Protein for **SARS-COV-2**.
- Analytical Method Development (ELISA, CWPS-ELISA, Sec-HPLC, Protein, Methyl Pentose Estimation, Assays for Sugar contents) for Serotypes (12F, 15A, 22F) in reference to **PCV**.
- Prepared documents pertaining to product and technology development.
- Proactive role in Technology transfer for Analytical Methods to clients.
- Proactively managed and established QMS for Clients.
- Qualification studies (Installation, Operation and Performance Qualification) and Validation of equipment and facilities to ensure compliance with international cGMP regulations and standards.

(C) BioGlobe Research & Solutions LLP, Delhi

➤ **Technical officer (Biotechnology)**

(July 2019 to July 2021)

JOB RESPONSIBILITIES:

- Performed Gel Electrophoresis (SDS), Western Blot and Imaging Techniques
- Tissue culture and Assay development methods
- Cell culture and ELISA; Flow cytometry,
- Development and execution of Cellular and biochemical assays
- Experience with primary human cells and cell lines.
- Mammalian & Induced Pluripotent Stem Cells (iPSC) Culturing and transfection

(D) Venus Remedies Limited, Baddi (H.P.) & Panchkula (Haryana)

- **Assistant Manager (QC)** (Apr. 2016 to Apr. 2017) Unit- I Panchkula, Haryana
- **Executive Microbiologist (QC)** (Jan. 2016 to Mar. 2016) Unit-II Baddi (H.P.)
- **Management Trainee (QC)** (May.2015 to Dec. 2015) Unit-II Baddi (H.P.)

JOB RESPONSIBILITIES:

- Successfully Conducted **GMP, GLP, EU-GMP, S-FDA, TEVA** and **WHO** audits for Quality Control Department (Microbiology).
- Audited and Inspected for Quality Control Department of loan licensed manufacturers.
- Antibiotic & Chromogenic Assay (RM &FP)
- SOP, STP Preparation and Documentation for QC.
- Validations (Instruments & SOP, STP)
- Trend Preparation and Analysis.
- Sterility Analysis and result interpretation by Open and Closed Method
- Bacterial Endotoxin Analysis and Validations (RM & FP)

ACADEMIC QUALIFICATION:

- **M.TECH- Biotechnology with Honors (2017-2019)**
"Institute of Engineering & Technology" (Dr. A.P.J. Abdul Kalam Technical University, Lucknow, Uttar-Pradesh),
- **B. TECH-Biotechnology with Honors (2011-2015)**
"Integral University", Lucknow Uttar-Pradesh.

EXTRA CURRICULAR ACADEMIC ACHIEVEMENTS:

- Invited as speaker & Resource Person by **BIRAC E-YUVA** at University of Kashmir, Srinagar, India (Jul-2025)
- Successfully Organized Yearly Training programs (2021-2025) on "The Basics of Bioprocessing: Upstream & Downstream" @BioNEST Bio Incubator Regional Centre for Biotechnology.

DECLARATION:

I hereby declare that the above-mentioned information is true to the best of my knowledge and belief.



Place: Punjab, India

(Shrish Chandra Pandey)