

SHRISH CHANDRA PANDEY

M.Tech., *Ph.D. (Biotechnology)

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PROFESSIONAL PROFILE

Multidisciplinary scientist-entrepreneur with 9+ years of cross-disciplinary experience spanning bioprocess development, analytical method validation, regulatory compliance, and biologics innovation. Currently completing a PhD in Biotechnology, combining computational biology and wet-lab validation to drive cancer-focused research (thesis submission: October 2026), uniquely integrating advanced bioinformatics, multi-omics data analysis, and machine learning with deep wet-laboratory and QMS expertise. Proven record of scaling complex biologics processes-including lentiviral vectors (LVV) and adeno-associated virus (AAV) platforms for Cell & Gene Therapy (CAR-T)- alongside large-scale vaccine development (COVID-19, PCV, MCV, Hepatitis-B, HIB, DPT, Pentavalent). Seasoned regulatory scientist with successful audit engagements across WHO, US-FDA, EU-GMP, TGA, ANVISA, CDSCO, and S-FDA frameworks, and a record of international technology transfer across eight countries. Invited speaker at BIRAC E-YUVA and established trainer within the BioNEST Bio Incubator ecosystem - uniquely positioned to translate deep scientific research into commercially viable, patent-grade innovations.

EDUCATION

*PhD — Biotechnology <i>*Pursuing (Submission: Oct. 2026)</i>	<i>Integral University, Lucknow (Jul. 2023 – Pursuing)</i>
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- Research focus: Identification of small molecule potential inhibitor against oncogenic Protein
- Multi-omics data integration, cancer genomics, and ML-driven biomarker discovery
- Bridges computational cancer biology with practical drug delivery and biologics process development

M.Tech. — Biotechnology (with Honours)	<i>Institute of Engineering & Technology (AKTU, Lucknow) · 2017–2019</i>
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- One year Research work
- Thesis: Purification and characterization of anti-tubercular compounds from *Coriandrum-Sativum* and its mode of action.

B.Tech. — Bioengineering (with Honours)	<i>Integral University, Lucknow · 2011–2015</i>
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- Six months Dissertation
- Dissertation: Antibiotic Assay Validation (Bleomycin for Injection)

PROFESSIONAL EXPERIENCE

Manager, Process Development (R&D) <i>Invigorate Biotechnologies LLP, PBTL · Mohali, Punjab</i>	Feb 2023 – May 2026
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- **Cell & Gene Therapy Scale-Up:** Developed and scaled LVV (Lentiviral Vector) production process to 2-cell stack system, consistently achieving titers of 10^9 – 10^{10} TU/ml — meeting clinical-grade specifications for CAR-T therapy.
- **Reagent Innovation:** Formulated a novel, cost-effective PEI based transfection reagent for LVV production (2024), significantly reducing reagent costs while maintaining batch-to-batch consistency — demonstrating applied innovation with direct commercial impact.
- **Platform Leadership:** Led all process development, analytical testing, and QMS activities for AAV and LVV platforms supporting Cell & Gene Therapy programs, ensuring GMP compliance throughout.
- **Client Technical Support:** Delivered GMP, QMS, and technical training to clients; provided qualification and validation support for equipment, systems, and facilities across international partner sites.

Senior Executive, Quality Control (R&D) <i>BioBridge Healthcare Solutions Pvt. Ltd.</i> · Chandigarh	Jul 2021 – Feb 2023
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- **Vaccine Analytical Development:** Designed and validated analytical methods (SDS-PAGE, Western Blot, ELISA, Total Protein Estimation, Sec-HPLC) for S1 and N proteins of SARS-CoV-2; executed QC testing for Bivalent Covid Vaccine.
- **Multi-Vaccine Platform R&D:** Led process development and scale-up for Hepatitis-B, HIB PRP conjugate, Pneumococcal (PCV serotypes 12F, 15A, 22F), Meningococcal, and DPT/Pentavalent vaccine platforms from bench to pilot scale.
- **International Technology Transfer:** Executed technology transfer of analytical methods (ELISA, CWPS-ELISA, Methyl Pentose Estimation) to international partners in Russia, Iran, Turkey, and Egypt.
- **Regulatory Compliance:** Conducted IQ/OQ/PQ qualification and validation of equipment and facilities to international cGMP standards; authored all associated technical documentation.

Technical Officer — Biotechnology <i>BioGlobe Research & Solutions LLP</i> · Delhi	Jul 2019 – Jul 2021
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- **Cell Biology Platforms:** Established and optimized tissue culture, primary human cell, and iPSC (Induced Pluripotent Stem Cell) culturing and transfection workflows.
- **Assay Development:** Developed and executed cellular and biochemical assays including ELISA, Flow Cytometry, SDS-PAGE, Western Blot, and advanced imaging techniques for research programs.

Asst. Manager / Executive Microbiologist / Management Trainee (QC) <i>Venus Remedies Limited</i> · Baddi (H.P.) & Panchkula (Haryana)	May 2015 – Apr 2017
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- **Regulatory Audit Success:** Managed and delivered successful international regulatory audit engagements: EU-GMP, GLP, S-FDA (Singapore), TGA (Australia), and WHO — for the QC Microbiology department.
- **Microbiology & Compliance:** Conducted sterility analysis, bacterial endotoxin testing and validations (open and closed methods) for both raw materials and finished products; managed SOP/STP documentation lifecycle.
- **Analytical QC:** Performed antibiotic and chromogenic assays; led trend preparation and analysis across QC functions.

TECHNICAL COMPETENCIES

Bioprocess & Manufacturing LVV / AAV process development & scale-up (Cell & Gene Therapy / CAR-T) Vaccine upstream & downstream process development PEI transfection reagent formulation & cost optimization GMP-grade biologics manufacturing: vaccines, polysaccharides, conjugates	Analytical Methods ELISA, SDS-PAGE, Western Blot, Sec-HPLC Flow Cytometry, Bacterial Endotoxin Testing, Sterility Analysis Antibiotic & chromogenic assays Protein & sugar content estimation (Methyl Pentose, Total Protein)
Computational Biology (PhD) Multi-omics data integration (genomics, transcriptomics, proteomics) Cancer biomarker discovery using machine learning approaches Bioinformatics pipeline development and data analysis <i>In-silico</i> assay design and infectious disease modelling	Regulatory & Quality Regulatory audits: WHO, US-FDA, EU-GMP, TGA, ANVISA, CDSCO, S-FDA, NPRA IQ/OQ/PQ equipment qualification and SOP/STP validation Quality Management Systems (QMS) design and implementation EUA, GRPs, Pharmacovigilance
Cell Biology Mammalian cell culture, iPSC culturing & transfection Primary human cell work, tissue culture, FACS Cellular and biochemical assay development and execution	Technology Transfer International TT to Germany, Russia, Egypt, Malaysia, Saudi Arabia, Iran, Cuba, China Client GMP & QMS training delivery Analytical method transfer and validation package

ACHIEVEMENTS, RECOGNITION & ECOSYSTEM ENGAGEMENT

BIRAC E-YUVA Invited Speaker: Invited as Speaker & Resource Person by BIRAC E-YUVA at the University of Kashmir, Srinagar (July 2025) — recognizing expertise at the intersection of biotech entrepreneurship and science.

BioNEST Bioprocessing Trainer (2021–2025): Successfully organised and delivered yearly training programmes on "The Basics of Bioprocessing: Upstream & Downstream" at BioNEST Bio Incubator, Regional Centre for Biotechnology (RCB), Faridabad — demonstrating a sustained, credible relationship with India's premier biotech incubation ecosystem.

International Technology Transfer — 8 Countries: Executed end-to-end technology transfer of vaccines and analytical platforms to partners in Germany, Russia, Egypt, Malaysia, Saudi Arabia, Iran, Cuba, and China — evidencing the ability to translate R&D into globally deployable, commercially viable technologies.

Regulatory Audit Track Record: Clean audit outcomes across WHO, US-FDA, EU-GMP, TGA, ANVISA, CDSCO, S-FDA, and GLP inspections — an asset for de-risking R&D pipelines during incubation and investor due diligence.

ENTREPRENEURIAL INITIATIVES

Co-Founder, CellXen Innovations LLP · *Cosmeceutical Deep-Tech Startup (In Progress)*

Developing Hygro-Responsive Plant Extracellular Vesicles (HR-PEV) — a climate-adaptive, plant-derived nanocarrier platform that delivers cosmetic actives (HA, Retinol, Ascorbic Acid) in direct response to tropical skin stress signals (heat, sweat pH, TEWL). Sourced from Agri-waste (rice bran, pomegranate peel, wheat germ). Patent-first model targeting BIRAC BIG grant, BioNEST incubation, and B2B ingredient supply to leading Indian cosmetic brands. Combines PhD-level computational biology with process development and regulatory expertise to accelerate formulation optimization and IP strategy.

I hereby declare that all information provided is accurate and true to the best of my knowledge. · Shrish Chandra Pandey · Delhi, India