PARESHKUMAR PUJARA

Biopharmaceutical Professional

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Disciplined and decisive biopharmaceutical leader with ability to drive excellence and increase productivity in manufacturing by inspiring innovation, optimizing efficiency and establishing standard work structure.

EDUCATION

MSc. (Biochemistry) [2011-2013]
University of Saskatchewan, Canada

MSc. (Biotechnology) [2006-2008]
Ganpat University, India

BSc. (Microbiology) [2003-2006]
Gujarat Vidyapith, India

CERTIFICATE COURSE

Fast track MBA (FMBA) in Biotechnology Management from National Institute of Management (NIM), India (2009)

Biotechnology and Intellectual Property (DL-204) from World Intellectual Property Organization (WIPO) Academy (2013)

INDUSTRY AWARDS

Recognition award (2017) - Sanofi Pasteur Canada for delivering outstanding performance as GxP trainer in bulk manufacturing

Recognition award (2015) - Sanofi Pasteur Canada for troubleshooting problems on manufacturing equipment

WORK EXPERIENCE

Dec 2018 to Present

Bulk Manufacturing Manager– Sanofi Pasteur

- Responsible for vaccine bulk manufacturing operation in $100M capacity expansion project
- Lead and empower a team of more than 35+ employees
- Enforce strict adherence with company Health, Safety and Environment (HSE) policy and Good Manufacturing Practice (GMP) requirements in manufacturing area
- Review and approve standard operating procedures, batch records, protocols, reports and technical documents
- Manage department deviations, change controls and CAPAs
- Respond to facility and equipment maintenance/break-down request and work with technical services to solve the issue
- Perform risk assessment and root cause analysis
- Lead biosafety HAZOP assessment, report and investigate incidents and closely monitor workplace related injuries
- Develop training strategy and metrics to expedite on the job training of new hire employees
- Schedule daily activities and evaluate team performance
- Serve as Subject Matter Expert (SME) during pre-approval and GMP regulatory inspections (US FDA, Health Canada)
- Manage internal supply-chain system and market demand to meet manufacturing targets
- Demonstrate leadership to implement 24/7 manufacturing schedule, lean manufacturing – value stream mapping, 5S
- Interview, recruit and reward required talent for the project
- Project management – Develop and track KPIs effective, cost reduction, resource management, lesson learn exercise
- People management – Development plans, team building, performance evaluation, conflict resolution, negotiation
- Establish strong cross-functional collaboration and lead digital transformation

Sep 2018 to Mar 2019

Visting Faculty at Academy Of Applied Pharmaceutical Sciences (AAPS) Inc., Canada

- Teaching Course - Microbiology

GenBio-Next Award (2010) - Intas Biopharmaceutical Ltd. India for conducting independent research study to evaluate commercial potential of a novel Bio-theraputic molecule

KEY KNOWLEDGE AREAS

- Good Manufacturing Practices
- Biopharmaceutical
- Contract manufacturing
- Project Management
- Capacity expansion
- Strategical leadership
- Health, Safety and Environment
- Lean Manufacturing
- Team Building
- Technology Transfer
- Statistical Data Analysis
- Cleaning/Thermal Validation
- Product Development
- Process Improvement
- Quality by Design (QbD)
- Cross-functional collaboration
- Analytical Testing
- Technical Writing
- On-the-job Training

- Train aspiring industry professional on GxP Practices
- Demonstrate hands on experiments in laboratory
- Teach clean room behavior and clean room requirements for biological product manufacturing

Nov 2014 to Dec 2018

Technologist – Sanofi Pasteur

- Execute Midstream and downstream purification processes for vaccine manufacturing in GMP environment – Centrifugation, Microfiltration, Ultrafiltration, Chromatography and Salt precipitation
- Actively participate and lead validation activities - Equipment, thermal and cleaning validation, Process validation and Environmental monitoring (EM) validation of Grade - D, C and C-1 manufacturing facility
- Update technical documentations - P&ID, Functional Requirement Specification (FRS) and Detail Design Specification (DDS)
- Execute process validation protocols - Cycle development and Engineering run batches. Lead process improvement
- Prepare comprehensive Training curriculum / Lesson plans for downstream processing department and provide technical training o the production floor
- Perform necessary SAP transactions for work order initiation, stock status updates and co-ordinate maintenance activity
- Routine environmental monitoring and Utility sampling
- Perform end-to-end HSE risk assessment and develop mitigation plan to address the hazards in the area
- Design and implement engineering solutions to avoid potential Hazards in manufacturing facility
- Change control leader for the manufacturing facility
- Lead gap assesemnt for downstream department

Jan 2014 - Aug 2014

Project Manager / Technology Lead Consultant Pacemaker Pharmachem, India

- Lead project management stream
- Execute technology trasnfer and review documentation
- Identify the critical process parameters (CPP) and perform worst case studies to create risk assessment matrix
- Perform Data analysis using statistical tools
- Support product portfolio management and intellectual property (IPR) teams with technical inputs
- Coordinate intra-departmental activities to track development of in-house product development projects

SELECTED PUBLICATIONS

PMID: 23486480

PMID: 26843168

ON-GOING DEVELOPMENT

Currently pursuing ,

Pharmaceutical GMP Professional Certification (CPGP) from American Society for Quality (ASQ)

Project management professional (PMP) Certification from Project management Institute (PMI)

VOLUNTEER WORK

Voice of Vaccine –
Ambassador to promote vaccination and generate awareness in rural villages of India

Healthy Nation –
Develop training material for the prevention of malnutrition in kids and women

REFERENCE

Available upon request

- Evaluate production bottlenecks and develop action plans to resolve. Set and monitor performance goals.
- Instituted Visual Management boards that provided production transparency and reduced set up time by 50% for each setup and reduced 30% floor space
- Facilitate inspections and develop strong relation with municipal and local government bodies

Jul 2008 - Dec 2010

Research Associate Intas Biopharmaceuticals, India

- Lead contract development and manufacturing (CDMO) and novel biomolecule development related projects
- Execute purification of recombinant human (rHu) therapeutic proteins expressed in mammalian cells and bacterial host
- Research on PEGylation of rHu-therapeutic proteins
- Support purification technology transfer from R&D to manufacturing facility and QC laboratory
- Participate for pre-clinical and clinical trial stockpile production for novel biomolecules
- Assist in submission of the pre-clinical and clinical trial data package of a novel biomolecule to a regulatory agency
- Perform molecular weight determination, isoelectric point determination, quantification of protein, Purity testing, isoform profiling, Immunoassay and impurity characterization
- Perform stability studies of rHu-therapeutic proteins and assisted in non-infringing formulation (NIF) development
- Analytical method development, qualification and transfer to QC for lot release, stability and in-process analysis
- Conduct Good Laboratory Practices (GLP) trainings
- Technical Writing – Process and method development summary, technology transfer document, feasibility report
- Monitor all clients supporting activity and provides regular updates within the company and with the client.

Jun 2007 -Jul 2008

Executive (Co-Op), Pacemaker Pharmachem, India

- Sample management and documentation support to process improvement team
- Assist documentation team in SOP, protocols, validation report writing. Archive COAs and MSDS for raw material
- Buffer and microbial media preparation
- Raw material testing and inventory tracking
- Participate in Process Mapping and data collection in a production environment
- Work closely with 5S teams to improve workplace organization and waste reduction.