Your Name Here

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Analytical and detail-oriented chemical engineer with years of cGMP pharmaceutical manufacturing experience. Comprehensive ability in process design, development, and optimization, providing technical floor support and implementation of technology transfer. Proficient in investigational root cause analysis, CAPA implementations, driving document change controls and handling product failures. Capable of delivering production manufacturing metrices and KPI's. Certified cGMP trainer, investigator and six sigma lean methodologies. Working according to current Good Manufacturing Practices cGMP, ISO standards and FDA regulatory guidelines. A team player, motivated and goal-oriented individual that adheres to organization goals, and objectives.

TECHNICAL SKILLS

- Process Design
- Process Optimization
- Manufacturing Scaleup
- Single Use Technology
- Aseptic Processing
- Quality Control
- Technology Transfer
- Equipment Selection Maintenance & Calibration
- Process Qualification
- Change Controls
- Laboratory Operations
- Analytical Methods
- Process Validation
- Root Cause analysis
- Investigations & CAPA
- JMP, LIMS, MS Office
- Lean and Six Sigma
- Project Management
- Statistical Analysis
- Batch Record Drafting

ACADEMIC ACHIEVEMENTS

Bachelor's of Engineering Degree XYZ University (2016)
Chemical Engineering

PROFESSIONAL EXPERIENCE

MSAT Engineer – Microbial Manufacturing | ABC Company **Aug. 2022 – Present**

- ***Process Development:*** Work with process development team to define common methodologies for conducting unit operations at the manufacturing scale and drafting batch records. Typical manufacturing operations include fermentation, lysis, chromatography, ultrafiltration, and depth filtration in a single use technology (SUT) facility.
- ***Technical leadership:*** Supporting process engineers, process development scientists, and production associates for process validation and commercial stage products including overseeing the design and execution of studies, investigation and data analysis of results, and writing/review of technical reports. Actively drive MSAT initiatives to improve procedures and Implement Corrective Actions.
- ***Technology Transfer:*** Manage technology transfer from clients and process development laboratory to commercial manufacturing; ensuring effective information flow, timeline execution, issue resolution, and documentation in accordance with governing tech transfer quality system requirements while leveraging robust risk management practices.
- ***Floor Support:*** Provide technical and scientific support to bulk drug manufacturing process related events such as manufacturing deviations, technical troubleshooting, change control and optimizations. Provide on-floor technical support for manufacturing processing.

- ***Implement Manufacturing Sciences Initiatives***: Define and implement the MSAT procedures, systems, and practices for new product introduction, process validation, and continuous process verification in CMO environment in accordance with cGMP and ICH guidelines.

Manufacturing Engineer – Bioproduction Group | ABC Company **April 2021 – Aug. 2022**

- ***Manufacturing Operations:*** Providing technical leadership for protein digestion and supporting safety, quality, and productivity improvement goals. Supporting execution of validation protocols and process change protocols according to cGMP.
- ***Root Cause Analysis & Investigations:*** Leading product related deviations and non-conforming Material reports in TrackWise. Performing process change control activities and root cause investigation. Implementation of corrective and preventive actions CAPA's.
- ***Process Optimization:*** Design of Experiment DOE and performing experiments at laboratory scale and pilot scale. Creation and revision of manufacturing formulas and standard operation procedures SOP's. Implementation of process adjustments and change controls and training production floor personnel.
- ***Project Management:*** Responsible for analytical method transfer from other sites and to ensure effectiveness and reproducibility of methods. Also, a member of site capital expansion project, providing insight and support for designing and selecting equipment for the new analytical laboratory. Providing project scope, timelines, resourcing, and budget in meetings.
- ***Statistical Analysis***: Manufacturing process data collection and data mining; performing analysis using statistical analysis tools such as JMP and Minitab.
- ***Equipment Selection & Sizing:*** Biological process improvements and cost savings projects. Unit operations improvements focused on Filtration, pumping and piping systems and improvement of overall bio-digests in continuous stirred tank reactors. Equipment selection and considerations for the new analytical lab development.

R&D Scientist – Development Operations | ABC Company **Oct. 2019 – Apr. 2021**

- ***Analytical & Development Operation:*** Analyzing Clinical Trial Material (CTM) batches, feasibility lots and stability batches. Performing method validation and design of experiment (DOE) according to test methods and customer protocols. Extensive use of analytical instruments and reporting obtained data.
- ***Documentation:*** Creation of batch reports and certificate of analysis for material release. Documentation in accordance with cGMP and FDA standards. Preparation of raw data and processed data packages for clients. Proficient in NuGenesis, Empower, LIMS and MS Office.
- ***Costumer Service:*** Client and patient conscious, able to provide aid to meet on time deliveries OTD and improve key performance indicators KPI. Able to troubleshoot and problem solve challenges on daily basis and attend client meetings.
- ***Regulatory Compliance:*** Execution of analysis according to regulatory guidelines and Standard Operating Procedures SOP's. Reporting out of specification OOS and out of trend OOT finding to management. Communication of risks to timelines of deliverables in a proactive manner. Performing GEMBA walks with the operations manager.

- ***Team Support:*** Deliver assigned tasks on time and work harmoniously with team members. Active engagement and adherence to departmental requirements to maintain smooth and efficient workflow.

Quality Control Analyst - Solid & Liquid Dose | ABC Company **Feb. 2017 – Oct. 2019**

- ***Analytical Testing on Solid dose pharmaceutical samples:*** such as delayed release (DR), sustained release (SR), enteric coated and immediate release tablets and capsules. Identify out-of-specification and out-of-trend results through sampling techniques and testing procedures such as, assay tests, content uniformity tests, dissolution sampling and related compound tests.
- ***Analytical Testing on Liquid dose pharmaceutical samples:*** such as sterile products, nasal sprays, syrups & elixirs; testing according to test methods and protocols.
- ***Data Entry & Documentation:*** Documentation in lab notebooks, LIMS, Empower and SAP according to GMP and in-house SOPs. Record all data in secure, prompt, and accurate medium.
- ***Equipment Operation & Maintenance:*** Performing various tasks on analytical instruments such as UPLC, HPLC, UV spectroscopy, FTIR spectroscopy and Karl Fisher auto-titrator. Troubleshooting, maintenance, and monitoring equipment if required. Calibrated and standardize equipment on daily and monthly basis according to SOP's and GMP requirements.
- ***Regulatory Compliance:*** Execute testing and record data according to FDA & Health Canada regulations. Conducted quality control procedures within FDA & Health Canada regulations, U.S. pharmacopeia USP and European pharmacopeia EP requirements.
- ***Deadline Adherence:*** Completed all testing procedures in a fast-paced environment and ensured products were fully tested, approved, and shipped according to scheduled deadlines. Prioritized and campaigning tests.
- ***Team Leadership:*** Laboratory project team leader, prepared the QC laboratory for regulatory, customer and internal audits. Introduce regulatory and standardized procedures to new hires. Designated health and safety coordinator, participated in audit preparations, lab checks and workflow improvement.

Quality Control Analyst (Internship) | ABC Company **Jan. 2015 – Sep. 2015**

- ***Sample Testing:*** Physical testing on value stream sample; such, as Omeprazole capsules and Atorvastatin tablets, reported findings and further documented results obtained.
- ***Equipment Maintenance and Calibration*** Performed daily standardization and monthly calibrations on quality control equipment. Prepared and checked solutions used and verified equipment performance.