John Doe

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Analytical and detail-oriented chemical engineer with years of cGMP pharmaceutical manufacturing experience. Comprehensive in tech transfer implementation, process design, development and optimization. Proficient in delivering production manufacturing metrics and KPIs, and technical floor support. Extensive background in investigational root cause analysis, CAPA implementation, driving document change control and handling product failure. Certified in Lean Six Sigma, and cGMP investigator and trainer. Adhere to cGMP guidelines, ISO standards and FDA regulations. A motivated individual with a goal-oriented and team player mindset that is conscientious of company objectives.

SKILLS

Process Design, Process Optimization, Manufacturing Scale-Up, Single Use Technology, Aseptic Processing, Quality Control, Technology Transfer, Equipment Selection Maintenance, Equipment Selection Calibration, Process Qualification, Change Controls, Laboratory Operations, Analytical Methods, Process Validation, Root Cause Analysis, Corrective and Preventive Actions (CAPA), JMP, LIMS, MS Office, Lean & Six Sigma, Project Management, Statistical Analysis, Batch Record Drafting, Technical Investigations, Support Development, Research and Development, Project Requirements, Process Control, Industrial Processes, Industrial Applications, Heat Transfer, Equipment Design, Energy Storage, Conducting Research, Chemical Engineering

WORK EXPERIENCE

MSAT Engineer - Microbial Manufacturing Aug 2022 - Present
ABC Company Los Angeles, CA

- Process Development: In communion with process development team, defining 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. This involves overseeing design and processes execution, data analyses, and technical reports review. Actively drive MSAT initiatives for procedure improvements and CAPA implementation.
- Technology Transfer: Tech transfer management, from clients and process development laboratories, all the way to commercial manufacturing. Ensure effective information flow, timeline execution, issue resolution and documentation. All in accordance with governing tech transfer quality system requirements, while leveraging robust risk management practices.
- Floor Support: Provide on-floor technical support for manufacturing execution. Handling process related events such as manufacturing deviations, out-of-specification results and providing technical troubleshooting.
- Implement Manufacturing Sciences Initiatives: Define and implement manufacturing sciences' procedures. Introduce new products to the manufacturing environment. Support process validation and continuous process verification in a CMO environment.

Manufacturing Engineer-Bioproduction Group Apr 2021 - Aug 2022
ABC Company Los Angeles, Ca

- Manufacturing Operations: Provided technical leadership with protein digestion and supported safety, quality, and productivity objectives. Supported validation protocol execution and process change protocols, according to cGMP.
- Root Cause Analysis & Investigations: Lead product related deviations and non-conforming material results in TrackWise. Performed process change control activities, root cause analyses investigations and CAPA implementations.
- Process Optimization: Design of experiment conduction (DOE) and experiment performance at both laboratory and pilot scale. Creation and revision of manufacturing formulas and standard operating procedures (SOPs). Implementation of process adjustments and change controls, in communion with production floor personnel training.
- Project Management: Performed analytical method transfers from other sites and ensured effectiveness, reproducibility and robustness. As former Site Capital Expansion member, drove the analytical lab development project. Provided facility design layout, equipment selection and procurement. Presented project scopes, timelines and resources in meetings.
- Statistical Analysis: Process data collection and data mining. Performed statistical analysis using tools such as JMP and Minitab.
- Equipment Selection & Sizing: Biological process improvements and cost savings projects. Unit operations improvement focusing on bio-digest performance in continuous stirred tank reactors, and adequate filtration, pumping and piping systems. Equipment selection and considerations for a newly built analytical lab.

R&D Scientist - Development Operations Oct 2019 - Apr 2021
ABC Company Los Angeles, Ca

- Analytical & Development Operation: Analyzed clinical trial materials (CTM), examined feasibility lots and conducted stability protocols. Performed method validation and design of experiment (DOE) according to test methods and customer protocols. Extensive use of analytical instruments and reporting such obtained data.
- Documentation: Batch reports creations and certificate of analysis (COA) creations for material release. Prepared raw data and processed data packages for clients. (Incorporated softwares, NuGenesis, Empower, LIMS and MS Office for report creations.)
- Customer Service: Contributed with on-time deliveries (OTD) and key performance indicators (KPI). Attended client meetings, addressed clientele comments/concerns in meetings and provided feedback.
- Regulatory Compliance: Execution of analysis according to regulatory guidelines and Standard Operating Procedures (SOPs)-documentations adhered to cGMP and FDA regulations. Reported out-of-specification (OOS) and out-of-trend (OOT) findings to management.
- Team Support: Delivered assigned tasks on time and worked harmoniously with team members. Collaborative engagement to ensure timeline adherence. As a team member, troubleshot analytical equipment and shared product-specific knowledge with coworkers.

Quality Control Analyst-Solid & Liquid Dose Depts. Feb 2017 - Oct 2019
ABC Company Los Angeles, Ca

- Analytical Testing on Solid-Dose Pharmaceutical Samples: Examined delayed release (DR), sustained release (SR), enteric-coated and immediate-release tablets, and capsules. Identified out-of-specification and out-of-trend results through sampling techniques and testing procedures, including: dissolution sampling, assay, content/blend uniformity and related compound testing.
- Analytical Testing on Liquid-Dose Pharmaceutical Samples: Examined sterile drops, nasal sprays, syrups and elixirs-tested according to test methods and protocols.

- Data Documentation: Documented data in lab notebooks, LIMS and Empower -according to cGMP and in-house SOPs. Recorded all data in a secure and prompt medium.
- Equipment Operation & Maintenance: Utilized analytical instruments including UPLC, HPLC, UV spectroscopy, FTIR spectroscopy and Karl Fisher auto-titrator. Troubleshot, maintained equipment, as necessary. Calibrated and standardized equipment on daily and monthly bases, according to SOPs and cGMP.
- Regulatory Compliance: Conducted quality control procedures (test execution and data recordation) according to FDA and Health Canada regulations, and U.S. Pharmacopeia (USP) and European Pharmacopoeia (EP) guidelines.
- Deadline Adherence: Completed all testing procedures in a fast-paced environment by campaign testing and prioritization. Ensured products were fully tested and approved, according to scheduled deadlines.
- Team Leadership: Designated environmental-health-and-safety coordinator-handled monthly safety meetings, lab safety checks, and provided EHS communication. As team leader, ensured workflow optimization, and prepared the QC lab for regulatory and customer audits. In addition, introduced SOPs and safety procedures to new hires.

Quality Control Analyst Jan 2015 - Sep 2015
ABC Company Los Angeles, Ca

- Sample Analysis: Performed physical testing on value stream samples, such as Omeprazole capsules and Atorvastatin tablets. Reported test results and documented raw data according to cGMP.
- Equipment Maintenance and Calibration Performed standardizations and calibrations on quality control equipment, on daily and monthly bases. Verified equipment performance and prepared solutions, as needed.

EDUCATION

Bachelor's of Engineering Degree; Chemical Engineering Jun 2016
XYZ University

LICENSES & CERTIFICATIONS

cGMP Investigator and Trainer 2022
Health Canada Regulations

Lean Six Sigma 2022
Health Canada Regulations

5. [NS - 01/15/24 18:52]:
Make your certifications stand out to continue ensuring you are a top applicant.