

# Julian Bunker

## Manufacturing Team Lead

Loveland, CO 80537

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Proficient in team lead role performing formulation of drug product and aseptic fill of finished goods. Proficient in scale cell culture, cell bank production, media preparation, buffer preparation, aseptic filling. Experienced in operating and troubleshooting manufacturing equipment and Instrumentation for cell culture analysis (Vi-Cell, NOVA Bioprofile 400). GDP Documentation preparation, revision and correction.

Willing to relocate to: Houston, TX - Austin, TX - Killeen, TX

Authorized to work in the US for any employer

## Work Experience

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### Team Lead

XBiotech USA, Inc - Austin, TX

February 2019 to May 2023

- Schedule, coordinate, plan and execute GMP processes and GLP process development tasks.
- Proficient capture of information in laboratory notebooks GLP.
- Proficient GDP documentation and GMP compliance.
- Perform basic laboratory tasks (pH, Conductivity, sampling, etc)
- Demonstrate aseptic technique in the handling of product/material (work in biosafety cabinets, laminar flow hoods, use of sterile filtration and pipetting.)
- Perform process monitoring including routine sampling using aseptic sampling devices.
- Perform operation of autoclaves and sterilizing equipment according to established procedures.
- Perform operation of media and buffer prep equipment according to established procedures. This equipment includes but is not limited to prep vessels, MixTainer, hold vessels etc.
- Perform solution preparation including medias and buffers according to established procedures.
- Perform large and small-scale filtrations.
- Perform operation of bench top centrifuge and water baths.
- Measure and record data associated with production equipment.
- Clean production equipment and work areas to maintain facility standards.
- Build product subassemblies or final assemblies to support manufacturing.
- Perform preventative maintenance on manufacturing equipment as required.
- Proficient understanding of critical process parameters and operational parameters.
- Ability to troubleshoot simple problems with equipment and processes.
- Certified and trained in aseptic filling.
- Proficient in planning, setup, document revision and executing processes for generation of cell banks (master cell bank, working cell bank).
- Process development at lab scale including CHO clone selection studies.
- Authoring and revision of SOP and GMP controlled production batch records.
- Initiate and execute Document Change Requests and investigations under the guidance of direct supervisor and Quality Assurance.

- Lead or assist with validation and qualification of new equipment.
- Lead or assist in developing test plans, process development experiments and updating new processes or procedures.

### **Packaging Technician**

GlaxoSmithKline - East Durham, NY

February 2014 to May 2018

- Senior level operation of packaging lines ran in teams of 2 to 6.
- Perform troubleshooting, basic maintenance, line clearance, changeover and LOTO of many various types of packaging equipment.
- Perform assembly and disassembly of all parts corresponding to packaging line changeovers. (Pre-changeover activities)
- Knowledge of tube loaders, tube fillers, cartoners, checkweighers, casepackers, conveyors, positive flow pumps, pressurized vessels.
- Operating lift equipment to transport bulk material and components that are compatible with packaging instructions.
- Perform routine finished goods quality checks to ensure consumer safety and customer satisfaction.
- Exercise GDP standards in a CGMP compliant environment.
- Provide certified training in operation, line clearance, changeover, LOTO and routine quality checks.
- Safety representative performing risk assessments to evaluate potential hazards and coordinate with EHS.

### **Attendant**

Storeroom Solutions, Inc. - East Durham, NY

July 2013 to February 2014

- Navigate inventory system and make adjustments to quantities and descriptions of parts.
- Working with mechanics to identify and locate parts needed for maintenance.
- Collect specifications, dimensions and end use functions on all parts brought in from the plant for stocking.
- Comply with GMP and documentation standards in an FDA regulated production environment.
- Problem solving with organization and storage of all spare parts ensuring safety, EHS and GMP compliance.
- Daily work consisted of: assisting mechanics in locating spare parts, cycle counting, receiving and stocking.

### **Database Analyst**

EmblemHealth, Inc. - Lake Katrine, NY

May 2010 to January 2011

- Analyzing, processing and reporting using large Microsoft excel files (data sets). Used to update New York down state region provider's records of demographic and contract information with EmblemHealth, Inc..
- Knowledge of state sponsored programs: Medicaid-(Family Health Plus, Child Health Plus) and Medicare. Along with different brands of such as PPO and HMO.
- Update database as requested via fax and email or data set from internal source or the practice. This database houses the published participating provider directory which is routinely audited both internally and by the state of New York.
- Work remotely from head quarters offices in Manhattan. Maintain contact with as many superiors and co workers as necessary to perform job duties via email and phone.

## Education

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### **High School Diploma in General Studies**

Thompson Valley High School - Loveland, CO

January 1998 to January 2002

## Skills

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- Lift Equipment: Counterbalance Trucks, Reach Trucks, Order Pickers, Ricoh custom lift equipment, Pallet jacks motorized and manual (8 years)
- Packaging Line Operation (4 years)
- Routine Finished Goods Quality Checks (4 years)
- LOTO (Lock Out Tag Out) (4 years)
- Line Clearance (4 years)
- Changeover of packaging equipment (3 years)
- Certified Trainer (2 years)
- Microsoft Office (4 years)
- Recieving / Stocking (2 years)
- Assembly / Disassembly (3 years)
- Filling
- Labeling
- Aseptic Technique
- CGMP
- CPT Coding