



1219 Glen Rock Avenue Waukegan, Illinois 60085

JOB DESCRIPTION

HPI Assistant Operator

Reports to HPI Production Supervisor

ABOUT PFANSTIEHL

Pfanstiehl, founded in 1919, is a leader in Carbohydrates and has over 40 years of experience in custom synthesis and process development with a specialty in carbohydrates, nucleosides and high potency APIs. Pfanstiehl's customers include most of the world's leading biopharmaceutical and pharmaceutical companies and its products are utilized in market leading drugs that treat life threatening and debilitating diseases including cancer, rheumatoid arthritis, STDs, and diabetes. Increasing regulatory and quality requirements are benefiting biopharmaceutical and pharmaceutical suppliers like Pfanstiehl with high purity, strong cGMP controls and a strong reputation with FDA and other regulatory agencies. Pfanstiehl is the premier manufacturer of cGMP high purity and low endotoxin injectable carbohydrate excipients ("High Purity Ingredients" or "HPIs") for the biopharmaceutical and pharmaceutical markets. In addition, the Company specializes in the isolation, purification, custom synthesis and scale-up development and manufacture of small molecule Active Pharmaceutical Ingredients (API) and High Potency Active Pharmaceutical Ingredients (HPAPI) in gram to multi-ton commercial quantities.

Pfanstiehl has embarked on a long-term growth and investment plan to build a HPI/HPAPI leader.

JOB SUMMARY

The HPI Assistant Operator job function is to assist in the production of a variety of High Purity Ingredients (HPI) and other related products by following written procedures. The HPI Assistant Operator will clean equipment and facilities, stage supplies, and perform daily and weekly cleanroom sanitization.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Operate in accordance and compliance with:
 - Current cGMP regulations and ICH Q7 guidelines
 - Work Rules, Quality Policies (QP), and Standard Operating Procedures (SOP)
 - Cardinal Rules of Quality, Delivery and Safety
- Meet daily individual production goals
- Clean equipment, carts, and facilities per procedures

- Perform daily and weekly cleanroom sanitization per procedures
- Accurately complete cleaning records and other documentation as required
- Stage and transfer drums, carts, and supplies to the cleanroom area and move finished product out of the cleanroom per procedures
- Follow instructions regarding the use of chemicals and supplies, as directed
- Perform daily housekeeping to maintain a clean safe and orderly workplace
- Identify requirements for sanitation supplies and consumable items for the non-GMP areas, ensuring that adequate stock is available to satisfy the needs of the facility.
- Utilize all assigned Personal Protective Equipment (PPE) to complete job tasks
- Develop awareness of all related Safety Data Sheets (SDS)
- Safely operate a forklift, floor scrubber, and other job related equipment
- Perform light maintenance in accordance with abilities
- Report any required repairs to the facility
- Maintain outside grounds, i.e. garbage, windows, and sidewalks
- Other duties as assigned

QUALIFICATIONS

- High School Diploma or equivalent
- Good written and verbal English communications skills
- Effectively communicates with supervisor and team members and other departments

Physical Requirements

- Must have good hearing and sight – adequate for safety programs in a pharmaceutical manufacturing plant
- Must be able to sit and/or stand for extended periods
- Ability to work effectively under pressure to meet deadlines
- Frequent sitting, standing, walking, climbing of stairs, use of computer monitor screen, talking, writing, listening
- Must be able to lift 25 lbs. or occasionally lift up to 50 lbs.
- Ability to wear proper safety equipment when working in plant

To perform this job successfully, an individual must be able to perform each duty satisfactorily. The requirements listed above are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

This job description reflects the general duties of the job but is not a detailed description of all duties which may be inherent to this position. Pfanstiehl may assign reasonably related additional duties to individual employees, consistent with company policy.