Reagent Manufacturing Supervisor

Job Summary: This is a position of leadership, where the incumbent will be responsible for leading a small group of technicians. Primary responsibility will be to manage employees and processes in manufacturing under ISO 13485 and cGMP environment. Products that will be manufactured in this group will be reagents and consumables that utilize Dynex Multiplier bead technology. Travel to Dynex UK facility is required. The goal is to understand the R&D process and then design and implement comparable manufacturing processes in Chantilly, VA.

Responsibilities: Reagent manufacturing Supervisor is instrumental in building a team and processes for manufacture of reagents and beads used in Dynex Multiplier immunoassays. The supervisor will work with QA, process engineer and other Supervisory team to ensure staff is trained and following established manufacturing protocols. The Supervisor will work in both a hands on and supervisory role comprising of creating processes, while working with R&D scientist and conducting training for staff to follow. Initially the position will require travel and flexible schedule. The supervisor will be performing all activities required to validate the site and instruments used for cGMP manufacturing under the guidance of QA. The supervisor will be involved in the hiring of staff within the department.
Other duties will include:

- Generate manufacturing procedures from R&D procedures, with the help of R&D Scientist(s).
- Participate in the transfer of new products related to reagents and assays from R&D into production.
- Lead activities related to site expansion/relocation and ensuring that the reagent manufacturing area is suitable for manufacture under cGMP.
- Ensure all equipment used in manufacturing is calibrated and maintained before use and updated in QT9 Quality System software. Timely schedule the maintenance and calibration of laboratory equipment either at Dynex or the manufacturer of the equipment.
- Follow all appropriate health and safety guidelines and OSHA regulations.
- Create meaningful manufacturing metrics to evaluate departmental effectiveness over longer time-periods.
- Ensure reagent manufacturing staff is trained in all aspects of the work they undertake and maintain records of training to demonstrate compliance to the appropriate standards.
- Ensure all employees in the department comply with the requirements of the ISO 13485/FDA quality system.

Supervisory Responsibilities:

- Hire manufacturing employees as needed to support new product movement to manufacturing.
- Ensure staff is trained, motivated and have an environment to successfully manufacture products.
- Conduct evaluations and give timely feedback to manufacturing staff.
- Continually improve processes.
- Work with QA to ensure, the site is always ready for an audit.

Qualifications: Bachelor's or Master's degree in Biochemistry or related scientific discipline. This position requires a minimum of 5 years' experience in commercial reagent/assay production. A minimum of 2 years of which should be in a supervisory or management capacity. Use of LIMS or other ERP system in a manufacturing environment. Proficient in MS Office.

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