BIOSPECTRA
Premium Pharmaceutical Ingredients

Job Description

Job Title:

Director of GMP Manufacturing

Reports To:

President

Direct Reports:

Production Manager

Job Summary:

The Director of GMP Manufacturing will be responsible for managing hands-on operations of BioSpectra's cGMP manufacturing suites. The role will require to liaise with Supply Chain, R&D, Quality, Project Management and Business Development functions in order to plan, resource and execute production campaigns.

Essential Duties and Responsibilities:

- ✓ Develops long and short-range manufacturing goals, operating plans, programs and objectives.
- ✓ Implements the manufacturing plan and establishes procedures for maintaining high standards of manufacturing operations to ensure that all products conform to established customer and company quality standards.
- ✓ Regularly ensure manufacturing operations are running efficiently.
- ✓ Identifies, recommends, develops and implements necessary changes, within the appropriate regulatory confines, to improve productivity and for continuous process improvements.
- ✓ Manage technical input to batch records and other quality documents according to ICH and FDA guidelines.
- ✓ Manage technology transfer of laboratory processes into the GMP manufacturing suites.
- ✓ Adherence to EHS policies and maintenance of work areas in a safe, clean and orderly fashion.
- ✓ Ensures the training program for all levels of manufacturing are current and complete and that all production personnel are qualified to perform work assigned.
- ✓ Builds new manufacturing polices or recommends updates to existing policies.
- ✓ Works with other departments to procure equipment and build new processes at BioSpectra.
- ✓ Establishes appropriate raw material inventory levels to meet manufacturing expectations and goals.
- ✓ Directs and leads manufacturing managers and supervisors to accomplish the goals of the manufacturing department, consistent with established manufacturing and safety procedures.
- ✓ Directs the establishment, implementation and maintenance of production standards.
- ✓ Builds manufacturing workflows and directs production, facility and equipment planning.
- ✓ Other duties may be assigned by President.

Qualifications:

- ✓ Bachelor's degree or 7+ years of related experience in management of pharma manufacturing or quality operations
- ✓ 7+ years' experience; managing multi-facility GMP manufacturing operations.
- ✓ Excellent verbal and written communication skills
- ✓ Extensive knowledge of USP, ICH, FDA, 21 CFR and other guidance documents
- ✓ Extensive experience in a GMP manufacturing environment
- ✓ Experience in process development
- ✓ Ability to prepare, review and execute GMP documents
- ✓ Experience in scale-up/process R&D and technical transfer a plus
- ✓ Strong scientific background with end-to-end understanding of CMC processes for GMP commercial operations
- ✓ Strong leadership and communication skills
- ✓ Experienced people manager with proven ability to develop talent and to achieve results through teamwork and leadership of others
- ✓ Ability to manage teams and make recommendations to management
- ✓ Must be driven and motivated to work in a group or work independently
- ✓ Functional knowledge of software used to perform functions.

Physical Requirements:

- ✓ Lift up to 20 lbs. occasionally
- ✓ Prolonged periods sitting at a desk and working on a computer
- ✓ Stand and/or walk for extended periods
- ✓ Work with and/or around chemicals and/or hazardous materials
- ✓ Repeating motion that may include wrists, hands, and fingers

Work Hours:

- ✓ Exempt Position
- ✓ Minimum of 40-45 Hours Week, or other agreed upon documented schedule
- ✓ Ability and willingness to work from all BioSpectra facilities