GeniPhys

JOB DESCRIPTION

POSITION	Director of Manufacturing and Quality
SUPERVISOR'S TITLE:	
POSITION OVERVIEW:	The Director of Manufacturing and Quality will be responsible for establishing and operating a GMP certified manufacturing facility for collagen-based medical products. They will assume leadership and oversee the manufacture of the base polymerizable collagen protein and associated collagen materials, ensuring production, performance, and quality standards are consistently met. Initial responsibilities will focus on expanding Quality Management System in accordance with FDA guidelines for cGMP manufacturing and adapting manufacturing process for commercial production. Over time, this person will be responsible for recruiting and managing the manufacturing team as well as identification and auditing of third-party facilities related to production of commercial materials. This individual will interface with product development and quality and regulatory team members to ensure that company goals and objectives related to regulatory submissions and product launch are achieved.

QUALIFICATIONS:

Required:

- BS in engineering or equivalent
- At least 10 years' experience
- Manufacturing process engineering experience in GMP environment
- Protein purification, biologics, and/or medical device manufacturing
- Familiarity with medical device quality management systems

Preferred:

- MS in engineering or equivalent
- Supervisory experience
- Familiarity with ISO 13485

Skills & Competencies:

- Process engineering
- Process design
- Equipment validation and qualification
- Experience building a manufacturing facility from the ground up
- Implementation mindset
- Strong business acumen
- Project management skills
- Strong communications skills
- Cross-functional team leadership

RESPONSIBILITIES:

Supervisory Responsibilities:

- Oversees and participates in the recruitment, hiring, and training of manufacturing and quality employees
- Oversees schedules and assignments for the division
- Conducts performance evaluations that are timely and constructive

Duties/Responsibilities:

- Develops and implements equipment qualification and validation protocols
- Supervises equipment purchase, maintenance, and layout
- Leads transition of current lab scale manufacturing process to pilot scale in new facility
- Supports new facility design and startup
- Accountable for compliance with appropriate GMP and other regulations and standards
- Selection and oversight of contract partners
- Develop and evaluate potential process improvements with a focus on efficiency and quality
- Ensures a healthy and safe working environment, and compliance with federal and state regulations
- Assists with long-range operating goals, expansion efforts, and implementation of new and advanced technology
- Identifies and shares training opportunities for staff to build and improve skills
- Organizes departmental management structure and teams for optimal, efficient operations
- Delivers progress and production reports to executive team members as requested
- Reviews production reports to ensure safety, quality, financial, and delivery goals and standards are met
- Performs other related duties as assigned