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Quality Assurance Specialist

SUMMARY:

The Quality Assurance Specialist will be responsible for Quality System elements including Quality Event coordination, Document Control and Training, Device History Record reviews, and Calibration maintenance.

ESSENTIAL FUNCTIONS:

- Coordinate and monitor Quality Events (i.e., deviations, non-conformances, CAPAs, customer complaints, change controls, etc.).
- Track and trend Quality Events.
- Coordinate, lead, and capture meeting minutes for routine Quality Event meetings.
- Process Change Orders and maintain Quality Records.
- Work with all departments to ensure training compliance.
- Perform incoming inspections, as required.
- Assist with quality system supplier audits, as required.
- Assist with the creation/revision of SOPs and work instructions.
- Participate in internal and external compliance audits.
- Provide day-to-day guidance and training to personnel, as required.

ADDITIONAL DUTIES:

- May perform additional duties as assigned or directed by management from time to time

EDUCATION/EXPERIENCE REQUIRED:

- Bachelor's degree in life science or related field or the equivalent combination of education and/or experience.
- 5+ years' quality experience, preferably in biotech and/or Medical Device industries.
- Key Standards and Regulations; 21 CFR 820, MDD, MDR, MDSAP, ISO 13485 and 14971

REQUIRED SKILLS:

- Knowledge of medical device quality systems.
- High level of personal and professional integrity and trustworthiness with strong work ethic and the ability to work independently with minimal direction.
- Excellent communications and presentation skills.
- Positive “can do” attitude and a sense of urgency to get things done right the first time.
- Highly detailed orientated with a critical degree of accuracy regarding data entry and analysis.
- Ability to collect and analyze information and contribute to problem-solving.

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REQUIRED COMPETENCIES:

- Performance Oriented – Is driven by personal performance; achieves objectives and comfortable with quantifiable assessments.
- Impact Oriented – Performs to stated objectives and driven to make an impact on company goals and patients’ lives.
- Competitive – Dedicated to a competitive spirit that supports the IRRAS goal to be the premier Medical Device company in the industry.
- Sense of Urgency – Has the speed and agility dedicated to the company’s goals and performance.
- Ability to Handle Pressure and Ambiguity – Comfortable with the pressure to be the best and the ability to maintain composure and focus in situations of ambiguity and uncertainty.
- Confidence - Confident in one’s skills and abilities; pursues everything with energy; demonstrates the drive and a need to finish especially in the face of resistance or setbacks.
- Multitasking – Capable of performing multiple tasks over a certain period of time by executing them concurrently, efficiently and accurately.

PHYSICAL DEMANDS:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- While performing the duties of this job, the employee is regularly required to talk or hear. The employee is frequently required to sit.
- The employee is occasionally required to stand; stoop; bend and walk; use hands to finger, handle, or feel and reach with hands and arms. Transition from standing and sitting often.
- Required specific vision abilities might include close vision, distance vision, color vision, peripheral vision, depth perception and ability to adjust focus.
- The employee may occasionally lift and/or move up to 10 pounds.

WORK ENVIRONMENT:

The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- General office environment.
- Daily exposure to PCs and networks.
- The noise level in the work environment is usually moderate.
- Travel might be required.

Disclaimer:

The above statements are intended to describe the general nature and level of work performed by employees assigned to this classification. They are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of personnel so classified.

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Department Head: _____ Date: _____

Employee: _____ Date _____