Date:	11/16/2021	***Incumbent***	
Position Title	Patient Tracking & Outreach Specialist	***Reports to***	Senior Director, Customer Care
Department	Customer Care	***Location***	Mount Olive, NJ

Accountability Objective:

To maintain patient implant registration files in accordance with all FDA and Flowonix regulatory and quality requirements. Perform tasks related to patient implant tracking forms; production and distribution of patient education and information materials and prepare and distribute outreach mailings both domestic and international for patients, healthcare providers and MRI facilities. Assist Customer Service with billing.

Essential Functions:

1. Review all incoming patient implant tracking forms for accuracy and completeness
2. Record, update and retain accurate paper patient tracking files and electronic database for all domestic and international patients
3. Maintain a patient tracking database in compliance with all FDA and Flowonix quality and regulatory requirements
4. Obtain missing or additional information necessary to the patient tracking, ID card production and adherence to FDA compliance and Flowonix corporate requirements
5. Create permanent patient implant tracking ID cards in accordance with the most recent work instruction
6. Coordinate with the Quality and Regulatory team to facilitate their review of all produced cards
7. Ship, log and track receipt of patient packages of permanent patient ID cards and Medical Device Alert Bracelets post-device implant, revision and or replacement and or when requested by the patient, healthcare providers or field representatives.
8. Work with vendors and Quality department to purchase ID card supplies, Medical Device Alert Bracelets and delivery companies to obtain tracking and shipping supplies
9. Maintain ID card printer and card printing software
10. Create patient and healthcare provider reports for field representatives, healthcare providers and marketing department as requested
11. Create and maintain Standard Operating Procedure and Work Instructions
12. Identify opportunities for process improvement
13. Implement workflows to enhance performance and minimize waste
14. Manage domestic and international outreach mailings for patients, healthcare providers and MRI facilities
15. Negotiate shipping and printing rates to ensure cost effective rates for production and delivery of all mailings and packages
16. Assist Quality with responding to and preparing possible corrective actions and or field safety notifications and participate in and respond to all internal Quality audits
17. Track and report mailing and delivery status for Regulatory effectiveness checks and FDA reporting
18. Work with other corporate departments to analyze data and ensure all relevant patient implant and or explant information is included in the patient tracking database to ensure FDA compliance
19. Assist Customer Service with monthly closing, inventory, and GL reconciliation.
20. Responsible for preparation and distribution of the monthly sales report to Sr. Management.
21. Assist Customer Service with the yearly audit as well as monthly, quarterly and yearly financial closing.
22. Other duties as assigned.

FLOWONIX

Decision-Making Authority:

1. Provide guidance for internal staff regarding matters of patient implant device tracking compliance with domestic and international quality standards and regulations. Instruct field representatives of patient tracking policies and procedures during training.

Position Specifications:

1. *Knowledge/Educational Requirements*

- Associates degree, or equivalent experience
- 2-3 years customer service

Preferable:

- Knowledge of FDA Requirements, and ISO 13485:2003 standards.
- 3-7 years medical device experience.

2. *Skills and Abilities*

- Proficient with computer spreadsheets, graphics, PowerPoint and database software.
- Highly proficient in Excel.
- Must have verbal and written communication skills, and be effective and comfortable working individually or in a team environment.
- Good organizational and problem-solving skills.
- Strong attention to detail, organizational and follow-up skills.
- Multitasks, prioritizes and meets deadlines in a timely manner.
- Proficient with Microsoft Office and accounting applications.
- Ability to learn and use corporate computer systems.

3. *Physical Demands/Work Environment*

Normal office environment, heavy PC usage;

Working Relationships:

1. *Internal Contacts*

All departments

2. *External Contacts*

Interface with consultants, agents, customers and sales. Provide and solicit information relating to all aspects of medical device regulatory compliance.