Medical Device Quality Engineering Technician

Job Description

Responsibilities

GENERAL

Include but are not limited to the following:

- Follows all Clean Room gowning and cleaning procedures and reports any discrepancies immediately to supervision.
- Follows all Standard Operating Procedures (SOPs).
- Ensures enforcement and compliance to Aptar CSP's Quality Management System in accordance with regulatory, legal and business requirements as well as adherence to Customer Specific Requirements.
- Demonstrates excellent verbal and written communication skills.
- Willingness and drive to do what it takes to get the job done.

JOB-SPECIFIC

Include but are not limited to the following:

- Works closely with Site QA Management, engineering and the Quality System Specialist on all Quality Control activities, including but not limited to the inspection of incoming, in-process materials and final product; initiation of deviations and nonconforming material reports, as required; and the execution of the environmental monitoring program.
- Inspects, measures and tests incoming, in process, and finished product to ensure they meet all standards and pre-determined specifications.
- Upon identification of an issue, initiates or communicates the non-conformance; provides feedback to QA, Operations or the appropriate personnel; and preliminarily troubleshoots product or process performance deficiencies, as required.
- Works closely with quality and manufacturing engineering. Assists, appropriately, during the coordination and execution of validation and/or qualification activities; completion of measurement systems analysis (MSA), and/or during any other areas where technical resources are required.
- Participates in failure investigations and CAPA resolution planning, and works with Site QA, and engineering personnel in the deployment of standard problem solving techniques to provide timely feedback to regarding repeat errors and program quality issues.
- Works with Site QA personnel in the coordination, review, and release of all production batch record by helping to ensure compliance to product and process specifications, good documentation practices, SOP's and cGMP's and any other requirements.