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## **Director of Quality Assurance**

The Director of Quality Assurance is responsible for overseeing the Quality Assurance Department, including developing and managing the team. This position is directly responsible for the implementation and execution of Sientra's Quality System. The Director of Quality Assurance drives the company's compliance with global quality system regulations and requirements.

### **Requirements**

- Implement a quality management software system.
- Manage the complaint process and ensure complaints are promptly and thoroughly evaluated, closed, and corrective action is implemented where necessary.
- Manage the CAPA process and ensure all non-conformances and corrective/preventive actions are implemented and documented appropriately.
- Manage the document control process and ensure employees and contractors are trained on applicable SOPs and policies.
- Write, approve and/or implement changes to controlled documents (e.g. SOPS, Specifications, Methods, etc.).
- Maintain accurate databases for complaints, CAPAs, nonconformities, document control, device tracking, etc. Establish Quality System metrics and monitor trends.
- Develop and administer Quality System training programs.
- Direct the Supplier qualification and auditing program, including oversight and auditing of the company's contract manufacturer.
- Conduct Management Reviews and Internal Audits.
- Interface with FDA and other regulatory bodies as required for Quality System compliance.
- Monitor evolving regulations, guidelines and standards, interpret relevant information and take appropriate actions to inform and educate stakeholders and revise Sientra Quality system processes as necessary.
- Supervise the QA Team and manage the budget for the QA Department.
- Initiate the development of continuously improved QA Department systems and processes.
- Identify resource needs and develop personnel resources to facilitate more efficient management of quality operations and maintenance of regulatory compliance.
- Other duties may be assigned.

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