



Job Title:	Quality Engineer	FLSA Status:	Exempt
Reports to:	Quality Engineering Manager	Location:	Escondido

Job Summary:

Responsible for evaluating, establishing and implementing quality requirements for products and processes used to manufacture Zest Dental Solutions devices. Additional responsibility can include maintenance of all inspection requirements, inspection programs, and inspection equipment.

Essential Job Duties and Responsibilities:

- Initiate and implement programs aimed at improving the quality of operations and reducing the total cost of quality.
- Develop quality plans, inspection processes, and sampling procedures. This includes validation of inspection methods and equipment and various gage R&R studies, as required.
- Assist in the upkeep of inspection equipment including development of new inspection programs for automated equipment and equipment maintenance.
- Design or procure fixtures used for testing and inspection purposes.
- Provide training to Quality Control and Operations personnel on inspection methods and techniques.
- Support external suppliers through collaboration and establishment of agreed upon inspection methods and equipment requirements.
- Support Quality Control in the MRB process with critical analyses and by offering potential disposition options as needed.
- Job duties are not limited to the areas of responsibility listed above. Specific responsibilities may be modified and additional responsibilities may be assigned which are in line with the job summary at the discretion of company management.

Education, Experience, Skills, & Abilities:

- Bachelor's degree in Engineering is required, 1-3+ years of experience in Medical Device other regulated industry serving, preferably in Quality.
- Have a working knowledge of the FDA Quality System Regulations and Design Control Requirements.
- Have a working knowledge of 21 CFR 820 (Quality System Regulation for Medical Devices), ISO 13485 (Quality Management Systems – Requirements for Regulatory Purposes), and ISO 14971 (Medical Devices – Application of risk management to medical devices).
- Experience working in a machine shop environment is highly preferred.
- Ability to communicate and interact with senior leadership, produce and deliver presentations to a wide range of audiences.
- Strong problem solving, critical thinking, analytical skills, organization and professionalism. Experience in the use of root cause analysis tools.
- Ability to prioritize and plan effectively.
- Highly motivated with demonstrated ability to work independently with minimal supervision.
- Demonstrated/practical application of Statistical methods, quality tools, and methodologies.



- Able to read and understand mechanical drawings using ASME Y14.5.
- Proficient with statistical analysis tools (Minitab or JMP), and high level skills working with Microsoft Excel, Microsoft Word and Microsoft PowerPoint.
- ISO auditing experience is a plus.
- Lean, Six Sigma Green or Six Sigma Black Belt Certification desirable.
- ASQ Certification is a plus.

Physical Requirements:

- Ability to sit, use hands and fingers, talk or hear, and smell continually. Ability to stand, walk and reach frequently. Ability to climb or balance, stoop, kneel, or crouch occasionally.
- Ability to frequently lift and carry up to 10 lbs. and occasionally lift and carry up to 25 lbs.
- Close vision required to inspect parts, see computer monitor, read documents, and operate copy and fax machine. Distance vision required to drive an automobile, if driving is a requirement of the job.
- Work environment is indoors and climate controlled. Occasionally exposed to outdoor weather conditions.
- Moderate noise levels as found in a business office with computer printers, households with TVs and dishwashers, and driving light traffic.

Employee Acknowledgement:

The above job description is intended to describe the content of and requirements for the performance of this job. It is not to be construed as an exhaustive statement of duties, responsibilities, or requirements. Zest Dental Solutions reserves the right to change, add, or delete at any time from this job description to meet the needs of the Company.

Employee Name – Printed

Date

Employee Signature