Quality Policy

At LumaDent, our commitment to quality and excellence is fundamental to our mission of enhancing precession and efficiency of dental professionals world wide. We are dedicated to designing, manufacturing, and distributing innovative products that meet the highest standards of our customers and comply with all regulatory requirements. Our Quality Policy is built on the following principles:

- **Customer Focus:** We listen to our customers and integrate their feedback into continuous product and service improvement.
- **Excellence in Quality:** Through rigorous designing, testing, and reviewing. We strive to create the highest quality products.
- <u>Regulatory Compliance</u>: We commit to meeting all applicable regulatory requirements, including maintaining the effectiveness of the Quality management System (per ISO 13485), to ensure our products are safe and effective for their intended use.
- <u>Continual Improvement</u>: We commit to the ongoing improvement of all aspects of our Quality Management System (per ISO 9001).
- <u>Employee Engagement and Wellbeing</u>: We recognize that our employees are vital to the quality goals. We are committed to providing a supportive environment which fosters collaboration, innovation, and professional development.

Management Commitment:

Our Leadership is committed to the dissemination and maintenance of this policy across all levels of the company. We ensure that this policy is regularly reviewed and aligned with our strategic goals and industry standards.

What is a Quality Policy?

Company Lens

A document developed by management to express the directive of the top management with respect to quality.

Manage. Commitment

"Our Leadership is committed to the dissemination and maintenance of this policy across all levels of the company. We ensure that this policy is regularly reviewed and aligned with our strategic goals and industry standards."

Employee Lens

Each employee contributes to the policy, how does their job function relate.

5 Keys to the Quality Policy

Key 1	Key 2	Key 3	Key 4	Key 5
Customer Focus - Listening to customers, integrating feedback - CAPA & Customer related procedures	Excellence in Quality - Design, Testing, and reviewing -Engineering & Product Realization -ISO Section 7	Regulatory Compliance - All QMS managers and Quality Manager -ISO Section 8	Continual Improvement -QMS Managers -ISO Section 5	Employee Engagement & well being -All Managers -ISO 9001 -ISO Section 6

What Must Your Team Know?



Solutions

(Customer Service)

- 1. *Customer Focus:* first point of contact, listening to their issues and helping to pinpoint issues.
- 2. Continual Improvement: relaying customer issues to management, to improve product design

Sales / Sales Support

- 1. *Customer Focus:* Creating and maintaining strong relationships with customers
- 2. Regulatory Compliance: verifying sales orders.

Marketing

- 1. Continual Improvement: Continuously collects and analyzes market data and customer feedback.
- Customer Focus: understanding customer preference & market trends.

HR

 Employee Wellbeing: all employees, regardless of their department, work in a supportive environment that encourages collaboration, innovation, and professional growth

Engineering

(LumaLab)

- 1. *Excellence in Quality:* Leads the charge in rigorous design, testing, and reviewing processes to ensure that products meet the highest standards of quality and performance.
- 2. Regulatory Compliance: Ensures that product designs meet all applicable regulatory standards.
- Continuously refines product designs and processes based on feedback, testing results, and new technologies, contributing to product and process improvements.

Production

- Excellence in Quality: Implements strict quality control measures during the manufacturing process to maintain consistency and excellence in the final products.
- 2. Regulatory Compliance: Adheres to regulatory standards during manufacturing processes, ensuring that products are safe, effective, and meet industry requirements.

Shipping

- Excellence in Quality: Ensures that products are carefully packaged and shipped, maintaining the integrity and quality of the product upon delivery.
- 2. Regulatory Compliance: Ensures compliance with regulations related to packaging, labeling, and transportation, contributing to the safe delivery of products.

Will have to break it down further for specific roles

How does a production agent (specifically assembling) contribute to the **Quality Policy?**

EX. Excellence in Quality -> Being the assembler I most closely contribute to the excellence in quality. By following the SOPs closely and recording the initial tests (light pictures) to ensure product quality. How does a shipping agent contribute to the quality Policy?

EX. Excellence in Quality -> By packaging the product correctly I am safeguarding it from changes in quality during shipping. How does a Solutions agent contribute to the quality Policy?

EX. Customer Focus -> By listening to the customer and writing down their issues, then relaying that to management.

Thank You!

Any More Questions?