NOVATEOR RESEARCH LABORATORIES LIMITED
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QUALITY MANUAL

1. CONTENT:

Our quality manual includes policies for all the areas of the business that affect company's ability to make high-quality products and meet our customers' and FDCA's requirements. These policies define procedures in the Quality Manual as follows:

- To communicate management's expectations to employees
- To demonstrate the company's plan to conform to the requirements of FDCA regulations.
- To demonstrate the fulfilment of organizational roles, responsibilities and authorities are assigned, communicated and understood.
- To provide a starting point for quality supervisors for the raw material, processes and the finished product:

    - Internal
    - External Analytical Laboratory.
    - End Users Feedback and surveys for internal quality purpose

2. MISSION:

Our mission is to strive relentlessly through incessant research and innovation by delivering exceptional performance in oral health care domain.

3. VISION:

Becoming an organization with strong ethics laid at a foundation that all its employees and associates are proud of.

4. SCOPE OF ORGANIZATION:

Design, Research and Develop innovative Oral health care products and create a brand value in the industry.

QUALITY POLICY: Novateor Research Laboratories Ltd. is committed to deliver quality products, in time possession, which meets and exceeds the needs & expectations of our customers. We promise our valued customer's commitment to excellence in each activity by each employee in the organization by adopting

innovative with continual improvement in business and quality management system as a part of our efforts for enhancement in customer satisfaction while assuring 100% quality and quantity.

KEY OBJECTIVES:

- Timely completion of orders.
- Increase customer satisfaction.
- Address customer complaint.

5. QUALITY DOCUMENTS:

Sr. No.	List of Documents
1	Research and Design
2	Approved Raw material Suppliers
3	MSDS of Raw Materials
4	Manufacturing Process SOP
5	Equipment Cleaning SOP
6	Finished Product Specification
7	Internal Quality Inspections / Quality Assurance
8	Marketing
9	HR- Employee Screening and Background checks
10	Distributors Screening Process
11	MRM- Management Review meeting every Quarter
12	Statutory & Regulatory Body – Complying with the statutory and regulatory requirements as defined from time to time

6. CONTEXT OF ORGANIZATION:

Novateor Research Laboratories Ltd. determines external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system through PEST and SWOT. The external and internal issues identified through PEST and SWOT are continuously being monitored and reviewed by the senior management.

PEST Analysis:

Political Factors and Legal Factors(P)	**Economic Factors (E)**
1. Political instability. 2. Regulatory and Legal requirements.	1. Seeing India as an Emerging Market. 2. Increasing disposable Incomes in Millennial.
Social Factors (S)	**Technology Factors (T)**
1. Increased literacy 2. Awareness for health and hygiene. 3. Increased per capita income	1. Leveraging Digital Marketing in these Pandemic Times.

SWOT Analysis:

Strength (S)	**Weakness**
1. Continuous hunt for Innovation & growth. 2. Strong Research and Development. 3. Targeting Consumer Driven Products	1. Less Awareness 2. Dependent on just Oral Health care Domain.
Opportunity (O)	**Threat (T)**
1. Potential in emerging markets other than India as there are very few manufacturers in the industry. 2. Mergers and Acquisitions.	1. High technology imports 2. Technology leakage 3. Global Competitors.

7. ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES:

Novateor management has ensured that the responsibilities and authorities for relevant roles are assigned communicated and understood within the organization. While assigning roles, responsibility, and authority, top management has considered and ensured that

1. The quality management system conforms to the requirements of the FDCA standards.
2. The processes are delivering their intended outputs
3. Reporting on the performance of the quality management system and on opportunities for improvement, in particular, to top management
4. The promotion of customer focus throughout the organization
5. The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Roles, responsibility and authorities assigned are available in process & as per Organization chart wise

Directors Responsibility:

- Overall Responsibility for formulating and communicating Quality Policy & Quality objectives.
- Formulation of Strategy for continuous up gradation of Business and Quality System.
- Ensure periodic assessment of the performance of Quality System.
- Approval of Quality System Manual.
- Budget Approval for the organization.
- Overall Responsibility for Business Development & all financial issues.
- Provision of resources as required.
- Strategic decisions on developments and technical setups.
- To provide the leadership for efficient implementations of the system.

- Approval of customers' orders, Invoices, P.O. and Cheque.
- Approval of funds for Training needs and marketing.
- Approval of POP designs, Materials and placements.
- Chairing Management review meetings.

- The entire responsibility of Quality.
- Disciplinary actions against the staff.
- Prime responsibility for the safety at the site
- Provision of a suitable working environment
- Ensure the quality system is established, implemented and maintained.

- Appointment of the staff, engineers and tech staff.
- Sanctioning the Leaves to Staff.
- All the authorities of downline personnel.

National Marketing Head:

Managing & motivating the sales force towards the achievement of target.

- Preparation of Sales plan.
- Monthly, Quarterly & Annual sales forecast.
- Implementation of sales plan.
- Authorized to appoint Distributors/ Super stockiest.
- Interview potential Sales Manager and Sales Executives in PAN India.
- Follow up for Primary Sales and Payment.
- Facilitate downline personnel with POP materials and tools to help in the field.
- Train the appointed Downline Personnel after appointment.
- Travel PAN India to Appoint Distributors and Super Stockiest after Extensive background screening.

InCharge – ADMIN (HR/Sales/Purchase/Account) Responsibilities:

- Online Order handling and Shipping.
- Document & Data control system pertaining to his department.
- Help with Supply Chain for the organization.
- Maintain all documents related to the quality system.
- Coordinator for Management reviews.
- Suitable working environment (cleanliness, ventilation, lighting, safety etc.).
- Record maintaining for Purchase Registers, Sales Register, Rent Register, Sale Files, and Stationery and Office equipment, Tax Files etc.
- Archiving and record keeping of old files.
- Payroll Monthly: Salary –To release monthly salary of the employees as per policy finalized.
- Leave – To keep the record of leave as per policy finalized.
- Annual Allowance – To release annual allowances as per policy finalized.
- Employee Record – To update employee details as per organization Policy and QMS.
- To prepare an appointment letter, confirmation letter, experience letter & all employee-related matter as per policy finalized with the help of the Managing Director.

Authorities:

- Approval of customer orders.
- Approval of documents as per the master list of Quality System Document.
- Authorized to decide corrective & preventive action.

Site Supervisor

- Coordinating with all staff for the Quality related issues of Construction.
- Monitoring of Work progress and daily reporting.
- Preparation of work progress report / Quality Documentation.
- Coordination with the Shipping consultant for the daily dispatch requirements.
- Ensuring that the equipments are properly used and cleaned.

8. PLANNING:

Actions to address Risks and Opportunities: Novateor addresses the issues, requirements the risks and opportunities to Give assurance that the quality management system can achieve its intended result(s), to Enhance desirable effects, to prevent, or reduce undesired effects and to Achieve improvement.

9. SUPPORT:

People: Our Company determines and provides to all departments personnel necessary for the effective implementation of its quality management system and for the operation and control of its processes.

Infrastructure: Novateor is determined, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure can include

1. buildings and associated utilities
2. equipment, including hardware and software
3. transportation resources
4. information and communication technology

Communication: Novateor is determined the internal and external communications relevant to the quality management system, including

1. On what it will communicate
2. When to communicate
3. With whom to communicate
4. How to communicate
5. Who to Communicate

10. STORAGE AND INVENTORY

A suitable inventory control system is established to optimize inventory turns, assure stock rotation & minimize inventory levels. Stores Section shall monitor stock levels and inform the purchase section in time & FIFO is emphasized.

Packaging: The packaging of products carried out according to packaging instructions/drawings wherever applicable, i.e., contractually agreed or if product nature calls for packing. Type of packaging material & its quality is ensured as per customer requirements if mentioned in the purchase order. Material/packages used for the packing of products are verified before packing to ensure its conformance to specified requirements as per Purchase Order/ Customer Requirement. The packing method employed will be adequate to protect the products fully till they reach their destination if contractually specified.

Finished Products: Finished products are handled carefully so as to protect them from any kind of damage and kept in Finished goods area is the duly cleaned condition.

Delivery: The product quality is protected after final inspection & testing and wherever contractually specified extended from delivery to destination. The deliveries of products are done as per contract terms/delivery schedules for the customer.

11. MANAGEMENT REVIEW

Top management of Our Company is reviewing the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization. Management review is conducted and chaired by MD quarterly to ensure continuing suitability & effectiveness in satisfying the requirements of the stated quality policy and objectives.

The Management Review includes all elements of the entire quality system as detailed in the procedure and schedule for the Management Review. The Director during review shall assess opportunities for improvement and the need for changes in the Quality Management System, including the Quality Policy and Quality Objectives.

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