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Rose Medicare Pvt Ltd
203, Prafulla Place,
Govind Mitra Road,
Patna - 800004
Formerly:

GST: 10AABCR2703B1ZF
Drug Licence No: 01/01A/2017
Tel: 0612- 230 3103/3182/1922
Email: jain@rosemedicare.com
Website: www.rosemedicare.com
Jain International
(A Unit of Rose Medicare Pvt Ltd)

ROSE MEDICARE PVT. LTD

QUALITY MANUAL

ADDRESS: ROSE MEDICARE PVT. LTD.
203, PRAFULLA PLACE
GOVIND MITRA ROAD
PATNA
BIHAR - 800004

E-mail: jain@rosemedicare.com, office@rosemedicare.com

Phone No. – 9334266374

APPROVED BY : MANOJ KUMAR SETHIA
APPROVED ON :06-01-2020
LAST REVISED ON: 05-05-2022

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QUALITY MANUAL (QM/RMPL)
COMPANY PROFILE

Rose Medicare Pvt Ltd located at 203, Prafulla Place, Opposite Mahima Place, Govind Mitra Road, Patna- 800004; is a leading established organization in the field of Diagnostics Specialties, Diagnostic Equipments, Point of Care Products, Research Products, Blood Bank Equipments, Cyto Toxic Drugs and branded Pharmaceutical Formulations.

The company has been operational under the name of **Jain International (A Unit of Rose Medicare Pvt Ltd)** , the name of the Business is now changed to Rose Medicare Pvt Ltd.

Our major Principals include companies of multination origin & national repute, which are leaders & trend –setters in their own respective areas which are:

- Beckman Coulter
- Qiagen
- Thermo Fisher
- Alere
- Diasys
- Cpc Diagnostics
- Labomed
- Biorad
- Himedia
- Tosoh
- Roche
- Tarsons
- Fresenius Kabi
- Waters
- Leica Biosystems
- Hemocue
- Remi
- Etc….

Our Customer/user segments consist of major Super Specialty Hospitals & Specialty Hospitals, Diagnostics Centers in the area of Laboratory Medicine, Radiology & Imaging, Nursing Homes, Large Public Sector as well as Private Sector Hospitals, Research Centers & Various other agencies fully or partially under Govt. Control, such as:

- Indira Gandhi Institute of Medical Sciences
- Mahavir Vatsalya Aspatal
- SRL Diagnostics
- Bihar Medical Services and Infrastructure Corporation Ltd
- Central University of Bihar
- Patna Medical College and Hospital
- Mahavir Cancer Sansthan
- Paras HMRI Hospitals
- Rajendra Memorial Institute of Medical Science
- Sen Diagnostics Pvt Ltd
- Mahavir Aarogya Sansthan
- Liverpool School of Tropical Medicine etc…

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Established on 08th June, 1983; this organization has grown over the years and today a name to reckon with in terms of following Special features:

1. Adequate trained & experienced Human Resources backed up by automation facility.

2. Highly organized storage system to handle temperature sensitive products by way of having 3 Walk-In-Coolers, operating round the clock throughout the year.

3. Organized marketing set up.

4. Availability of technical support staff exposed & trained to handle Semi-automated equipments & supplies.

5. Organization opens to training modules for staff members for exclusive focus.

6. Availability of technical experienced consultants in the field of marketing and hospital/healthcare management.

7. Well organized logistic & financial management system.

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QUALITY MANUAL (QM/RMPL)
QUALITY POLICY

1. Rose Medicare Pvt. Ltd, Established in 1982 thrives fully on the policy of Quality.

2. Quality has been and shall be the Key Guiding force in every aspect of its activities, i.e. : Selection of Principal Companies, Product Range, Identification, Sort listing and selection of Customer Points/ accounts, Total Turnaround Time, Internal Logistics and Distribution preceded by transit systems, Financial Control, Taxation System Adherence and also in the areas of HR Management.

3. Quality shall be the underlying process compliance methodology in terms of Human Resource Management within the Internal Organizational System.

4. Quality orientation in terms of process formulation shall/ is be the benchmark in terms of customer grievances and objection handling.

5. QUALITY shall be the main Keyword for denoting the identity of Rose Medicare Pvt Ltd.

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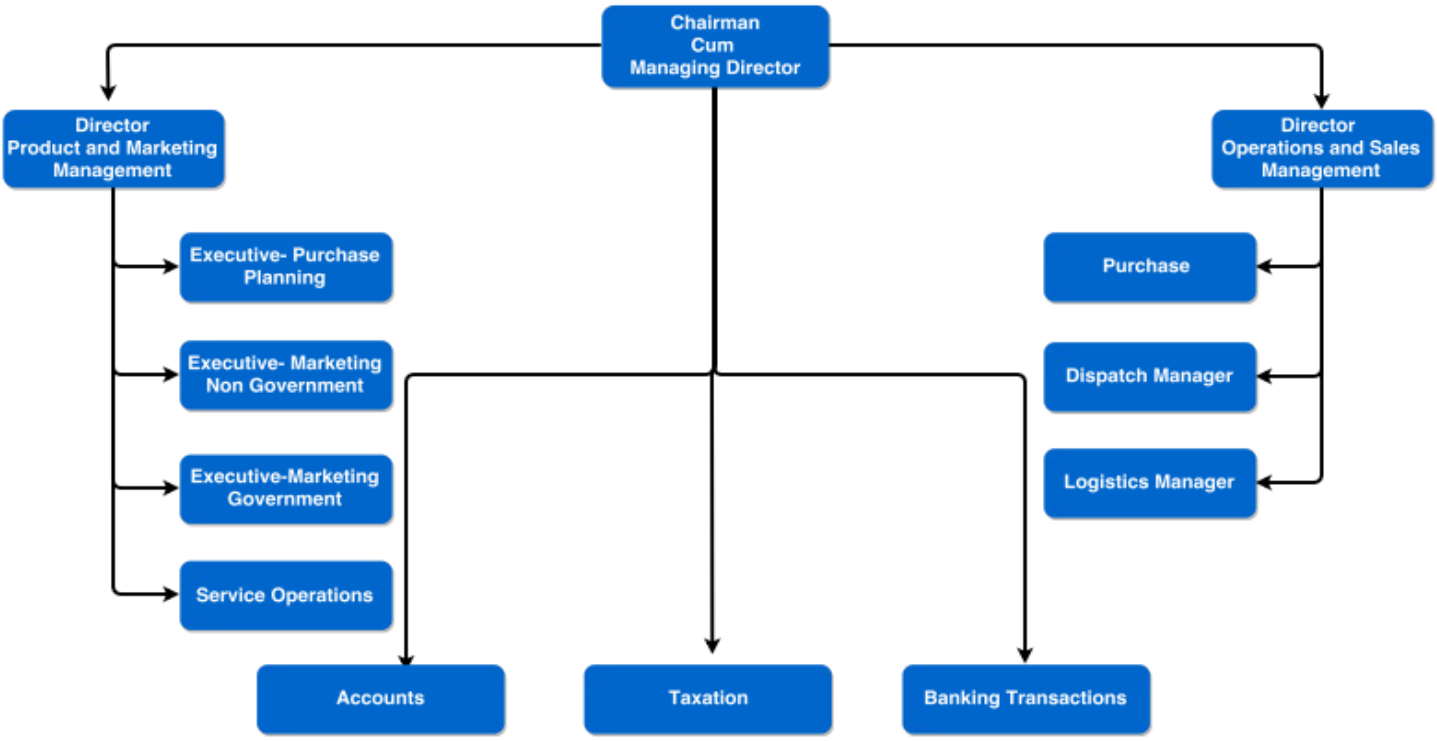
QUALITY MANUAL (QM/RMPL)
ORGANISATIONAL CHART



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The above Quality Policies are finalized with the active participation of all respective functional heads in the Organization and after approval of the Directors.

The Quality policy is implemented through Measurable Quality Objectives. Measurable Quality Objectives are used for continual improvement of processes needed by QMS.

Communicating the Quality Policy:

The Quality Policy is communicated to employees and those working on behalf of the
Organization through display boards, periodic meeting and internal discussions.

DIRECTORS ensure understanding and application of the quality policy by the employees and others in their own work area through internal audits. Quality policy is made available to the interested parties by display in all prominent places of the organisation.

A copy of the documented Quality Policy can be sent to the Clients, Suppliers and other interested parties on request.

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QUALITY MANUAL (QM/RMPL)
ORGANISATIONAL ROLES AND RESPONSIBILITIES

Purpose:

To ensure that responsibilities and authority for relevant roles are documented, assigned, communicated, and understood by the employees at different levels within the Organization.

Scope:

Roles, Responsibilities and Authority of all employees of RMPL, at different levels, including Management Representative and Departmental / Functional Coordinators.

Responsibilities: Director, Management Representative, Departmental/ Functional Coordinators

System:

It is ensured by top management to determine, assign and communicate the responsibilities and authority to all relevant roles of the organization. It also ensured that these details are understood by all concerned. The roles and responsibilities of process coordinators are given below and for all others the information please refers to various departmental procedures...

Director appointed, Mr. Siddharth Kuhar, Management representative in addition to his normal duties.
The Management representative is assigned with following responsibilities and authority.

- Ensuring that the quality management system conforms to this international standards
- Ensuring that the implementation of processes is resulting in, delivering outputs as planned and expected
- Reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management.
- Ensuring the promotion of customer focus throughout the organization
- Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
- Mgt. Rep. ensures that risk based thinking is addressed throughout the organization, to identify risks and opportunities in all processes.

- He also ensures measurable quality objectives are established and all departments are guided to plan to achieve the objectives set by them
- Mgt. Rep. ensures that internal audits are conducted well in time as planned and management reviews are also planned and carried out at regular intervals.

Directors ensured the responsibility and authority for all identified roles in RMPL, PATNA (BIHAR) as mentioned below:

Functional Head, Establishment (Admin and HR)
The Dept provides resources to the organization, to send the employees to the training programmers' and reviews the employee's output vis-a-viss training inputs, To create awareness on the Government of India rules and the Quality Management Systems to streamline the day to day working and to maintain the essential records.
Reports to Director, RMPL.

HOD, Purchase Deptt(major functions of the purchase deptt.)

Receiving of enquires, preparation/ compiling of quotations, placing purchase orders, receiving stocks, storing stocks properly, issuing stock as per indent, Inventory accounting, physical verification of stock/ stock taking, preparing for stock invoicing and dispatch against purchase orders from customers.

HOD, Accounts (Major accounting functions)

Maintaining, controlling and monitoring all activities pertaining to finance and accounts. Obtaining all budget and reports as needed for being forwarded to Directors to facilitate Decision making

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QUALITY MANUAL (QM/RMPL)
PLANNING

Purpose:

To ensure that Quality Objectives are established at relevant functional levels and processes needed for QMS (Quality Management system)

Scope:

Establishment of /Establishing Quality Objectives and planning of changes to QMS, with a view to implement management by objectives (MBO)

Responsibilities:

Director
Heads of all Departments
Departmental Coordinators

System:

Quality Objectives and planning to achieve them:

- Each functional head ensures quality objectives are established and implemented at all functional, levels and processes of their areas and ensures transfers of data at periodic intervals (by annually) to thye concerned Directors / Mgt. Rep.
- Director Consolidate Quality Objectives from each function and prepare/ prepares organizational objectives.

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QUALITY MANUAL (QM/RMPL)
SUPPORT RESOURCE

Resources: Man power/ Human resource, Environment

Purpose:
To determine and provide the resources needed for establishment, implementation, and continual improvement of QMS including monitoring and measuring resources and their organizational knowledge.

Scope:
The scope of QMS includes Quality Management System requirements implemented in the Establishment section of the organization.

Responsibilities:
Management Representation (Mgt. Rep.) HODs and Departmental Coordinators Director System:
The responsibilities of Directors include consideration of the existing capabilities, constraints and internal resources and determines what more has to be obtained from the external environment.

Manpower / no of employees required for maintaining operations of the organization, should be as per Sanctions of the directors from time to time. Recruitment under taken by the HRD section from time to time with information to top management from time to time.

Work environment within the organisation is aimed at be being maintained as Quite,Comfortable, Conginion and Productive.
The management aims at providing a satisfactory work environment through:

- Good House Keeping.
- Adequate Lighting
- Adequate Ventilation
- Acceptable Noise levels
- Refreshment area.

Also safety, security, aspects are taken care of by providing :

- Medical facilities.
- Provision of Fire safety System.
- Adequate Security
- First aid kits.
- Pest Control operations

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Infrastructure:

Organisation has provided the infrastructure needed to achieve conformity of all the Services provided and cater to requirements of all other processes. These are as under:

- Building, Work places and associated utilities.
- Proper Maintenance
- Support Services
  - Telephone / EAPBX
  - Computerization and associated ancillary attachments

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QUALITY MANUAL (QM/RMPL)
CODE OF CONDUCT/ WORK ETHICS BENCHMARKS

We are committed to and for providing Genuine Value Adition to our customers. We are guided by our core values of Integrity, Quality, Innovation and commitment through performance and expect the same/ similar values from all our Principals and vendors

Child Labour
We do not engage in or support the use of child labour. Suppliers are expected to comply with the applicable child labour laws. Suppliers should employ only workers who meet the applicable minimum legal age requirement for their respective locations.

Forced Labour
We do not engage in or support the use of Forced or Involuntary labour. We do not purchase material or services from a supplier utilizing forced or involuntary labour.

Working hours
Employees are expected to comply with their working hours and should ensure discipline regarding the same.

Discrimination
Employees are expected to not discriminate with other employees and should respect each and everyone.

Environment
We believe in being an eco-friendly enterprise and conduct operations in compliance with applicable laws and regulations. Employees shall conduct their operations in a way that protects the environment and are also expected to comply with all applicable environmental laws and regulations of the State and Central Governments.

Health & Safety
The organization is committed to the health and safety of its human resources and conducts its operations in compliance with the applicable laws and regulations. The organization aims to provide a working environment that supports accident prevention and minimizes exposures to health risks nad hazards.

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Compliance to Trade Laws

The organization is committed to comply with the applicable laws concerning proprietary, confidential and personal information. Employees are expected to comply/ follow with/ follow the applicable laws and regulations governing the protection of the organization proprietary rights, confidential and personal information.

The organization shall comply with the requirements of the Drugs Control Department, GST and other statutory requirements.

QUALITY MANUAL (QM/RMPL)
CUSTOMER ORDER PROCESSING

Stage 1 – Receiving the customer's order

The first stage of our customer order management process begins when a customer places an order. After accepting the order from the customer the order is entered in our operating system/ software as " Sales Order" . Hereafter it is converted to a Delivery Challan, Subsequently in the form of an Invoice as needed to facilitate the entire process.

Stage 2 – Fulfilling the customer's order

In the second stage, we actually fulfill customer's order. This stage can be further sub divided into 3 different sub stages:

Step 1 – Pickup

Fulfilling an order starts with the picking process, in which the items are retrieved/ picked up from the warehouse.Ou warehouse consists of properly arranged in shelves, which are stocked with different types of products.Our warehouse staffpicks up the appropriatematerial against an order being processed. Once the material has been picked, it is sent to a packing area for being packed under proper transit conditions.

Step 2 – Packing

The packing area has more responsibilities than just packing items and sending them off for shipping. The involved in the packing area are also in charge of using the right packaging materials for each product so that it reaches the customer in an intact manner and in good condition. It is expected of the packing staff that function diligently with decication and sincerity, so as to incur minimal mistakes.For example, extremely fragile items like glassware and plasticware items where the probability of transit damage is high, in such cases the packaging staff should use the bubble wrap/ air pillow material to ensure transit safety and damage free delivery. Items which are temperature sensitive need to be properly packed with adequate temperature sensitive material in Thermocol/ Insulated Boxes. There should be a Minimum of 6 ICE Pack in a box and should be increased by 1 Ice Pack on adding each Kit.

Step 3 – Shipping and Transportation

After the material has been picked , invoiced, processed and packed; the material is ready for shipment ad transportationt. The warehouse staff working at the shipping station typically take care of 3 tasks:

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- Attaching the applicable shipping label and invoice to the order
- Marking the order as shipped in all documents concerning the sales channels
- Sending out shipping confirmation and order tracking emails/Whatsapp to the customer with all relevant documentary information.

QUALITY MANUAL (QM/RMPL)
PROCESSING THE INCOMING MATERIAL

Upon receipt and before acceptance in the premises, instrument,reagent and consumables are inspected visually in order to check the identification, container damage (if any), broken seals and evidence of tampering and shortage, contamination. Materials should be held/ kept under quarantine according to their required temperature if any nonconforming products are found.

And if the inspection is cleared and then as per temperature requirement mentioned in the packaging the product is stored in its respective place.

WALK-IN-COOLER/ REFRIGERATION INSPECTION

- Temperature levels of the WALK-IN-COOLER and Refrigerator are maintained in the Data Logger regularly.

- Cold Room and Refrigerators are maintained / serviced at regular intervals
- There shall be defined intervals for checking temperature variations. The equipment used for monitoring such variations shall be checked/ calibrated at suitable predetermined periodic intervals and the results of such checks shall be recorded retained and informed to the Mgt. Rep.

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- Internal warehouse conditions are regularly monitored for controlling the temperature and humidity levels.
- Quarantined components and materials are monitored according to the Warehousing policies, Procedure and pratices and the logbooks associated with the quarantine area.
- All the items are placed according to their respective location.
- Storage areas shall be suitably secured, structurally sound and be of sufficient capacity to allow for the safe storage and handling.
- Precautions shall be taken to prevent unauthorized persons from entering storage areas.
- Segregated areas shall be designated for storage of the pharmaceutical products chemotherapeutical formulations in quarantine and for storage of released, rejected, returned or recalled products as well as those suspected to be spurious.
- Premises and storage areas shall be cleaned, disinfected and sanitized regularly.
- There shall be appropriately identified areas with adequate segregation for storage of quarantined, rejected, expired, recalled or returned products to prevent unintentional or unauthorized use of such products.
- Equipment used for monitoring room temperature levels of storage conditions shall also be calibrated at defined intervals.
- Batch number and expiry date of pharmaceutical and diagnostics products shall be recorded at the point of receipt to facilitate traceability and the inventory control system shall be based on the First In First Out system(FIFO) .

QUALITY MANUAL (QM/RMPL)
INVENTORY

- Identification, Special Handling, Labeling and Segregation are part of inventory processes prior to being released for distribution.
- Any non-conforming materials which are identified, is immediately labeled quarantined and segregated to prevent distribution of the wrong material. There are written procedures which describe the handling of non-conforming materials.
- When applicable, traceability to a supplier's lot number or material identification number is established at the time of product receipt or during receiving inspection, and maintained.
- Regular Stock Audit is carried oute every 6 months and corrective action is taken in case of any discrepancies.

CORRECTIVE AND PREVENTIVE ACTION for NON CONFIRMING PRODUCTS

If during receipt and inspection of product, or inspection prior to shipment to the customer, the product is determined to not conform to customer specifications or requirements, then the product is tagged as "Non-conforming" and separated from the conforming inventory. We have to deal with the non-conforming product by one or more of the following ways:

- By taking action to eliminate the detected conformity
- By authorizing its use, release or acceptance under concession by a relevant a designated authority and, where applicable, by the customer
- By taking action to preclude its original intended use or application
- By taking action appropriate to the effects, or potential effects, of the nonconformity when non-conforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subjected to re-verification to demonstrate conformity to the requirements. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

If there is any Notification received from company/ Supplier regarding Stop Shipment / Product Call back. This needs to be immediately processed through the following way:

1. Check Warehouse for the Batch No and Mark it and remove it from Saleable area
2. To Inform customers to stop using the particular batch and recover the same product at the earliest.
3. To coordinate with Supplier regarding further course of action.

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QUALITY MANUAL (QM/RMPL)
SALES

Our marketing team first identifies the target customer, after identifying the target customer they identify their needs and desires and after all the this they try to customize a solution according to their needs and technically discuss with the customer regarding sales.

Steps of Sales are as follows:

1. Identify Target Customer/ Segments.
2. Identify their needs, wants and desires faced in their day to day running of the Laboratory.
3. Design a solution for the customer this may include but not limited to:
    a. A new instrument according to their workload.
    b. To provide them reagents/ consumables/ Quality control servicesto improve overall lab performance.
4. Present a solution package to the customer which will help them to solve their problem.
5. Never give any false expectation/ commitment to the customer.
6. Close your sales