extra PHARMA CO.,LTD.

GOOD DISTRIBUTION PRACTICES QUALITY ASSURANCE GUIDELINES

QUALITY POLICY

INTRODUCTION

The purpose of this manual is to document the company's quality system, to instruct and guide employees whose actions affect product quality and to inform the company's customers what controls are implemented to assure product quality and good distribution practices applied.

The Quality Policy of Extrapharma for drugs and medical appliances is based on customer satisfaction. We strive for continuous improvement in our quality systems and meeting the objectives of our company:

- Supplying products that meet or exceed our customer's requirements
- Providing a service that results in customer satisfaction
- Continuous development of a dependable vendor base

We are committed to continuous improvement in quality and the assessment of the quality system to assure its suitability to meet the requirements of our company and the requirements of our customers.

By meeting our objectives defined within this manual we will be able to:

1. Provide defect free products.
2. Provide customer satisfaction by providing:
   a) On time deliveries.
   b) All contract requirements are met.
   c) Exceptional product quality.
   d) Exceptional service quality.
3. Assist vendors and work with subcontractors to reduce late deliveries and delivery of defective product.

GDP-Quality Assurance Manual

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1.0 STATEMENT OF OBJECTIVE

1.1 The Objective of Extrapharma for drugs and medical appliances is to clearly define the procedures and responsibilities of a total quality assurance program with the ultimate goal being to provide our valued customers with a precision part or product that will meet or exceed their individual specifications or requirements.

1.2 Provide detailed procedures required to accomplish uniform quality assurance for this company's parts or products.

1.3 Furnish general-purpose information useful in the administration of quality assurance activities.

1.4 Any product supplied by Extrapharma for drugs and medical appliances under contract shall be manufactured under appropriate institutes' and societies' specifications or their supplemental specifications and shall be subject to the quality control standards outlined therein.

1.5 A Copy of this manual will be issued to all department managers, sales representatives and manufacturers for Extrapharma for drugs and medical appliances as a required reference.

1.6 A copy of the Extrapharma for drugs and medical appliances Quality Manual is available to qualified personnel upon request.

1.7 Revisions to our policy will be issued when deemed necessary and shall be recorded and authorized on the revision notice page of this manual. Revisions shall be numbered, dated and indicate sections and paragraphs revised.

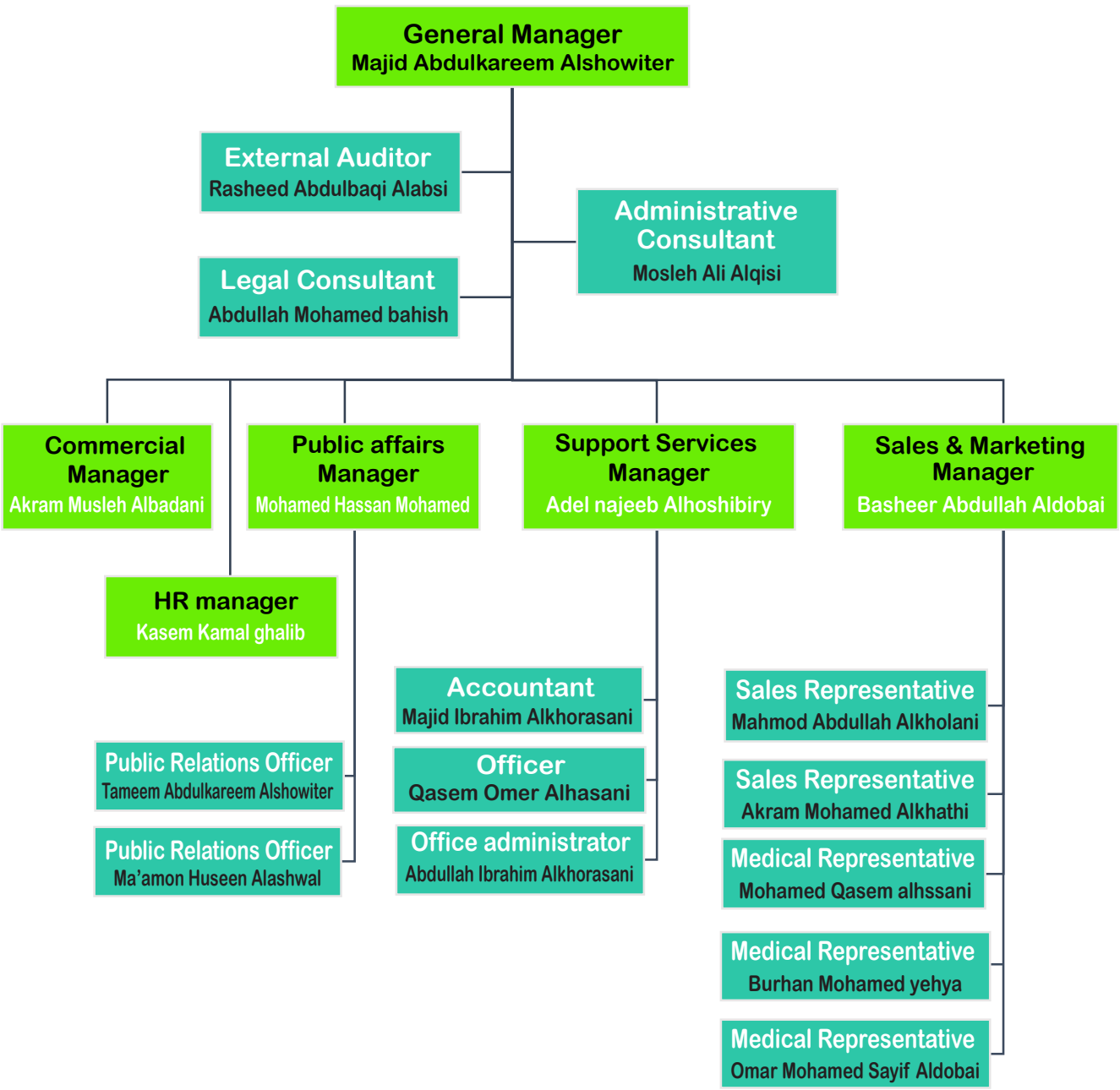
2.0 AUTHORITY FOR IMPLEMENTATION

2.1 The general management of Extrapharma for drugs and medical appliances authorize the policies and procedures contained in this Quality Assurance Manual.

2.2 The General Manager and Operations Manager delegates to the sales supervisors the authority to establish, document and administer the necessary guidelines, requirements and controls to effectively implement the statement of Objective.

2.3 The Sales Supervisor shall have the responsibility and authority to assume compliance to this manual.

3.0 ORGANIZATIONAL STRUCTURE



4.0 SALES RESPONSIBILITY

4.1 The correct interpretation of customer needs and specifications, whether verbal or written, cannot be overemphasized. The sales order is the foundation for the complex chain of events leading up to shipment of a finished quality product.

4.2 All sales orders and specifications must be routed through the General Managers office for approval. The General Manager will require written customer acceptance of particular specifications prior to a sales order being finalized for all first time orders and parts. The purpose of the contract review is to verify that the customer's requirements are adequately defined and documented and have been understood.

4.3 On all first time orders customers will be required to fill out Part Information Sheets that details all critical information for that part such as tolerance, radius, finish, packaging and any other pertinent facts. These sheets will be kept on file and all orders will be made according to that information. That information will be reviewed with the customer upon acceptance of each order thereafter.

4.4 Upon acceptance of a sales order, delivery will be based on current backlog and materials availability. The Production Manager shall be consulted regarding unusual customer requests and/or specifications before a delivery date is scheduled.

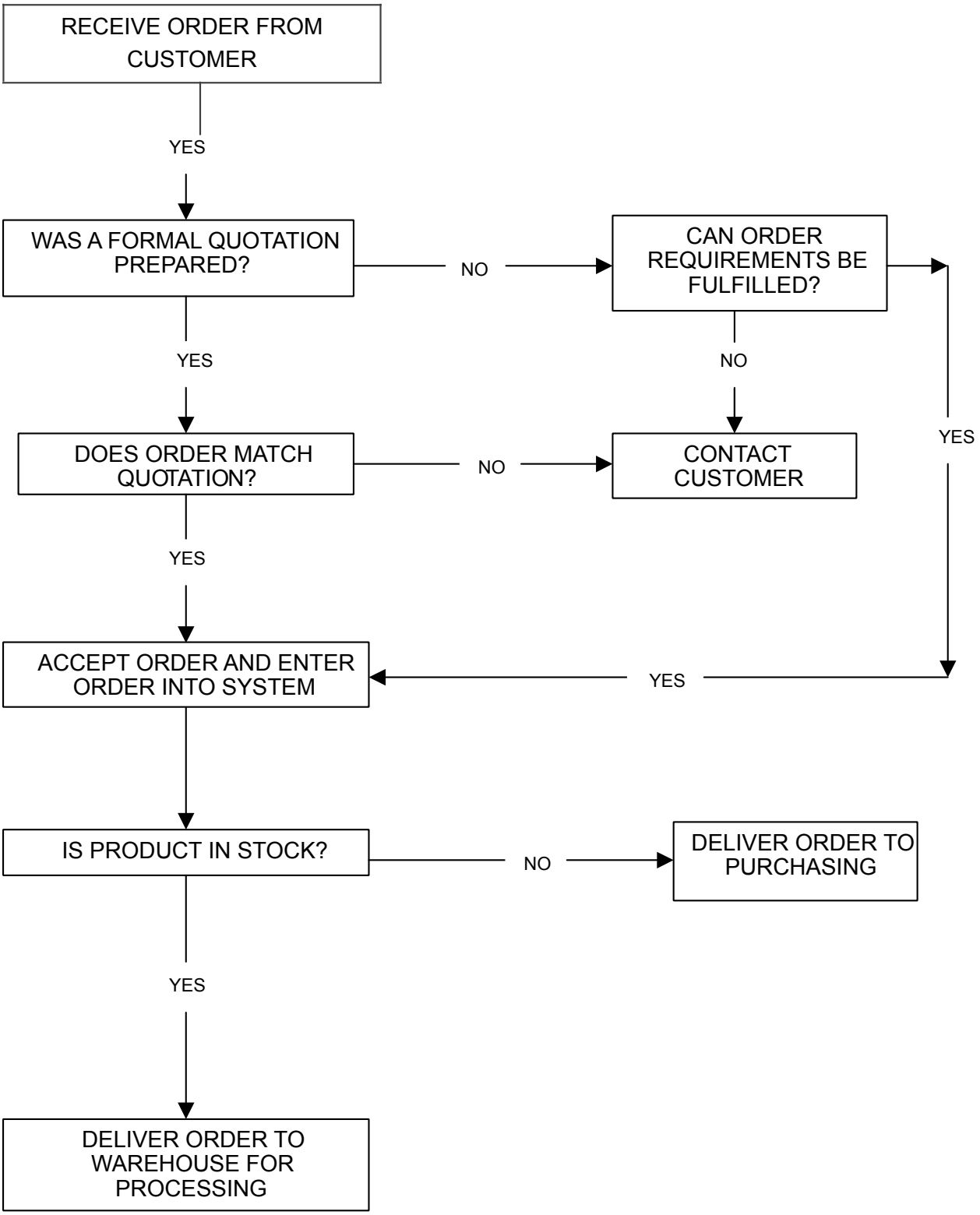
4.5 Upon acceptance of the purchase order based on the information above, samples will be provided for all first time parts. These samples will need written acceptance confirmation by the customer prior to the production run.

4.6 Throughout the sales process, customers must be confident that Extrapharma.Co.,Ltd is working hard to provide them assured quality in both a product and a reliable delivery schedule.

4.7 Copies of the sales order, along with other pertinent information are kept on file in the sales office. Records of all review activities are maintained as evidence.

4.8 All products are identified with the actual product batch number or where only a description exists, the company's internal part numbers are assigned by the Sales Department.

5.0 CONTRACT REVIEW AND ORDER ENTRY FLOW CHART



6.0 PURCHASING - SALES DEPARTMENT / MATERIALS MANAGEMENT

6.1 The company assesses its subcontractors and purchases only from those that can satisfy the company's quality requirements. Purchasing documents clearly and completely describes ordered products, including quality requirements.

6.2 The Sales Department prepares all purchasing documents.
The documents clearly and completely describe ordered products. They include precise identification of the products, reference applicable standards and state quality requirements. The General Manager reviews and approves all purchasing documents prior to release.

6.3 The company defines subcontractors as vendors who deliver their standard products, as vendors who design and/ or manufacture products from the company's drawings or specifications, or vendors who perform processing operations.

6.4 All requisitions for materials that require mill certifications or special processes must contain full information as to work order number, part number, applicable specifications and/or requirements necessary.

6.5 Quality performance of all subcontractors is monitored. Those showing inadequate performance are asked to implement corrective actions and are discontinued if there is no improvement or desire to improve.

7.0 RECEIVING INSPECTION

7.1 Copies of all purchase orders, pertinent to Section 6.4 and 6.5 of this manual shall be submitted to the quality control department to determine compliance to the contractual obligations and aid in determining which upcoming inspection functions will be necessary.

7.1 When any employee becomes aware of the arrival of any delivery, he / she is to contact the supervisor immediately. Only the previously mentioned Managers are authorized to sign for the receipt of any incoming product.

7.2 The Manager is to inspect the arriving goods against the associated Purchase Order, Service Order, or other affiliated documents indicating the quantity and criteria of the goods or services ordered.

8.0 IN-PROCESS INSPECTION

8.1 To assure that the proper quality level and all contractual obligations are met, all parts, processes and work-affecting items are subject to inspection.

8.2 It is the Supervisor and warehouses keeper responsibility to establish inspection points wherever and whenever it is necessary to guarantee the Price Extrapharma policy.

8.3 The preparation, maintenance of and compliance with work instructions shall be monitored as a function of the sales Department.

8.4 Any tooling or fixtures being used to produce customer parts is subject to periodic inspection.

8.5 A first part inspection will be performed at every operation outlined on the process sheet or work order as directed by the Sales department Supervisor in conjunction with the Commercial Manager.

8.6 Any parts or material determined to be scrap must be permanently marked and placed in a special holding area(Restricted area) and disposed of as quickly as possible.

9.0 PRE-SHIPMENT INSPECTION

9.1 Prior to the shipment of an order, all customer product will be subjected to pre-shipping inspection on a lot sample basis.

9.2 The medical Representative at sales department will ensure that parts are packaged or palletized properly according to customer requirements and that all outside labels or tags list necessary and pertinent information

9.3 Containers of products are identified by the part number and/or the internal lot control number / manufacturers lot control number prior to shipment or placing into stock.

10.0 MATERIAL REVIEW

10.1 The purpose of the material review is to determine the future use of any nonconforming products or equipment.

10.2 The basis for products review shall be to determine a course of action for the discrepancy in question and the Material Review Board may suggest a corrective action.

10.3 In normal cases the decision would be; use as is, rework, return to vendor or scrap.

10.4 If the discrepancy in question is in violation of a customer requirement the decision of the review board must be approved by the customer and the decision must be in writing.

10.5 Until any such decision is made the parts or material will be on “hold” in a pre-designated area.

10.6 Extrapharma shall not delegate Material Review Board authority to sub-tier suppliers without customer approval.

10.7 Disposition of customer owned parts must be approved by the customer.

11.0 CORRECTIVE AND PREVENTIVE ACTION

11.1 Corrective action is taken to help assure nonconformance are resolved and permanent solutions are implemented. Corrective actions are issued, recorded and verified in accordance with documented procedures.

11.2 Preventive action is taken to assist management in continuous improvement efforts. Preventative actions are issued, recorded and verified in accordance with documented procedures.

11.3 Everyone in the organization is responsible for instituting, monitoring, or requesting corrective / preventive actions. Problems are evaluated for potential impact on production processes, safety, quality, performance, reliability and customer satisfaction. Sources of data and information used in the evaluation may come from failure analysis results, manufacturing operations, or customer feedback.

11.4 Problems are analyzed to determine whether immediate corrective action is required. Action may include purchasing stoppage, shipping hold, stock purge, supplier hold, or product recall. Once immediate control action has been taken, the cause is analyzed to determine required corrective action. Short-term corrective actions may include customer notification, rework, or product screening. Long-

term corrective actions may include product redesign or production process revision.

11.5 After the cause of the problem has been identified, measures are taken to prevent its recurrence. Nonconforming items are properly disposed of or corrected. The effects of these measures are audited to assure the desired goals are met and the permanent changes are in place, documented and communicated.

12.0 Accounting Management system - Documentary cycle.

Extrapharma for drugs and medical appliances is using ALMUTAKAMEL PRO - ERP Sales and accounting management system, which is the best management software system at the country (Yemen Soft developer company)
http://yemensoft.com/en/products/al-motakamel/accounting-management-system

The system is working with ORACLE software which is guaranteed the following features and benefits :

1. It contains an automatic mechanism documentary cycle, which covering all accounting and finance operations' company.

2. Created charts of accounts in a manner compatible with the type , nature and size of the company and its subsidiaries, branches and activities.

3. Contains projects management system, which serves a lot of construction companies and the various contracts and projects.

4. Preparation of the estimated budget of the facility at the level of the main and sub-accounts, projects and cost centers and all operations of facility to observe the actual movement and to correct the variances go.

5. Automatic recording in all related accounts to balancing documents accounting processes .

6. Review of reports' operations with multiple options and design reports that wish to get with.

The benefits of Accounting Management System:

1. Preparing the financial year to annual or determine the length of the accounting period according to your business requirements.
2. Control for accounts influential and linked with any other subsystem.
3. linked the cost centers with accounts by several options for the distribution of the costs to departments, projects or ... etc..
4. Balancing operations in the cost centers for coming years, especially to projects under implementation.
5. flexibility to deal with different types of accounting entries (periodic, outstanding, reverse, exchange rate differences).
6. Possibility the automatic issue for bonds, and get support bond for a certain bill if repaid.
7. Automated controls to prevent common accounting mistakes or repeal or modify any process unless make another process.
8. follow the movement of the guarantees, insurance and alert for guarantees before it is finished ..
9. possibility preparing of accounts in the manner appropriate to the Company by modern ways allocation according to the concepts and principles and the international accounting standards and generally accepted.
10. The Accounting management system is under supervision of accounting manager and External audit consultant which has been trained from the developer company trainers.

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