**Requirement Specification Document (RSD)**

**Module Name:** Purchasing Module  
**Standard:** ISO 13485:2016 – Clause 7.4  
**Prepared for:** Ibhan Agile Talent Technologies Pvt. Ltd. (IATT)  
**Version:** 1.0

**1. Purpose**

To define the purchasing module requirements of the QMS to ensure purchased products and outsourced services conform to specified requirements that directly impact the safety, quality, and compliance of medical devices manufactured by IATT.

**2. Scope**

This module governs all procurement activities critical to the functioning and compliance of IATT's medical device manufacturing operations. Specifically, it applies to:

* **Suppliers of Raw Materials, Components, Packaging, and Consumables:** Includes vendors who provide critical and non-critical inputs that directly or indirectly influence product quality and patient safety.
* **Outsourced Services:** Covers third-party providers involved in calibration, testing, validation, manufacturing, sterilization, and other processes essential to product conformity. Control of such services is exercised via formal agreements and periodic evaluations.
* **Supplier Lifecycle Management:** From initial registration, risk classification, evaluation, approval, and periodic re-evaluation to final de-listing, all stages are documented and system-controlled.
* **Purchase Order (PO) Management:** Encompasses the creation, approval, issuance, and traceability of POs, ensuring that purchasing information complies with predefined specifications, quality expectations, and regulatory requirements.
* **Supplier Performance Evaluation:** Involves annual performance scoring based on defined KPIs (e.g., quality, delivery, cost, responsiveness), corrective action tracking, and status updates to the Approved Supplier List.

This scope ensures adherence to ISO 13485:2016 Clause 7.4 requirements and enhances procurement decision-making through risk-based and quality-focused controls.

**4. Functional Requirements**

**4.1 Supplier Qualification & Registration**

* Suppliers must be registered in the system with full organizational, financial, and operational details, including company profile, ownership, GST/Tax ID, and production capabilities.
* Certification documentation such as ISO 9001, ISO 13485, and IMDR 2017 compliance certificates must be uploaded and verified.
* Each supplier must be risk-classified (e.g., critical, non-critical) based on their product/service type, role in the production chain, and potential impact on medical device quality.

**4.2 Supplier Assessment & Approval**

* Initial assessment is performed via structured on-site or remote audits using the standardized Supplier Assessment Form (F05), focusing on capabilities, quality systems, documentation, and infrastructure.
* Suppliers must submit trial samples or pilot lots for testing and verification against product specifications.
* Only those suppliers that pass both the documentation and product evaluation stages are added to the Approved Supplier List (F03 for materials, F03A for services).
* Supplier status and documentation history must be recorded, including rejection notes if not approved.

**4.3 Purchase Requisition & Order Management**

* System must allow users to raise Purchase Requisitions (PRs) based on:
  + BOM demand
  + Production planning
  + MSR (Minimum Stock Requirement) thresholds
* PRs route through department heads and finance for approval, with audit trail.
* Upon approval, Purchase Orders (F06) are generated including:
  + Supplier name, material specs, quantity, unit price, delivery date, and quality documentation required (e.g., COA/COC)
* POs must be traceable for at least 10 years and searchable by multiple parameters (item code, date, supplier, PO number).

**4.4 Verification of Purchased Products**

* All received materials are logged and inspected by the QA team before being accepted into inventory.
* Verification includes:
  + Dimensional checks
  + Specification matching
  + Certificate of Analysis/Compliance review
  + Sampling if needed
* Inspection outcomes are documented using the Quality & Delivery Summary (F07).
* In case of non-conformance:
  + Materials are tagged as NC (Non-Conforming)
  + QA triggers investigation, and a SCAR (F09) is initiated if required

**4.5 Supplier Rating & Review**

* System calculates supplier performance ratings annually using the following weightages:
  + Quality of supplied material – 40%
  + Adherence to ordered quantity – 35%
  + On-time delivery – 15%
  + Customer service/responsiveness – 10%
* Ratings are auto-calculated based on Quality & Delivery Summary and feedback inputs.
* Suppliers with scores below the threshold (e.g., 80%) are flagged for review and possible delisting.
* Corrective actions are documented and tracked via SCAR (F09).

**4.6 Outsourced Process Control**

* System must support registration and categorization of outsourced service providers (e.g., testing labs, calibration partners).
* Formal Supplier Agreements (F10) must be stored with clearly defined scope of service, quality responsibilities, timelines, and documentation.
* Service quality is monitored through:
  + Service delivery performance
  + Timeliness
  + Non-conformance incidents
* Periodic evaluations are conducted by the QARA department. Providers not meeting quality or compliance expectations may be suspended or removed from the Approved List (F03A).

**5. Non-Functional Requirements**

* **Security:** The system must support robust role-based access control (RBAC), ensuring that users only access the functionalities and data relevant to their roles (e.g., QA, Purchase, Finance). Sensitive data such as pricing, audit reports, and supplier ratings must be protected from unauthorized access.
* **Traceability:** Every action performed within the system must be recorded in an audit trail, including timestamps, user IDs, document revisions, approvals, and changes. This enables full traceability from supplier onboarding to product receipt, supporting audits and regulatory compliance.
* **Retention:** All purchasing records, including POs, audit results, supplier evaluations, certificates, and quality verification documents, must be stored securely for a minimum of 10 years to align with regulatory shelf life and traceability expectations for medical devices.
* **Compliance:** The module must ensure conformance with ISO 13485:2016 Clause 7.4 and IMDR 2017 by enforcing supplier control, documentation, verification, and continuous performance evaluation mechanisms.
* **Integration:** The purchasing module should be designed to seamlessly integrate with:
  + **Inventory module** – for real-time stock updates and material inwarding
  + **QA module** – to trigger quality checks and receive approvals
  + **Finance module** – for tracking budgets, payments, and generating cost reports

**6. Stakeholders and Roles**

| **Role** | **Responsibilities** |
| --- | --- |
| Purchase Executive | Raise PRs, manage POs, liaise with suppliers |
| QA Inspector | Validate received materials |
| Dept. Heads | Approve PRs and vendor selections |
| QARA / MR | Final supplier approval, waiver handling |
| Finance | Review budget and payment approval |

**7. Associated Forms**

| **Form Code** | **Title** |
| --- | --- |
| F02 | Supplier Rating |
| F03 | Approved Supplier List |
| F03A | Approved Service Provider List |
| F04 | Supplier Registration Form |
| F05 | Supplier Assessment Form |
| F06 | Purchase Order |
| F07 | Quality & Delivery Summary |
| F08 | Material Indent |
| F09 | Supplier Corrective Action Request |
| F10 | Supplier Agreement |

**8. Reports & Dashboard Outputs**

* Procurement Status Summary
* Supplier Performance Scorecard
* Open SCAR Tracker
* Material Acceptance/Rejection Dashboard

**9. Constraints & Considerations**

* Forms will be digitized and accessible via the system
* Approval workflows must align with internal matrix

**Visual Deliverables**

**10.1 Wireframe - Supplier Management Interface**

* Tabs: Registration, Assessment, Approval, Rating
* Key Fields: Supplier Info, Certification Upload, Evaluation Score, Status

**10.2 Wireframe - Purchase Requisition Workflow**

* Flow: Create PR → Review by Dept. Head → PO Generation → QA Approval → GRN
* Key Features: BOM linkage, Approval Trail, Notifications

**10.3 Workflow Diagram - End-to-End Procurement**

1. Identify Need (Stores/Production)
2. Raise PR (Purchase Executive)
3. PR Approval (Dept. Head)
4. Generate PO (Purchase Head)
5. Supplier Dispatch
6. Receive & Inspect (Stores + QA)
7. Accept/Reject (QA)
8. Update Inventory / Trigger NC Process
9. Supplier Rating & SCAR if applicable

**10.4 UI Mockup Suggestions**

* Dropdown for Supplier Category (Critical/Non-critical)
* Score sliders for Rating Criteria
* Attachment module for Certificates and Agreements
* Status badges (Active, Pending, Delisted)