RPI RESEARCH PRODUCTS INTERNATIONAL

410 Business Center Drive
Mt. Prospect, Illinois 60056-2190
Ph: 847.635.7330
Fax: 847.635.1177

Quality Management System Overview

Research Products International is a global company with sales, manufacturing, and distribution facilities in US and UK. Both these locations have quality systems that adhere to the requirements of ISO 9001:2015 and ISO 22716:2007. Both sites have received third party certifications through ACM (UKAS accredited registrar).

Quality System Details

Quality Manual

Research Products International/ Melford Labs. has developed a Quality Manual, which provides information on the elements of the Quality Management System including the sequences and interactions of the primary processes.

Document Control

Quality Management System policies and procedures are maintained under document control. Procedures include administration, good manufacturing practices, operations, QC, QA, equipment calibration/maintenance/operations, trainings, risk assessments, context of organization, management reviews, and others.

Training

Research Products International has established training programs that include corporate, departmental and job specific requirements. Corporate training includes mandatory trainings on quality policy, quality system, cGMP and safety. Job title trainings include job specific trainings as on job trainings. Trainings are supervised and evaluated by Departmental Managers or Training manager. In addition to job training, each position has a written job description that describes the necessary educational and experience qualifications to adequately perform the required tasks. Training requirements are reviewed and amended/ updated as needed.

Corrective Action

RPI has established a Corrective Action procedure to identify areas for improvement to current products and processes and to implement actions that will prevent issues from reoccurring or happening at all. Corrective actions are based on root cause analysis and designed to eliminate/ mitigate factors contributed to a non conformance.

RPI RESEARCH PRODUCTS INTERNATIONAL

410 Business Center Drive
Mt. Prospect, Illinois 60056-2190
Ph: 847.635.7330
Fax: 847.635.1177

Customer Complaints

Customer complaints are communicated to QA for review and if necessary investigation. RPI has procedures that define how the complaint is investigated and, when applicable, the corrective actions implemented. The procedures define the actions necessary to accomplish corrections or recall. In the event of a recall, affected customers will be identified and contacted.

Audits

Internal Audits

RPI has established internal Audit Program to ensure the integrity and continuous improvement of the Quality Management System. Internal Audits are conducted by certified lead auditor(s).

Customer Audits

Quality audits by our customers are permitted at our facilities. We request that adequate notification be provided (45-days prior to visit) and that an agenda be sent from the customer within 3-weeks of the requested audit date(s). Research Products International reserves the right to cancel or revise the audit schedule.

Supply Chain

Suppliers

Our supplier's (Biochemicals and Laboratory Supplies) are qualified using any or a combination of criteria such as, supplier audit questionnaire, on-site audit, historical performance (quality, on-time delivery) and/or third party certifications. A supplier may be "Rejected" after non-compliance with the Research Products International expectations. New and alternate suppliers are qualified as necessary to maintain product supply, purity and competitiveness.

QA / QC Staffing

The Research Products International Quality Assurance / Quality Control program team comprise of 6 employees at both sites.

RPI RESEARCH PRODUCTS INTERNATIONAL

410 Business Center Drive
Mt. Prospect, Illinois 60056-2190
Ph: 847.635.7330
Fax: 847.635.1177

Process Control

Procedures

Documentation exists for providing appropriate instructions for receiving, producing and testing final product. A robust change control process is in place, when changes to the manufacturing or testing process are warranted the work instruction document(s) in QISS reflects the procedural change and approval. All interested parties are notified of change(s) in advance.

Equipment

Documented procedures exist for equipment operation, calibration and maintenance. Equipment and usage records are maintained and available. Equipment tags are also used to indicate equipment calibration and maintenance status.

Quality Records

Where appropriate quality records for a product's lifecycle within Research Products International are maintained and available, quality records include: customer inquiries including orders and complaints, raw material information, in-process manufacturing and testing data, packaging, final quality analysis, batch disposition, training and equipment. A product and batch numbering system is employed to allow traceability throughout the entire process.

Nonconformance

Documented procedure for Non conformances elaborate the actions required in case of non conformity. When a batch is determined to be nonconforming to product specifications, the batch is "flagged Unavailable" in our ERP system and physically labeled and segregated to reflect this "Unavailable" status so as to prevent shipment. Non conformities are investigated, root causes determined and appropriate corrective actions are taken to correct and prevent reoccurrence.

RPI RESEARCH PRODUCTS INTERNATIONAL

410 Business Center Drive
Mt. Prospect, Illinois 60056-2190
Ph: 847.635.7330
Fax: 847.635.1177

Specification Control

Incoming Materials

Approve specifications are maintained through QC module of ERP. For materials from our suppliers, Certificates of Analysis are received and reviewed against RPI/Melford specifications. In addition if warranted, incoming materials also pass through a physical quality inspection, analytical/microbiological testing and review process. These materials are maintained in a "Not Available" status until the review is complete. Status of the incoming material is identified with ERP generated labels/tags with status "Unavailable".

i. Requires/ Waiting QC, Status as "Unavailable"
ii. Released, Status as "Available"
iii. Rejected Status as " On Hold/ Unavailable"

Development

Operations, Quality Control, Quality Assurance and Product Management/ Marketing functions are all involved with establishing product specifications. Customer and regulatory requirements and market demand are considered in specification development.

Accessibility and Control

The majority of general catalog product's specifications are available to our customers and employees. A product specification is considered a controlled document, in either an electronic format and/or in hardcopy, and is handled as such, with revision control, approval and issuance. Any special customer specification(s) are maintained as confidential. Confidential specifications are disclosed only to personnel who have authorized access as part of their job function.

RPI RESEARCH PRODUCTS INTERNATIONAL

410 Business Center Drive
Mt. Prospect, Illinois 60056-2190
Ph: 847.635.7330
Fax: 847.635.1177

Product / Batch Documentation

Product Specifications & Certificate of Analysis (C of A)

The majority of Research Products International/ Melford products have established product specifications. A product's specification information may be found on the Certificate of Analysis, catalog listing and/or on the label. Certificates of Analysis report batch level information including:

- Formula & formula weight
- CAS number
- Grade
- Analytical test Specifications and results
- Retest date
- Expiration date (wherever applicable)
- QC Authorization signature for Batch Release

Certificates of Analysis can be found at www.rpicorp.com or requested from our Technical Service group and/or included in the shipment. Customers will need to contact Customer Service for further information on how to arrange receiving Certificates of Analysis in the product shipment.

RPI also provide certificates of compliance per customer request.

Container Label

Product information provided on the container label may include:

- Product and Lot/Batch number
- Product Name
- Physical chemical properties
- Risk & safety statements in multiple languages w/pictograms
- Regulatory information incl. country of origin, usage claim
- Storage and handling information (upon Customer's request)
- Customer PO and / or product number(upon Customer's request)