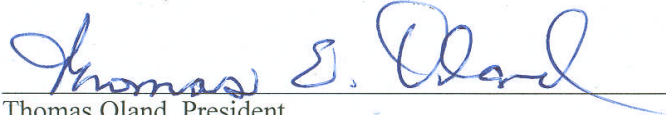




## QUALITY MANUAL

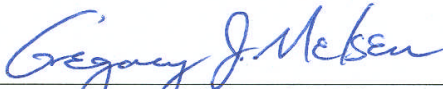
Authorized By:



Thomas Oland, President

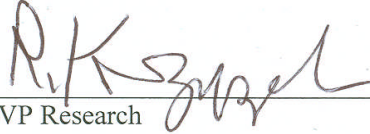
Date:

5/18/2009



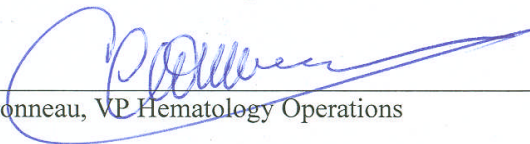
Gregory Melsen, Chief Financial Officer

5/19/2009



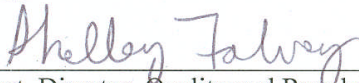
Richard Krzyzek, VP Research

5/15/2009



Marcel Veronneau, VP Hematology Operations

4-7-2009



Shelley Falvey, Asst. Director, Quality and Regulatory Affairs

5/19/09



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SECTION TITLE: **CONTENTS**

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**QUALITY MANUAL**  
Section Title: Quality Policy

Number: 540308  
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Supersedes: 540308.10  
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Revision Date: 4/2/2009

**R&D Systems Inc. Quality Policy:**

R&D Systems is committed to the highest level of quality in the manufacture, sale and support of our products. Product quality, compliance to all applicable regulatory requirements, continuous improvement and customer satisfaction shall underlie all of our efforts in development, manufacturing, advertising, sales, shipping and technical support.

**Definitions:**

**Quality:** the totality of features and characteristics that bear on the ability of a product to satisfy fitness for use, including safety and performance (§ 820.3 (s)).

**Quality system:** the organizational structure, responsibilities, procedures, processes and resources for implementing quality management (§ 820.3 (v)).

Assurance of quality and integrity are the responsibility of:

1. the President, who has responsibility for creation of an atmosphere of high standards;
2. the officers, directors, managers and supervisors, who are charged with development and implementation of quality systems; and
3. each employee, who is responsible for the quality of his or her work and for suggesting improvements in quality.

This Quality Manual is the top tier of our documentation system. It gives an overview of our Quality System. It is supported by corporate and division standard operating procedures (SOPs) which are the second tier of our Quality System documents and are listed in this Quality Manual. The third tier of the documentation system consists of manufacturing/testing documents, forms and specifications developed by each operating unit.

Our policies are in conformance with the applicable requirements of the Code of Federal Regulations (21 CFR) Quality Systems Regulations for Medical Devices; ISO 13485 Standard: 2003, ISO 9001 Standard: 2008, the In Vitro Diagnostic Directive 98/79 EC and the Canadian Medical Device Regulations.

Sections of the ISO 13485 Standard which do not apply to R&D Systems are as follows:

- Section 7.5.1.2.3 - Service activities (Reason: Applicable to equipment)
- Section 7.5.1.2.2 - Installation activities (Reason: Applicable to equipment)
- Section 7.5.1.3 - }
  - Section 7.5.2.2 - } Particular requirements for sterile medical devices (Reason: No sterile products)
  - Section 7.5.3.2.2 - }
- Section 8.2.4.2 - Particular requirements for active implantable devices (Reason: No implantable devices)

**Related Procedures:**

- 540007 Canadian Medical Device License, Facility License and Quality System Certification
- 540120 Required Standards Listing, Maintenance and Review



**QUALITY MANUAL**  
Section Title: Company Profile

Number: 540308  
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R&D Systems was founded in 1976 in Minneapolis, MN. It is a wholly owned subsidiary of TECHNE Corporation (a holding company with no employees). The stock is traded publicly on NASDAQ's National Market System under the "TECH" symbol. TECHNE has two operating subsidiaries: Research & Diagnostics Systems, Inc. (R&D Systems) and R&D Systems Europe Ltd. (R&D Europe).

R&D Systems has two operating divisions: Biotechnology, which manufactures reagents primarily for the research market, and Hematology, which manufactures controls and calibrators for hematology analyzers. The Minneapolis manufacturing facility is certified to ISO 9001:2008 and ISO 13485:2003. The ISO Certificate numbers are FM547845 and FM547846, respectively.

In July, 2005 R&D Systems purchased BiosPacific, which became a wholly owned subsidiary. BiosPacific is located in Emeryville, CA and consists of a sales force which provides raw materials for development of Immunoassay kits.

R&D Systems Europe in Abingdon, England distributes biotechnology products and is the European Representative for the Biotech Division. They received ISO 9001: 2000 certification in June, 2007. Their ISO Certificate number is 951074360. EuroCell Diagnostics, Village de la Metairie Batiment B, 35131 Chartes de Bretagne is the European Representative for the Hematology Division.

R&D Systems Europe has a sales subsidiary, R&D Systems GmbH, in Germany.

R&D Systems established a wholly owned subsidiary in the People's Republic of China in May 2007. R&D Systems China Co. Ltd. opened its Warehouse and Distribution Center in Shanghai, China on October 1, 2007. R&D China provides products, marketing and technical support to our Chinese distributors.

R&D Systems' physical plant includes over 498,460 square feet of laboratory, manufacturing, shipping and office space as of December 1, 2008. Offices are in Minneapolis, MN, Abingdon, UK, Wiesbaden, Germany, Shanghai, China and Emeryville, CA with over 665 employees as of December 1, 2008.



**QUALITY MANUAL**  
Section Title: Management Responsibilities

Number: 540308  
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Quality is the responsibility of each employee throughout our organization.

Management is responsible for communicating our Quality Policy to all employees and for ensuring full understanding of, and commitment to, quality.

- The President has executive responsibility for the Quality System and is responsible for creating an atmosphere where quality is the highest priority.
- The Vice Presidents are responsible for overseeing the development, implementation and maintenance of the Quality System.
- The Asst. Director, Quality has been appointed as the Management Representative by the company president. The Management Representative has responsibility for ensuring that quality requirements are effectively established and maintained in accordance with the appropriate regulations and for reporting on the quality system to upper Management.
- The Asst. Director, Quality, Vice President of Operations (Hematology), and the Quality Assurance (QA) staff are responsible for ensuring that our quality system is fully maintained and implemented.
- Each director, manager and supervisor is responsible for assuring that Quality Systems are followed in his or her area.
- Each employee is responsible for the quality of his or her work.

Two groups are dedicated exclusively to Quality:

1. The Quality Assurance Department assists operating departments in the development of quality systems and conducts periodic audits to assure that those systems are implemented faithfully and effectively. Quality Assurance has the responsibility to:
  - identify and evaluate quality-related problems.
  - recommend solutions to quality problems and verify that any problems have been resolved (corrective actions).
  - initiate action to prevent the occurrence of quality problems (preventive actions).
  - control non-conforming products until corrective action has been taken.
  - set quality goals and objectives for the company and develop plans to meet those goals and objectives.
  - report to Management on quality related issues.

**The Quality Assurance Department is responsible for quality systems, but implementation of these systems and quality *per se* is the responsibility of each director, manager, supervisor and employee.**

2. The Quality Control (QC) Departments inspect and test products at all stages of the manufacturing process, from raw materials to finished goods. Quality Control Managers have responsibility for product release against predetermined specifications. Due to the varied and highly technical nature of our products, QC functions are distributed throughout the corporation to ensure that testing and inspection are done expertly.

The following charts describe the organizational and functional structure of the Company. While the structure and organization of the Quality function varies between the two divisions of R&D Systems, their goals are identical.

Related Procedures:

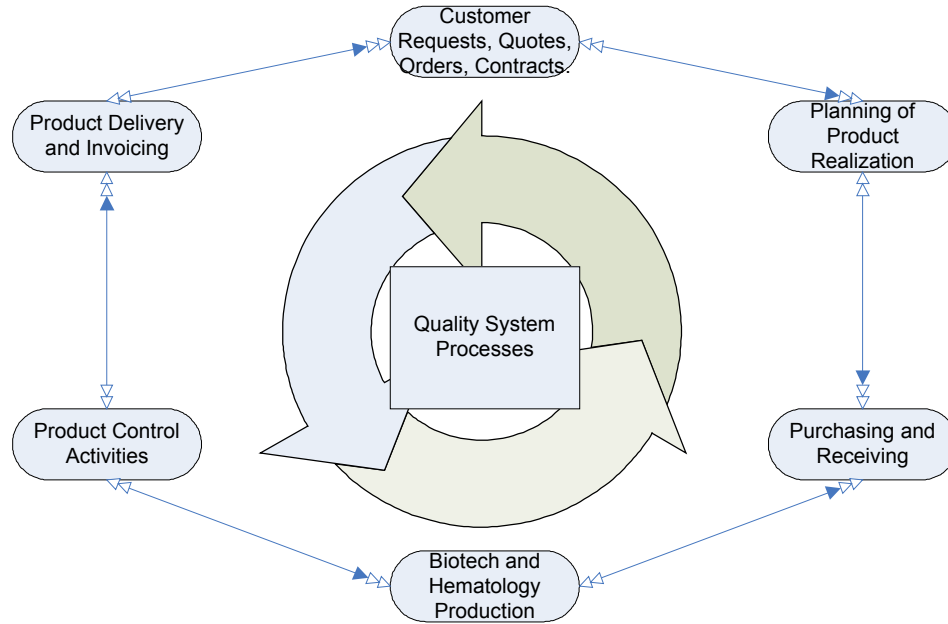
- 540009 Management Quality Systems Review Procedure
- 541138 Quality Assurance Organization



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# Quality Systems Flow Chart



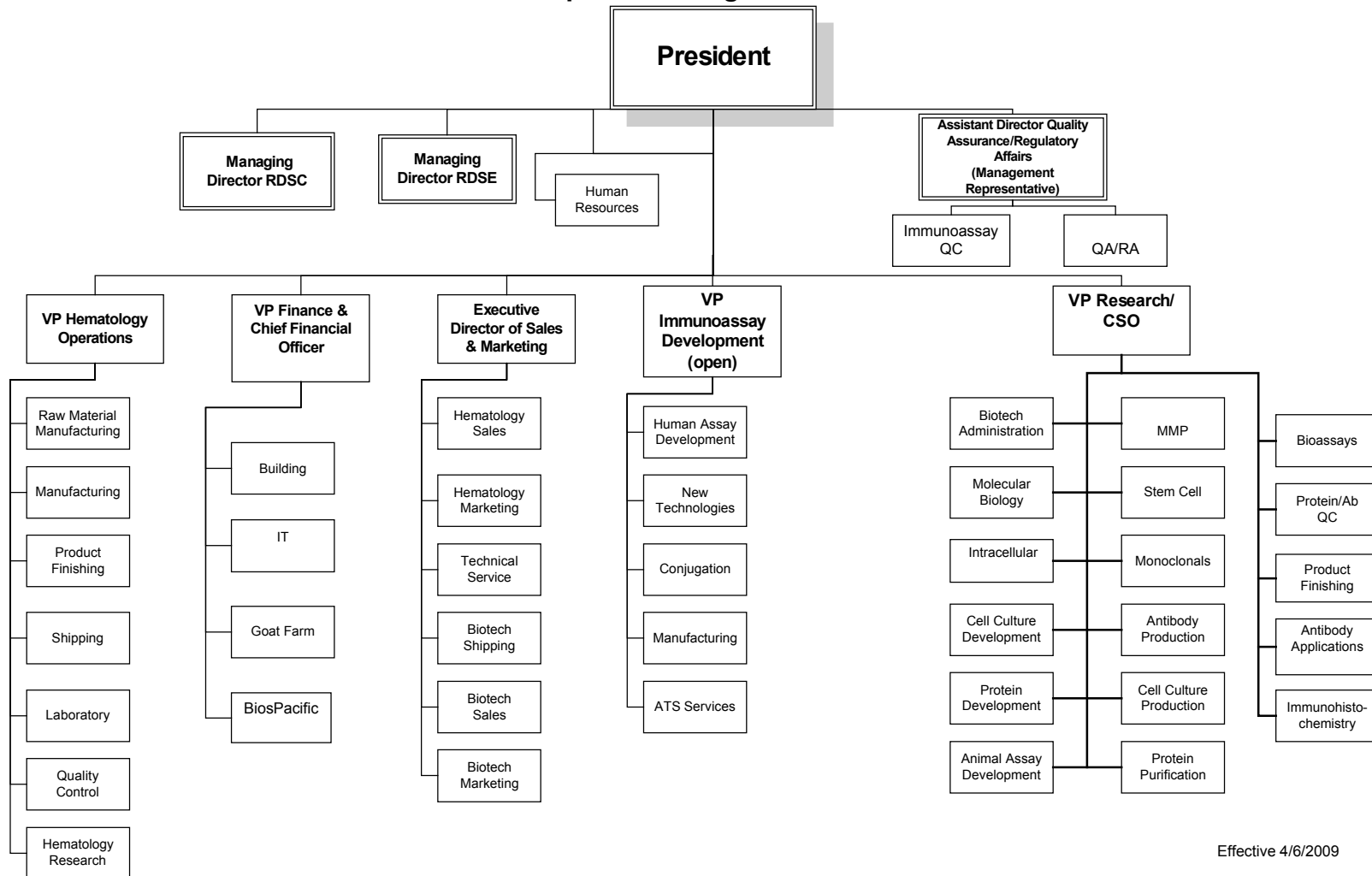
- Human Resources
- Customer Service
- Manufacturing Operations
- Research and Development
- Quality Assurance  
Regulatory Affairs
- Finance
- Facilities
- Systems Administration



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**R&D SYSTEMS, INC.**  
**Department Organization**



Effective 4/6/2009



**QUALITY MANUAL**  
Section Title: Quality Audits

Number: 540308  
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Supersedes: 540308.10  
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Periodic audits assure adherence to our quality systems.

Internal Quality System audits are performed by the Quality Assurance staff and by other trained personnel under the guidance of Quality Assurance. Results of audits are reported to the Assistant Director of Quality, the appropriate Vice President, the Company President, and the operating units involved. It is the responsibility of those units to develop corrective actions, to correct deficiencies and to present evidence of correction.

Vendor audits are performed by Quality Assurance staff on an as needed basis.

Other Quality System effectiveness checks are made by department managers and senior management, through periodic review of product complaints, non-conforming material tracking/trending and material review board meeting minutes.

To ensure that the Quality System is effective and relevant, it is reviewed annually by the Senior Management Team, the Asst. Director of Quality, the Regulatory Affairs Specialist and other managers, as appropriate. The agenda for the meeting will be written by Quality Assurance based upon audit results and other outstanding issues related to Quality Systems and product quality. Minutes from the meetings shall be distributed to those present at the meeting as well as any designated attendees that are absent from the meeting. A copy of the agenda and meeting minutes will be maintained on file in Quality Assurance.

Related Procedures:

**Corporate:**

- 540009 Management Quality Systems Review Procedure
- 541131 Quality Meetings
- 540167 FDA Inspection Procedure
- 540291 Internal Audit Procedure
- 540335 Vendor Audit Procedure
- 540552 Corrective and Preventive Action

**Biotechnology:**

- 540135 Customer Feedback System, Biotech
- 540259 Material Review Board Responsibility Procedure
- 540550 Quality Assurance Auditing of GLP Studies

**Hematology:**

- 6016 Material Review Board Procedure
- 8034 Technical Service Protocol/Complaints





**QUALITY MANUAL**  
Section Title: Personnel

Number: 540308  
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It is our policy to hire only qualified personnel and to assure that they are trained in all aspects of their jobs.

Copies of job descriptions, job applications, resumes and annual performance reviews are kept on file in the Human Resources Department.

The Company has a QSR/GMP training program (including the applicable regulations), conducted by Quality Assurance, which all employees are required to complete. Upon satisfactory completion of this training by an employee, a certificate of completion is given to the employee's supervisor. Quality Assurance maintains a master log of all certificates of completion issued. Ongoing training, as necessary, assures personnel are familiar with applicable requirements.

The Company has provided ISO 13485/CMDR and risk analysis training to Managers and Directors responsible for the manufacture and testing of our products. It is the responsibility of these trained employees to assure that all of their employees are familiar with the pertinent aspects of these regulations.

Regulatory Affairs maintains a file of all pertinent Standards and assures that the latest revisions are available. When revisions are available, this is communicated to Quality Assurance and other pertinent personnel so that we can keep up-to-date on the latest regulations and standards.

Each department maintains job-specific training records for its employees. Supervisors are responsible for job-specific training, for training on new or revised documents, for assuring that training is effective and for maintaining training records. Notification of document changes are issued as a trigger for training.

Related procedures:

- 540189 Personnel Training Procedure
- 540816 Procedure for Generating Training Reports
- 540120 Required Standards Listing, Maintenance and Review



**QUALITY MANUAL**  
Section Title: Design Controls

Number: 540308  
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We have different Design Controls for different types of products. In general, they cover the following points.

1. Approval of the design goals (Design Input)
2. Review of feasibility studies (Design Review)
3. Approval of the product description (Design Output)
4. Review of process development and preparation of manufacturing documents (Design Verification Review)
5. Review and approval of product validation (Final Design Review/Data Review)
6. Transfer to manufacturing

The specific procedures for the different product lines are referenced below.

Related Procedures:

**Biotechnology**

- 540045 Definition of Product Design Goals for Assay Development
- 540325 Design Controls
- 540266 Procedural Elements in a Validation
- 540215 Specific Immunoassay Validation Procedures (i.e., Linearity, Precision, etc.)
- 540217 through 540221, 540223, 540235 - 540238, 540288, 540337, 540409, 540729, 540804 and 541002

**Hematology**

- 6009 Procedural Elements in a Validation
- 6009A Testing Protocol Request
- 3421 Procedure for Developing Operational Procedures
- 6015 Product Introduction/Product Improvement Procedure
- 6015A Design Control and Transfer Worksheet
- 6039 Product Development Request Form
- 6026 Design Input
- 6027 Design Output
- 6040 Design Review Procedure

**Corporate**

- 540819 Risk Analysis and Management



**QUALITY MANUAL**  
Section Title: Document Controls

Number: 540308  
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To assure consistent quality, we use written, approved procedures for all operations. The Document Control and Quality Assurance departments or their designee(s) are responsible for controlling the issue, distribution, revision and archiving of these procedures.

The documents that must be controlled include:

- The Quality Manual and Quality Systems SOPs
- Device Master Records
- Internal Audit Reports
- Standard Operating Procedures
- Manufacturing Procedures
- Testing/Inspection Procedures
- Calibration and Maintenance Records
- Device History Records
- Design Control Records
- Forms
- Data from ATS Studies
- Essential Requirements and Technical Document Indexes

Biotechnology uses a formal Document Change Request (DCR) procedure for creating new documents and revising existing documents. It involves review and approval by multiple departments generally including a technical department, the affected department and the Quality Assurance department. The Hematology Division initiates formal Document Control in each Department. The Departmental Supervisor reviews a draft with assistance from designated individuals.

Related Procedures:

**Corporate**

- 540643 Standard Operating Procedure (SOP) Review Procedure
- 540578 Record Keeping Guidelines
- 540146 Creating a Document
- 540748 MasterControl™ Electronic Documentation System
- 540750 MasterControl™ Functions

**Biotechnology**

- 540205 Document Change Request Procedure
- 540382 Preparation & Maintenance of Document Master Files
- 540411 Master Document Replacement Procedure
- 540532 Data Management: General Procedures & Definitions (ATS Lab)

**Hematology**

- 3007 New and Updated Procedure Protocols
- 3008 Procedure Format
- 6005 Document Organization (Document Control)
- 3421 Procedure for Developing Operational Procedures
- 6006 Updating the Device Master Record (DMR)
- 6030 Format for "Product Description/Device Specifications" Documents
- 6031 Format for "Product Type" Documents



**QUALITY MANUAL**  
Section Title: Purchasing Controls

Number: 540308  
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Consistent quality of raw materials and contracted services is a key part of our quality system.

Purchasing control covers the following areas:

- Specifications: Requirements for raw materials are stated in written specifications available to all personnel doing purchasing and receiving activities.
- Vendor Control: Qualified vendors are listed on each raw material specification. Document 540000, Vendor Qualification describes how to qualify new vendors in Biotechnology and Hematology including outsourced services and processes. Vendor performance is tracked and Vendors who do not perform well may be disqualified and replaced.
- Purchasing Control: The purchase order includes our part number and a request for a Certificate of Analysis where appropriate. All materials used in the manufacture of products are verified against the purchase order. Purchasing interacts with suppliers regarding non-conforming or damaged materials.
- Contract and Supply Agreements: Purchasing, Sales or Business Development is responsible to assure customer contracts and supply agreements are in place when required. Intellectual property contracts, customer contracts and supply agreements are managed by the Corporate Legal Department.

Related Procedures:

540687	Purchasing Procedure, R&D Systems
540192	Receiving Procedure, R&D Systems
540000	Vendor Qualification
540335	Vendor Audit Procedure
540876	Quarantined Product Procedure
540805	Policy Regarding Contracts and Supply Agreements
640xxx	Non-biological Raw Materials Specifications (Biotech)
645xxx	Biological Raw Material Specifications (Biotech)
54xx, 55xx	Biological Raw Material Specifications (Hematology)
56xx, 57xx	Non-biological Raw Materials Specifications (Hematology)



**QUALITY MANUAL**  
Section Title: Identification and Traceability

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The ability to trace a lot of product back to all raw materials used in its manufacture and to trace any lot of raw material to products it became part of is an essential feature of our Quality System.

A part number and lot number (or receiving number) control all materials used to manufacture products. This provides complete traceability from receipt of raw materials through final shipment to the customer. In Biotechnology, Document Control is responsible for assigning part numbers. An MRP System (RenCS) is in place in the ELISA kit manufacturing area which is used to track inventory, assign job (lot) numbers and plan the production of the ELISA products. Lot numbers for all other products may be sequentially assigned from the Lot Number Database or are assigned at the time of bottling.

The Hematology Director of Operations assigns final product lot numbers for Hematology products.

Receiving departments are responsible for assigning receiving numbers to incoming raw materials.

Related Procedures:

- 540153 Part Number Assignment (Biotech)
- 540523 Electronic Part Number Requisition Procedure
- 540206 Lot Number Assignment (Biotech)
- 540540 Receiving of Specimens for RDS-ATS Lab
- 540831 RenCS, Add and Maintain Part Records
- 8862 Assigning Final Product Lot Numbers (Hematology)
- 6019 Identification and Traceability (Hematology)



**QUALITY MANUAL**  
Section Title: Production and Process Control

Number: 540308  
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We design quality into our products. Areas of the manufacturing process that require control are identified during the development of a product and the effects of variables and appropriate limits are established.

Process Control is accomplished through planning, written procedures, inspection, calibration, training, supervisory oversight and employee awareness. Changes to the manufacturing process, if required, are controlled, qualified and validated.

- Written procedures provide bills of materials, instructions for production, equipment required, working environment, filling and labeling instructions, record sheets, expiration dating, in-process testing, and acceptance criteria.
- Monitoring of product manufacture is accomplished through the use of Batch Records (Device History Records) containing the current revisions of the documents required for the manufacture of a product. Document Control assembles batch records for kit component manufacturing. Other manufacturing and Quality Control departments print official copies of their documents from MasterControl™. Operations, in Hematology, assembles the batch records. Quality Control verifies compliance through review and approval of completed batch records prior to final product release.
- The Specification Deviation Procedure handles deviations from the written procedures.
- All new inspection, measuring and test equipment is inspected and validated, when appropriate, against manufacturer's specifications and identified with a permanent preventive maintenance number. Equipment is calibrated on a regular schedule. Improperly maintained or calibrated equipment will not be used. Records of calibration and maintenance are maintained by the Facilities & Equipment Department. Quality Assurance audits equipment periodically, to ensure that calibration is proceeding according to schedule.
- The supervisor or lead personnel contributes to quality through training employees, assisting employees with new or specialized processes, interpreting instructions for and communicating process changes to employees.

Related Procedures:

- 540126 Specification Deviation Procedure
- 540142 Procedure for Documentation of Equipment Maintenance and/or Calibration
- 540310 Software Validation
- 540133 Internal Notification Procedure: Receipt of New Equipment



**QUALITY MANUAL**  
Section Title: Production and Process Control

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**Biotechnology**

- 540781 Planning Guidelines, Immunoassay Manufacturing
- 540834 RenCS, Recipe Authorization
- 540833 RenCS, Add, Copy and Maintain a Process Specification
- 540832 RenCS, Adding and Copying a Recipe
- 540207 Product Finishing Label Control
- 540072 Filling Operations Procedure
- 540267 Preparation, Completion and Approval of Batch Records
- 540278 Bottling Procedure for Cytokines and Antibodies Designated for Retail Sale
- 540256 Labeling Procedure for Cytokines and Antibodies Designated for Retail Sale
- 540134 Incoming Equipment Validation Procedure
- 540503 Process Deviation Form, Dept 374
- 540657 Process Deviation Form, Dept 375 and 394

**Hematology**

- 9090 Product Finishing Label Control
- 9054 Bottling Procedure
- 8812 Finished Device Inspection Procedure
- 8813 Guideline for Determining Assay Ranges
- 8006 Bottled Product Release
- 8809 Assay Sheet Printing and Release
- 6009A Testing Protocol Request
- 6017 Product Type, Product Type Revision, Product Change Notification



**QUALITY MANUAL**  
Section Title: Acceptance Activities

Number: 540308  
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Acceptance/inspection activities are critical to the manufacture of quality products.

- Incoming materials are received in accordance with documented procedure(s).
- Deliveries are inspected against the purchase order for type, quantity and external transit damage. Additional inspection may include verification against Certificates of Analysis, in-house material specifications or incoming testing procedures.
- In-process testing is specified by the manufacturing and/or Quality Control procedures. Testing may include the recording of physical parameters such as pH and temperature, actual functionality testing and/or visual inspection.
- Final inspection and testing are completed before any product is released for sale. Quality Control signs the product release forms. Proteins and antibodies are released by the Director of Manufacturing. All documentation is reviewed and the product is physically inspected before release stickers are placed on the product and batch record.

All inspections and testing must be supported by completed documentation. Release by exception must be documented and approved by the Material Review Board. Such approval must be documented.

Related Procedures:

- 540192 Receiving Procedure, R&D Systems
- 540080 Raw Materials Departmental Receiving and Inspection Procedure
- 540124 Inspection of Assembled Kits
- 540143 Literature and Label Approval Procedure
- 550449 Immunoassay Approval/Rejection Criteria
- 540267 Preparation, Completion and Approval of Batch Records
- 540526 Receiving of OEM Products
- 540363 Releasing Retail Product
- 540194 Certificate of Analysis Procedure
- 541138 Quality Assurance Organization
- 8812 Finished Device Inspection Procedure (Hematology)





**QUALITY MANUAL**  
Section Title: Non-Conforming Product

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Our quality system provides for the identification, documentation, evaluation, segregation, and disposition of non-conforming product.

Quality Assurance administers the non-conforming materials system with the participation of the Material Review Board (MRB). Within departments producing research use only materials, appropriate technical personnel will review non-conforming material and make decisions concerning disposition of that material. Any employee with knowledge of non-conforming material may call for a Material Review Board meeting. Minor non-conformities may be released by Quality Control with adequate documentation. Disposition of major non-conformities lies with the MRB. QA is responsible for documenting the activities of the MRB. The Biotech MRB is composed of representatives from Quality, Manufacturing, and Development. Additional representatives from Product Support, Marketing, Technical Service or Sales may also participate as required. All corrective actions must be fully documented. Minutes from meetings of the MRB are published and maintained in MasterControl™.

In Hematology, MRBs are documented using the Material Review Board (MRB) form. Minutes from meetings of the MRB are published and maintained in MasterControl™. A summary of MRBs is distributed quarterly to managers for review.

All non-conforming material is clearly marked with Quarantine stickers or labeled appropriately. In addition, it is physically separated from conforming material until final disposition.

A Specification Deviation is issued for any deviation in the manufacturing procedure even if it ultimately meets final release specifications. If a product is reworked, it must undergo all required inspections and tests as well as any additional inspection or testing required by the MRB. Reworked material must pass the same release criteria as the original product.

Related Procedures:

- 540126 Specification Deviation Procedure
- 540552 Corrective and Preventive Action
  
- 540259 Material Review Board Responsibility Procedure
- 540265 Reprocessing Procedure
- 540330 Procedure for Quarantine/Rejecting Approved Product (Biotech)
- 3009 Adjustment/Replacement of a Finished Product (Hematology)
- 6016 Material Review Board Procedure (Hematology)
- 1012 Rework Procedure (Hematology)
- 541214 Corrections, Removals and Recalls for IVD Products



**QUALITY MANUAL**  
Section Title: Corrective and Preventive Action

Number: 540308  
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We are committed to taking preventive and corrective action to remedy any customer dissatisfaction or non-conformity that is identified. Whenever appropriate, a root cause analysis will be done to identify the root cause of the dissatisfaction or non-conformity.

A Customer Feedback System is maintained by Quality Assurance using the input from Technical and Customer Service. All customer complaints are logged and then classified as to type of complaint (performance, physical, etc.). All complaints are numbered and tracked by QA from receipt of initial call until closure. A summary report of Biotech complaints is available monthly for review by appropriate personnel. Weekly and monthly summaries of Hematology complaints are circulated to Management.

In Biotechnology, quarterly meetings are held to review performance complaints. Each meeting is attended by members of the appropriate department(s), MRB members and Technical Service. In Hematology, complaints are reviewed weekly by members of the MRB and Technical Service.

Corrective action is taken to remedy non-conformities that are identified and to prevent future recurrences. Preventive action is taken to eliminate the cause of a potential non-conformance. The Material Review Board reviews non-conformities. An action plan is put together with QA being responsible for monitoring and documenting the progress of any corrective or preventive action plan to ensure its completion. Corrective or preventive action that changes approved documents or processes is handled through the Document Change Request System in Biotechnology and through department level document control in Hematology.

Related Procedures:

- 540775 Medical Device Reporting (MDR) of Injury or Death
- 540552 Corrective and Preventive Action
- 540260 Field Notification Procedure
  
- 540135 Customer Feedback System, Biotech
  - 8034 Technical Service Protocol/Complaints (Hematology)
  - 6025 Protocol for Investigating a Product Problem and Applying a Corrective Action Plan (Hematology)
- 540331 Returned Goods Procedure (Biotech)
  - 8036 Procedure for Investigation of Returned Product (Hematology)



**QUALITY MANUAL**  
Section Title: Statistical Techniques

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Statistical methods are very powerful tools when used correctly within the quality process. These methods should be selected with care to assure they suit the application required and will produce an objective output.

The motivation to use these statistical methods is a desire to improve quality and to meet customer requirements. The quality system is subject to variations from components, design and equipment. Statistical methods can assist with the elimination or minimization of the variation.

Statistical methods should be used whenever possible or applicable to ensure product consistency.

Test and control should be implemented to release product, and to improve the knowledge base to allow for product improvement.

Tools that should be used or considered are:

- Experimental Design - Design of Experiment(s) software is available and is being used by kit development groups.
- Analysis of Variance/Regression Analysis
- Risk Analysis
- Root Cause Analysis
- Statistical Sampling Inspection
- Histograms - Plot frequency of events
- Pareto diagrams - Assist with sorting crucial problems
- Flow charts - Pictorial diagrams of processed or systems

Examples of where Statistical techniques may be applied:

- Design Input - Determining requirements and expectations
- Design Control - Periodic evaluation to provide assurance of acceptable product performance
- Shelf Life - Determine appropriate dating for products
- Process Control - Determine machine or process capabilities
- Defect Analysis - Assist with understanding problems
- Data Analysis - Review and understanding of products

Related Procedure:

- 540865 Statistical Methods
- 540537 Test for Outlier Determination (Grubb's Method)



**QUALITY MANUAL**  
Section Title: Labeling and Packaging Control

Number: 540308  
Revision: 11  
Supersedes: 540308.10  
Section: 2.13  
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We present to our customers only the highest quality labeling and packaging, and ensure that they meet all regulatory requirements.

All labels, literature and packaging are subject to incoming inspection.

Label control is the responsibility of the Quality Assurance and Manufacturing Departments. Document Control maintains the Literature Approval system through which new Biotech label and literature copy is circulated for approval prior to printing. The variable information on labels is printed in Manufacturing from password secured files. Each label is assigned a part number, and is revision controlled. All labeling operations require label inspection and reconciliation.

The QA Specialist monitors label control in Hematology.

Pre-printed labels are stored in locked cabinets or access-controlled areas.

Product packaging is designed to protect the product from environmental stress and physical damage during shipping. The effectiveness of the packaging in protecting the product has been documented and is monitored on every lot by analyzing data received through the external QC program and through customer complaints.

Finished products are assembled according to written procedures. Final product packaging is done so as to protect product integrity through physical separation of different operations. All packaging areas are cleared prior to the start of the next operation. Quality Control or other appropriate personnel inspect finished products using statistically valid sampling plans and release product only after it meets inspection criteria.

Related Procedures:

**Corporate**

541104 Labeling Guidelines, IVD

**Biotechnology**

540207 Product Finishing Label Control  
540256 Labeling Procedure for Cytokines and Antibodies Designated for Retail Sale  
540143 Literature and Label Approval Procedure  
540124 Inspection of Assembled Kits  
540467 Line Clearance

**Hematology**

6029 Labeling Control  
6029A Labeling Review Form  
9090 Product Finishing Label Control  
8809 Assay Sheet Printing and Release  
8855 Instruction Sheets – Revising, Printing and Inspecting  
3002 Labeling Guidelines



**QUALITY MANUAL**

Section Title: Material Handling, Storage and Distribution

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It is our goal to minimize damage or deterioration of products throughout manufacturing to delivery to the customer. Stability studies are conducted during development to validate recommended storage conditions.

Storage conditions for raw materials, work in process and finished goods are specified in the appropriate specifications or manufacturing procedures. Storage areas are environmentally monitored to protect product integrity. Back up generators are available in case of a power outage. Products are properly identified with part number, lot or receiving number and acceptance status before they are placed in storage areas.

Materials are handled in a manner to ensure first in-first out use when required. Materials are marked with an expiration date where appropriate. This date is monitored and outdated product is removed from stock for appropriate disposal or retesting.

Products are packaged and labeled for distribution to assure physical and functional integrity during transportation. The mode of transportation is chosen to protect the quality of the product.

Related Procedures:

- 540281 R&D Systems Shipping Procedures
- 540180 Identification and Breakdown of Expired Product in Inventory
- 540221 Validation: Stability Testing of Immunoassay Kits
- 541069 RenCS, Removing Expired Components from Inventory
- 6100 Storage of Products (Hematology)



**QUALITY MANUAL**  
Section Title: Records

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We believe that it is essential to maintain quality records not only to conform to the regulations but to also aid management in reviewing the effectiveness of our quality system and making decisions on how to improve it. The records that are maintained also demonstrate that products were manufactured to specifications and standards.

The quality records that are maintained include:

- Quality System documentation
- Device Master Records
- Device History Records
- Document Change Requests
- Calibration and maintenance records
- Internal Audit Reports and Management Reviews
- Customer Complaints
- Vendor Qualifications
- Purchase Orders
- Customer Orders and Contracts
- Personnel Records/Training records
- Design History Files (Validation Data)
- Field Notifications and Recalls

All of our records are stored in conditions to facilitate their preservation and ready access by appropriate personnel. The records are retained for at least three years, or as specified in individual SOPs or customer contracts.

Related Procedures:

- 541138 Quality Assurance Organization
- 540008 Quality Record Retention
- 540539 Archiving Documents for the RDS-ATS Laboratory
- 540534 Computer Systems Back-up Procedure