

Selleck Quality Manual

1. Selleck Quality Policy

Selleck Chemicals is committed to being the leading global supplier for research, development, and manufacturing in life science and innovative technology. To achieve our strategic vision, we must meet and exceed customer requirements. We will realize this goal by establishing and maintaining outstanding Quality and Quality Assurance standards.

2. Product Dating Information Statement

Selleck Chemicals has programs to monitor, preserve, and protect the quality of our products. For materials where shelf life information is a specific requirement, we have defined expiration and retest periods in our specifications product level information database which are used to generate corresponding expiration dates and recommend re-test dates (batch level information). The Quality Release Date on the Certificate of Analysis is the original date the batch data was reviewed against specification. If a product was retested as part of a recurring inspection or Recommended Retest, the actual Date Retested will be additionally displayed on the Certificate of Analysis. This program reflects Selleck Chemical's commitment to providing materials that meet customer requirements. When dating is indicated by month and year only, the product is expected to meet specifications until the last day of the month.

3. Shipping Conditions & Recommended Long-Term Storage

According to your experimental design, select a suitable solvent to prepare a concentrated stock solution. The information of solubility can be found on the product page of our ebsite, which is tested by our Quality Control Department. For in vitro experiments, DMSO is often used to make stock solution. Afterwards, it is diluted to make the working solution (e.g. 1:1000 dilution in cell culture medium). A typical table for solubility is explained below:

INSERT TABLE HERE

1 Shipping Conditions

When there is short-term exposure (i.e. during shipment) to conditions other than those recommended for long-term storage that will not affect product quality, Selleck will ship at ambient temperature. If you receive the product at room temperature, please rest assured, the Selleck Quality Inspection Department has conducted experiments to verify that the normal temperature placement of one month will not affect the biological activity of powder products. After collecting, please store the product according to the requirements described in the datasheet.

2 Recommended Long-Term Storage

The storage conditions that Selleck's publications and labels recommend for products are deliberately conservative. For many products, long-term storage at low temperatures will increase the time they are expected to remain in specification, and are therefore labeled accordingly.

The recommended long-term storage temperature for different types of products is different, please store according to the instructions of each product.

4. Quality System

The Quality System applies to all activities of the Company, and is fully documented and structured in the chart 1.

5. Quality Manual

This document details the corporate quality policy, structure of the Company, and references appropriate to Operating Procedures.

(1) Document Control

Quality Management System policies and procedures are maintained under document control. Procedures include administration, manufacturing, analytical methods, equipment operation and others.

(2) Training

The policy of Selleck Chemicals is to ensure that all personnel are trained and experienced to the extent necessary to undertake their assigned activities and responsibilities effectively. The company generally procures and recruits employees capable of meeting the technical, skill, experience, and educational requirements of Selleck Chemicals' activities.

All staff and senior employees are responsible for recommending the training needs of others, and for ensuring that all employees allocated specific tasks are suitably qualified and experienced to execute those tasks. Once training needs are identified, it is then the responsibility of the Directors to provide the training necessary. Full records are maintained of all training undertaken by employees.

(3) Customer Complaints

Customer complaints are communicated to the appropriate site for review and investigation. These locations have procedures that define how the complaint is investigated and, when applicable, corrected for. The procedures define the actions necessary to accomplish field corrections or to implement a recall on particular products. In the event of a recall, affected customers will be identified and contacted.

6. Supply Chain

Our suppliers' materials & services can be qualified using a combination of criteria such as assessment questionnaires, on-site audits, historical performance (quality, on-time delivery), and/or third party accreditation. New and alternative suppliers are qualified when necessary to maintain product supply, purity, and competitiveness.

7. QA/QC Staffing

The Selleck Quality Assurance / Quality Control program staffs over 35 employees.

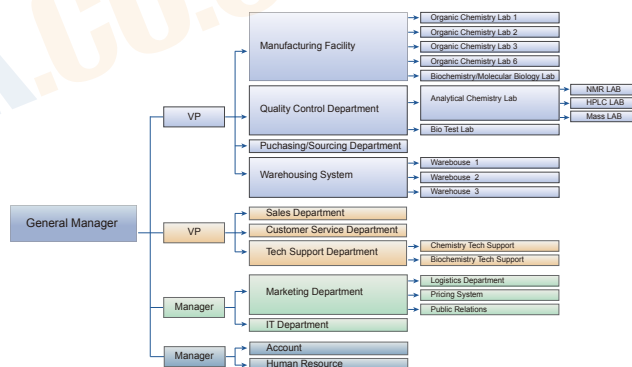


Chart 1 Departmental Organizational Structure

8. Process Control

The Selleck Quality Assurance / Quality Control program staffs over 35 employees.

(1) Procedures

Documentation exists for providing appropriate instructions for producing and testing final products. If changes to the manufacturing or testing process are warranted, the work instruction document(s) will reflect the procedural change.

(2) Equipment

Critical equipment, defined as equipment where monitoring and output are controlled and recorded, is maintained in a calibration and testing program. Where applicable, traceable standards are utilized. Documented procedures exist for equipment operation, calibration, and maintenance, and can also include how the equipment is cleaned. Equipment and usage records are maintained and available. Equipment tags are also employed to further indicate equipment calibration and maintenance status.

(3) Quality Records

Where appropriate, quality records for a product's lifecycle within Selleck Chemicals are maintained and available. Quality records may 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 for traceability throughout the entire process.

(4) Nonconformance

When a batch is determined to be nonconforming to product specifications, the batch is "flagged" in our electronic systems and may also be physically labeled and/or segregated to reflect this "blocked" status to prevent shipment. Procedures exist to describe this process.

9. Product/Batch Documentation

(1) Product Specifications & Certificate of Analysis (C of A)

The majority of Selleck 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 and formula weight
- CAS number
- Stability
- Molecular structure
- Analytical test results

Certificates of Analysis are available upon request from our Technical Services Group at www.selleck.co.jp.

(2) Analytical Test Methods

Some of the analytical methods used by the Quality Control groups to test Selleck products are available. Specific analytical methods can be requested from our Technical Service group.

(3) Product Information Sheets

Certain products include a product information sheet, which provides general product information or specific product usage instructions. Product Information Sheets can be found at www.selleck.co.jp, requested from our Technical Service group, and included in the shipment.

(4) Container Label

Product information provided on the container label include:

- Product and batch number
- Product name
- Physical chemical properties

Material is available for retest for batches that are in stock. Sample quantity availability will vary depending upon the product. Certain products may have retained material from batches no longer available. Inquire for availability on specific products.