



INNOVATIVE SOLUTIONS FOR CRITICAL ENVIRONMENTS

Valutek Quality Manual and Policy

1. Scope

The purpose of this Quality Manual is to describe and define the quality policy and the Quality Management System of Sierra Scientific, Inc. dba Valutek.

2. Company Overview

Valutek has been servicing the cleanroom and critical environment needs for thousands of customers in the pharmaceutical, electronic and biomedical industries since 1988.

Valutek offers customers best-in-class products and superior customer service. Valutek not only meets customer's demands but also consistently exceeds them and has fostered a culture of continuous improvement. Valutek has built up the reputation for quality, performance, dedication, and knowledge, providing customers with a trusted business partner that they can count on for years to come.

Valutek has been a proven technology leader focused on quality and performance. Valutek is the only manufacturer to provide ongoing independent testing at a research lab of a leading university.

3. Quality Policy

Our objective is to develop the Company as a fast growing, profitable business by providing best-in-class products and superior customer service for cleanroom and critical environment industries.

We are committed to comply with any applicable requirements and our Quality Management System and also work in line with the following principles:

- To Execute with Excellence
- To meet or exceed our customers' requirements and expectations on every occasion
- To continuously improve our processes, services and systems
- To gauge our performance by benchmarking and constant monitoring of our quality indicators in order to stay ahead of our competitors

- To involve our employees, suppliers and business partners in the improvement of our business, leading them by example and to share our success with them
- To measure our progress by self-assessment using internationally accepted standards, input from customers, suppliers, employees and by independent recognition. We will also maintain compliance with appropriate external standards

4. Organization

The Valutek quality organization is comprised of four departments

- o Operations Department
- o Sales Department
- o Finance Department
- o Marketing Department

5. Quality Management System

This section outlines in principle how the quality policy of Valutek will be achieved. It defines the quality policy, organization structure, quality responsibilities, business process and procedures.

Procedures across Valutek are defined in our Quality Management System (QMS), for example, Internal Audit, Corrective, and Preventive Action Procedures can all be easily accessed.

5.1 General Requirement

The operation and processes are continuously reviewed through means such as Monthly Business Review Meetings, Weekly Meetings, and Management Reviews.

Continuous monitoring of quality data and Key Performance Indicators (KPIs) is completed to ensure all these process management activities are carried out effectively and as per customer requirements.

Through the use of reviews, audits, process outputs and the involvement of top management, we can continually review and improve as necessary to ensure effectiveness and suitability of the QMS.

6. Management Responsibility

6.1 Management Commitment

The senior management of the company ensures that all members of the staff are aware of the need to meet customer and regulatory requirements and that the necessary resources are available.

Keeping the Company's quality policy and quality objectives current are reviewed and maintained by regular management review.

6.2 Customer focus

Customer requirements, needs and expectations are determined, and fulfilled, in order to enhance and maximize customer satisfaction.

6.3 Quality Policy

The Company has established, through its quality policy, the need to meet requirements and continually improve the effectiveness of the quality management system (QMS).

6.4 Planning

The Company has established that all relevant functions and levels within the organization have clear, measurable quality objectives that are consistent with the company quality policy plus product and service requirements.

6.5 Responsibility, authority and communication

6.5.1 Responsibility and authority

Organizational responsibilities are defined in organization charts and job descriptions. Responsibility to carry out tasks is also detailed where applicable in operating and process procedures.

6.5.2 Management representative

A member of the Company's own management has been appointed as Management Representative (MR). The Management Representative (MR) has the authority and responsibility to ensure that the Quality Management System is maintained and its efficiency is continuously improved.

The MR also has responsibility for monitoring the effectiveness of the QMS, reporting to top management on the performance of the QMS, recommending changes as required, ensuring continued suitability, and promoting the awareness of customer requirements throughout. Valutek liaises with external parties on matters arising from the quality management system such as third party or second party quality audits.

6.5.3 Internal communication

The management team will then communicate its QMS to their employees via appropriate channels e.g. email, telephone, notice boards and meetings.

6.6 Management review

Top management carries out annual review of the QMS to ensure its continual suitability, adequacy and effectiveness. The review uses data from all parts of the organization in order to identify changes or improvements to the QMS and Quality Policy.

Review input

The inputs to management reviews are:

- o Previous management review minutes
- o Audit results
- o Customer satisfaction
- o Process performance & product conformity (KPIs)
- o Corrective action and preventive action status
- o Changes that could affect the QMS
- o Recommendations for improvement

Review output

Data from the management review is to be used to identify areas of improvement to the QMS, meeting customer requirements and ensuring adequate resources are made available. Decisions and actions raised during Management Review shall be recorded and followed-up closely.

7. Resource management

7.1 Provision of resources

The Company has ensured that necessary resources are provided to implement, maintain and continually improve the QMS, and to address and enhance customer satisfaction.

7.2 Human resources

Where personnel are assigned quality responsibilities, the Company has ensured that they are competent on the basis of appropriate education, training, skills and experience.

The Company has identified the training needs for quality related activities and provides training to satisfy these needs. The performance of all members of the staff, including how they contribute to the achievement of quality objectives, is evaluated and appropriate training plans and records are maintained.

The review and identification of current and future needs is an agenda item at the management review meetings.

7.3 Company facilities and infrastructure

The Company provides and maintains suitable buildings and other workplaces with sufficient associated utilities, appropriate equipment, both hardware and software, with supporting transport, communication and other service needs.

7.4 Work environment

All aspects of human and physical factors in the work environment that effect conformity of the product have been identified and are managed. These include the control of temperature, humidity, lighting, cleanliness, protection from electrostatic charge, and other issues likely to affect the conformity of the product.

Good housekeeping practices are maintained in every department in support of an adequate and controlled work environment.

8. Product Realization

8.1 Planning of product realization

Product realization planning will be consistent with the requirements of all processes of the QMS. Where appropriate the following activities are determined at the planning stage:

- the quality objectives of the product
- the processes and documents needed to be established
- the resources required for the product
- validation and verification of the product through qualification and inspection
- Identification of records

8.1.1 Review of requirements related to the product

The Company will ensure that all the requirements related to the product are reviewed prior to any agreement to supply products to the customer. The review will ensure that:

- product requirements are defined and understood.
- any differences that are identified will be resolved prior to agreement to ship

8.2 Purchasing

8.2.1 Purchasing process

The Company will ensure that suppliers are selected on their ability to supply product in accordance with the requirements of the product and customer.

8.2.2 Purchasing information

The documentation shall be adequately reviewed prior to purchasing the product or placing orders. Any purchase order will indicate a description of goods, quantity, and price approved prior to purchase.

8.3 Production operation

8.3.1 Control of production

The Company has implemented production process control such as a Process Management Plan, Contamination Control, Schedule Attainment, Material Planning, Failure Analysis (FA), Factory Yield Management, Quality Assurance (QA), and Systems Operation.

Manufacturing Process Instructions, Procedures, Visual Aids and other relevant documentation are maintained at workstations to ensure that all build and repair activities are carried out in controlled manner. These documents will instruct personnel in the suitable use of all equipment installed within the process. Release to each stage of the production process is to be indicated in a tracking traveler. Delivery and post delivery activities will be defined and implemented for each product or service.

8.3.2 Identification and traceability

All products within the process will be identified by appropriate means such as:

- o Lot number

- o Part number
- o Tracking traveler

This identification will include the test and inspection status of the product.

8.3.3 Handling, Preservation, Storing and Shipping of Products

The Company recognizes the need to provide an effective means of handling, preserving, storing and shipping procured products. The handling, preservation and environmental control procedures are designed to prevent damage or contamination and to cover safety, shelf life, hazardous material handling, etc. with personnel trained in these requirements. Storage is in designated areas under adequate control and protection and all packaging is to specified requirement. Shipping, and associated documentation, is also recognized as part of the Company's activity that requires control and specification.

8.4 Control of monitoring and measuring devices

The Company establishes processes to ensure that monitoring and measuring is carried out in line with product and process requirements. All measurement and test equipment is subject to calibration and preventive maintenance. Preventive maintenance and Calibration are carried out at regularly scheduled intervals.

Equipment used for monitoring and measuring will be:

- o Calibrated at regular scheduled intervals.
- o Carry unique identification, such as serial number, tag number.
- o Verified as determined by throughput or critically of measurement.
- o Be stored in a safe manner to avoid damage.
Records of calibration & preventive maintenance are maintained

9. Measurement, Analysis & Improvement

9.1 General

To ensure continued conformity of the product, the Quality Management System (QMS), and to enable continual improvement, the Company will implement measurement, analysis and improvement processes, where applicable statistical techniques can be employed. These processes will

include but not be limited to audits, inspection, production and test data analysis, yield analysis, failure analysis and customer feedback.

9.2 Monitoring and measurement

9.2.1 Customer satisfaction

Valutek will maintain close contact with the customer at all times to ensure that the customer requirements are met. Regular conference calls with customers are held to review performance and customer perception. Customer complaints are logged into a QC Corrective Action Form.

9.2.2 Internal audit

All applicable processes are established and audited at planned intervals to ensure the Quality Management System is effectively implemented and maintained. These audits are used to determine whether the Quality Management System conforms to production realization planning and the Quality Management System requirement set up in this Quality Manual.

Trained personnel who are independent from his / her work will carry out audits.

The audit results are reviewed at Management Reviews to ensure the Quality Management System is continually suitable and that action items are generated to improve the Quality Management System.

9.2.3 Monitoring and measurement of processes

Methods are established to monitor and measure the Quality

Management System processes.

These methods include:

- o Internal audit
- o Process audit
- o Contamination audit
- o Customer satisfaction measurement

The results are reviewed at regular meetings to ensure planned results are achieved. If planned results are not achieved, action items will be generated to improve the process.

9.3 Control of nonconforming product

All products, which are found not to conform to product requirements, shall be identified, segregated to avoid unintended use, and reported to the customer.

Nonconforming product will not be reworked or regraded. All nonconforming products shall be rejected or scrapped.

In the event of non-conforming product reaching the customer, appropriate corrective action is taken including timely reporting with a clear description of the non-conformity and full reference to any parts affected and the date of delivery. The Company will review the need for product recall.

9.4 Analysis of data

Data to indicate the suitability and performance of the Quality Management System is collected, collated and analyzed. When changes to the Quality Management System will offer improvement, these changes are introduced.

Areas for attention are Customer rejects and complaints, Customer Satisfaction, the meeting of customer needs, conformance to product characteristics, and supplier performance.

9.5 Improvement

9.5.1 Continual improvement

Respective department heads and staff shall make use of relevant data that was collected during monitoring and measurement of processes and product to initiate necessary actions to continually improve the effectiveness of the Quality Management System.

Continual improvement of the Quality Management System will assure effectiveness of the stated quality policy, company quality objectives, department quality objectives, audit results, data analysis, corrective and preventive actions, and management review.

9.5.2 Corrective action

Corrective action shall be initiated to prevent re-occurrence when non-conformities are detected related to product, process and the Quality Management System. The most appropriate countermeasure, evaluation of need for action, determination and

implementation of corrective action, shall all be applied to eliminate the nonconformity.

The Management Representative shall review the effectiveness of the corrective action taken at management review processes.

A record of the results of the corrective actions shall be maintained.

9.5.3 Preventive action

Preventive action shall be initiated to eliminate potential non-conformities through the use of information such as contamination control & process audit trends to prevent re-occurrence. The Management Representative shall verify the effectiveness of the preventive action taken at management review processes.

A record of the preventive actions shall be maintained.