Scope

Purpose

Seralab aims to be the leading resource for a complete range of animal and human biological tools needed for the research and development of new drug discovery

We hope to achieve this by specialising in providing control and disease state matrices manufactured from human and animal whole blood, plasma and serum, which are used by our customers in drug discovery, compound development, clinical and research diagnostics.

Our mission is to expand our operations by consistently meeting our customers' expectations, and by continually improving our products and services.

Seralab is dedicated to providing a bespoke service to meet the customers' expectations on quality laboratory research products and services with particular attention to customer care, cost-effectiveness and prompt delivery.

The personnel of Seralab are committed to achieving quality through the following:

- Focusing on the customer by applying flexibility and innovation to meet specific requirements
- Developing relationships with our customers that emphasises continuous improvement in product quality, customer service and support.
- Promoting a supportive work environment that facilitates the delivery of a quality product on a consistent basis.

Applicability

Seralab's Quality Management System (QMS) applies to all activities of our Company.

From the scope of the standard (ISO 9001:2015) all clause requirements are applicable to the scope of Seralab's QMS except: 8.3 (Design and development of products and services). This is because the company does not design its products and services but provides these according to established and defined standards and customer guidance.

Document Control

Seralab maintains a document management system, M files which allows us to track, and control all documents. This ensures that only current approved documents are available for use and only authorised staff are enabled to edit documents. All documents have a unique reference number applied automatically by M files.

Procedures and Processes

Standard Processes are described in flow charts and work instructions. Reference documents are also available.

Processes performed are recorded on forms and logs to maintain traceability of product, orders, and interactions with customers.

Training

Scope

The policy of the Company is to ensure that all personnel are trained and experienced to the extent necessary to undertake their assigned activities and responsibilities effectively. Training is monitored and recorded in individual training logs for each member of staff.

Contract Review

Seralab offers a range of both, standard products and a specialised bespoke product service to meet the needs of each individual customer. Standard products are listed on the Company's web site (www.seralab.co.uk) and various e-procurement platforms for customer information and reference.

Specific product enquiries and projects are processed and recorded electronically with a formal estimate being sent direct to the customer by email. Once an estimate is accepted by the customer and an order is placed, it is recorded with the customer's unique purchase order reference. The order is reviewed to establish that the requirements of the order are adequately defined and documented, and a confirmation of the order is issued to the customer providing information on shipping and delivery.

In addition to the original order/contract specification the customer may also request additions or variations to the work to be undertaken by the Company. In these circumstances the additional work content and price is documented and agreed with the customer prior to execution of the order to ensure that no ambiguity exists.

Contract Manufacture

Manufacturing processes carried out on behalf of the Company by contract manufacturers shall be developed, validated, verified and implemented in a controlled manner. Implementation shall include appropriate audits and controls to monitor performance and quality over a period of time. Full documentation as to the manufacturing process and quality assurance testing shall form part of the product history file.

Product Traceability and Stock Control

All products are defined by part number and other identifiers that correspond to the Company catalogue, web site, data sheets, technical specifications or customer documents.

All manufactured and purchased products are identified by a unique batch number that allows traceability to purchase, source and processing history files.

Purchasing

Suppliers of product, materials and services are selected on their ability to meet the Company's requirements given due consideration to the quality, statutory regulations, timescale and cost. Due to the unique nature of some of the products supplied and requested a list of Approved Suppliers is maintained which is compiled on the following criteria:

1. Previous performance in supplying to similar specifications and requirements
2. A trial order and evaluation of performance
3. Recommendation by other similar purchasers or manufacturers
4. Compliance with statutory regulations
5. Ability to match customer specification and requirement

Scope

All supplies are subject to an authorised Purchase Order providing full description and clarification as to the type and extent of supply.

Receipt and Storage

All items received by the Company are identified and verified. The identification of product and materials is confirmed by the presence of the Company product identification number or description label or the supplier's part number or description label, or other marking for each item.

In the event of non-conformance, the goods are segregated in the appropriate quarantine area.

Product is stored at the temperature dictated by the manufacturer, supplier or as indicated on the product information sheet.

Handling, Packaging and Delivery

All products are carefully checked for content and product details are checked against Customer Orders before labelling and are packaging for transportation. Transportation to a customer shall be carried out by a third-party company to be nominated either by the Company or by the customer.

Customer Complaints and Non-Conformances

All customer complaints and non-conformances are subject to review and rectification by nominated personnel. The type and extent of the complaint is documented in order to establish trends, identify possible areas for improvement and ensure customer satisfaction.

The corrective action required to prevent recurrence or resolve the issue is evaluated, documented and its effective implementation monitored. All rectification is subsequently reviewed to ensure customer satisfaction.

The investigation and rectification of all non-conformances are logged and monitored. All employees are encouraged to suggest improvements in methods, materials and suppliers.

Monitoring of QMS

Internal audits are an important part of evaluating the performance of our QMS processes. It is not only used to identify the need for corrective actions, but also to identify opportunities for continual improvement of the QMS processes.

Management review is used as a tool for reviewing the overall QMS system to ensure that the processes are effectively integrated together.

It allows us a chance to look at the QMS performance so that we can see where the system is functioning well and where it needs improvement, and come up with improvements needed to maintain and modify the system, gather any information we need where we are improving, which is why we implement ISO 9001 in the first place.

Internal Audits

Internal audits of all processes are undertaken at least once a year to confirm that the function concerned is adhering to the standard processes. Audits are undertaken by staff not directly responsible for the functions being audited within the Company. An audit report is completed

detailing any non-conformances observed and dates for timely rectification are agreed by staff responsible and Quality Assurance.

Management Review

A Management Review of the suitability and effectiveness of the Quality System takes place at least twice a year. During the management meetings, a review of the reports which are used to monitor various activities is carried out. An assessment of the status of all relevant interested parties and other pertinent issues is also performed. Actions are allocated and logged to record the development of the Seralab's quality management system and to promote continuous improvement