somalogic

Summary of SomaLogic's **Quality Management System**

The Quality Management System enables a Total Quality Management approach and culture.

General

SomaLogic has established, documented, and implemented a Quality Management System (QMS) in accordance with the appropriate requirements from regulations and standards.

The top document is the SomaLogic Quality Policy. Following the Quality Policy is the SomaLogic Quality Plan, which in turn describes two Quality Manuals, the Products Quality Manual and the Laboratory Services Quality Manual. Processes are established with process owners who monitor the health of their respective processes through key performance indicators (KPIs) that are reviewed and assessed during regular quality management reviews. The Quality Management System enables a Total Quality Management approach and culture.

Documentation

Documents are revision-controlled, readily identifiable, legible, and accessible. Records provide evidence of conformity to SomaLogic procedures. Documents and records are kept current and are retained in an electronic QMS (eQMS) system.

Management Responsibility

Management Commitment

SomaLogic's Executive Committee, its top management, is committed to a strong QMS that complies with appropriate regulatory requirements and standards. The Executive Committee ensures an adequate organizational structure is in place with the necessary resources to develop and implement quality planning and objectives.

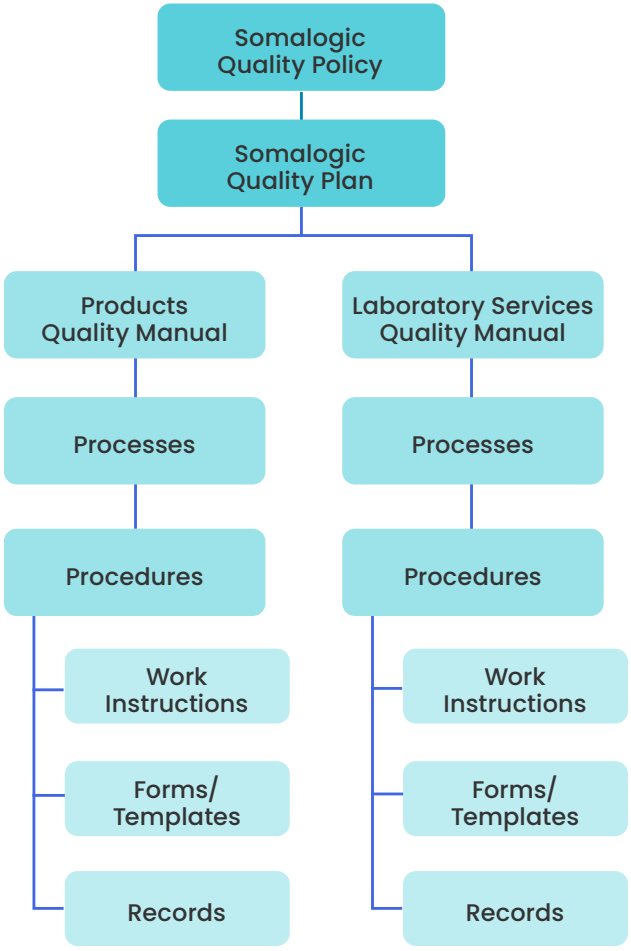
Customer Focus

Somalogic's Executive Committee ensures that customer requirements are determined and met via marketing research prior to product development, release and post-market surveillance methods. With customer needs in focus, SomaLogic has an established customer support program to capture customer feedback and complaints, with clear and open communications to resolve concerns.

Quality Policy

There is one common Quality Policy across SomaLogic. This is a key input into the QMS. The policy is found in the eQMS and is approved by the Chief Executive Officer (CEO), ensuring a shared commitment to quality in proteomics applications to both research and healthcare, with good professional practice, compliance, and continual improvement in support of delivering to SomaLogic customers.

Figure 1: Hierarchy of Quality Management System documented information



Resources

People & Culture

SomaLogic ensures that personnel are competent to perform work directly or indirectly affecting product quality and services. Training and competency requirements and records are documented.

Infrastructure

SomaLogic determines, provides, and maintains the infrastructure needed to achieve conformity to product, services and QMS requirements while complying with applicable global standards and national standards for each country. Infrastructure includes buildings, workspaces, utilities, information systems, cybersecurity, manufacturing and laboratory equipment, supporting services and requirements for maintenance.

Work Environment

SomaLogic ensures a proper work environment to achieve product/service quality via QMS requirements. This includes control or minimization of contaminants that have the potential to adversely affect product quality (such as dust, humidity, and insects), control of contaminated or potentially contaminated products, to prevent contamination of other products, the work environment, or personnel, as well as control of the physical environment and other factors such as temperature and humidity.

Laboratory Services

SomaLogic is a CAP-accredited and CLIA certified laboratory and is accredited to ISO 15189:2012. The laboratory activities encompass end-to-end processing including order intake, sample receipt and processing, SomaScan assay, and bioinformatics data analysis and reports generation. Each assay includes well characterized controls, thorough documentation, and Quality Assurance reviews. Good Laboratory Practices (GLP) are in place with support from a Study Director and additional QA oversight, available for customers with those specific needs. The Laboratory Director heads the department and ensures there is appropriate management and oversight for all laboratory operations.

Product Realization and Customer Support

Planning of Product Realization

SomaLogic has processes for planning of product realization and identification of required resources.

The product realization procedures determine quality requirements for the product, needed processes, documents, and resources specific to the product, required specifications, verification, validation, monitoring, measurement, inspection, and test activities specific to the product, criteria for product acceptance and records required for evidence that the realization processes and resulting product meet requirements.

Customer Support

SomaLogic has processes to communicate with customers. These processes address product information, inquiries, contracts, order handling, including amendments. The Customer Support organization receives customer feedback, including appropriate handling, reporting, and communication to Quality Assurance for investigation of customer complaints and notifications of quality issues for delivered products. Customer support provides change control notifications where required and defines responsibilities for communication with customers.

Product Design Controls

Design Planning

SomaLogic has processes for the design and development planning for products. These design and development plans include identification of relevant roles and responsibilities, identification of design and development stages with appropriate design review(s) of design inputs, design verification, design transfer, and validation prior to the product release / design transfer.

Design plans are documented, approved, and updated as appropriate throughout the design process to reflect the status of the design and development effort.

Design Inputs

SomaLogic has processes for the development of product design input requirements to address the intended use(s) of the device, including the needs of the user and patient. These include the product's functional performance, and safety requirements, intended use and user needs (product usability), applicable statutory and regulatory requirements, information derived from previous similar

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designs where applicable. Other requirements essential for design, development, purchasing, manufacturing, installation, cybersecurity and service are included in design inputs, as well as respective output(s) of risk management activities.

SomaLogic's design input procedures require that design input requirements must be adequate, verifiable, complete, unambiguous, and not in conflict with each other. Design inputs are reviewed for adequacy, approved, and maintained per established procedures.

Design Outputs

SomaLogic has processes to ensure design outputs are documented in terms that provide for verification against the design input requirements. Design outputs are verified and are approved prior to release to ensure conformance to design input requirements. Design outputs include or reference acceptance criteria, identify characteristics of the product that are essential for its safe and proper use and provide information for purchasing, production, installation, and the provision of service.

Design verification & validation

SomaLogic has design verification processes, which demonstrate that the design output meets the design input requirements. And where required, SomaLogic performs design validation to demonstrate the user needs are met in the design. Design validation is performed under actual or simulated use conditions representative of the environment in which the product will be used.

Design and Technical reviews

SomaLogic has processes that define the appropriate stages for systematic reviews of the design. Design reviews are planned and performed at appropriate stages and documented. These reviews include an evaluation of the design outputs to meet design input requirements and user needs and identification of potential problems and proposed necessary actions. Technical reviews are carried out to assess the adequacy and robustness of the design.

Reviewers include representative functions concerned with the design stage(s) being reviewed as well as identified independent reviewers not directly responsible for the product design.

Design transfer

SomaLogic has design transfer activities that define how the design is translated into procedures for production, installation, and service for the product. Design transfer includes activities that are performed on the product to validate the production, installation, and service processes. Design transfer activities during the design process ensure that design outputs are verified as suitable for manufacturing before becoming final production specifications.

Design changes

SomaLogic has design change processes that define how changes are proposed, reviewed, approved, and incorporated into a product. Design changes are modifications that may affect requirements for form, fit, function, interchangeability or compatibility of a part or assembly; software/firmware; or require change to the assembly or testing of the final product or its materials.

Design records

SomaLogic maintains a design history file for each product demonstrating the design was developed in accordance with the approved design and development plan.

Purchasing Controls and Supplier Management

SomaLogic ensures that purchased products, processes, or services conform to specific requirements, including verification of purchased product/service. SomaLogic also selects suppliers according to defined criteria per procedure.

SomaLogic takes a risk-based approach to determining the level of supplier control needed based on product criticality, supplier performance and other criteria defined in procedures.

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Production and Service Provision

Control of Production and Service Provision

SomaLogic has processes for production and service provision that include documented procedures, documented requirements, work instructions, and measurement procedures to ensure product quality, the availability and use of suitable monitoring and measuring systems, the implementation of controlled processes for release of product, delivery and post-delivery activities, as well as labeling and packaging.

Installation Activities

SomaLogic develops, provides, and maintains procedures and documentation required to carry out installation and verification activities. SomaLogic establishes acceptance criteria for verifying installation of products at the customer site. Records of installation and verification are documented and retained.

Identification and Traceability

SomaLogic has processes for product identification and quarantine of nonconforming products. SomaLogic provides necessary controls to ensure traceability.

Preservation of Product

SomaLogic has processes for preserving and protecting the product, including identification, handling, packaging, storage, distribution and delivery.

SomaLogic has processes for the control of products with a shelf life or products that require special storage conditions.

Change Control

SomaLogic procedures define the evaluation of changes to QMS processes, design, manufacturing, testing, labelling, and packaging. Anything that may impact the quality of products is processed through change control. Change requests are evaluated and, following approval, change orders defining actions needed to execute the change are established, reviewed, approved and executed, with verification and validation of the change defined as needed. Stakeholders and interested parties are identified and notified as needed.

Monitoring of Processes and Products

SomaLogic has an internal audit program to evaluate and ensure compliance to the overall QMS and application of respective procedures. SomaLogic and process owners identify key performance indicators (KPIs) to ensure processes remain in control. These are reviewed regularly with actions taken for any KPIs that may go off target. Products are monitored through quality control for key measures to ensure product meets requirements.

Continual Improvement

SomaLogic seeks trends through monitoring to identify larger opportunities for improvement, ensuring the effectiveness and suitability of the Quality Management System.

Internal Audits

SomaLogic conducts periodic internal audits to evaluate that the organization is adhering to the QMS. The audits ensure conformance to applicable regulations, standards, other requirements and guidelines as well as conformance to Quality Management System requirements established by SomaLogic. Internal audits ensure that these requirements have been effectively implemented and maintained.

The audit criteria, scope, frequency, and methods are defined and documented.

The management responsible for the area being audited ensures corrections and corrective and preventive actions are taken to address detected nonconformities and their causes. Audit results, including the timeliness and effectiveness of corrective actions, are reviewed by management.

Control of Nonconforming Product

SomaLogic has established and maintains procedures defining the controls and related responsibilities and authorities for dealing with nonconforming products and potentially nonconforming products, ensuring product or delivery of service which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

SomaLogic takes actions where applicable to disposition nonconforming product including rejection of the nonconforming product, addressing the detected nonconformity, authorizing its use, release, or acceptance of the nonconforming product if a thorough investigation supports such disposition, including documented rationale and approval. SomaLogic also takes actions appropriate to the effects or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

Complaints Management and Post-Market Surveillance

SomaLogic has established and maintains a process for timely complaint handling. Complaint Handling procedures include requirements and responsibilities for receiving and recording information, evaluating information to determine if the feedback constitutes a complaint, investigating complaints, determining the need to report the information to the appropriate regulatory authorities, and determining the need to initiate corrections or corrective actions.

Continual Improvement and CAPA

SomaLogic identifies and implements any changes necessary to ensure and maintain the continued suitability, adequacy, and effectiveness of the Quality Management System using SomaLogic Quality Policy, quality objectives, audit results, analysis of data, corrective and preventive actions (CAPA), and Management Review. Proposed Quality Management System changes are assessed for regulatory implications, documented, and approved.

SomaLogic takes appropriate action to address the cause of nonconformities in order to reduce likelihood of recurrence.

SomaLogic has established and maintains procedures to assure the causes of potential nonconformities are addressed in order to reduce any likelihood of their occurrence.

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somalogic®

Founded in 2000, SomaLogic® is a global leader in proteomics. Our pioneering SomaScan® Platform provides more coverage of the proteome than any other technology, measuring 7,000 proteins from only 55 µL of a variety of body fluids, including plasma, serum, CSF, urine, and more.

The proprietary SomaScan Assay measures proteins with high specificity, high throughput, and high reproducibility, which enables the possibility of faster, more precise drug discovery. Our A.I. and machine learning-powered bioinformatics algorithms, operated in tandem with the company's database of more than 550,000 protein samples, helped to create a growing suite of SomaSignal™ tests. These tests are clinical proteomic diagnostics that provide additional insights into the current health status of patients and the future risk of conditions and diseases. Custom and disease-specific panels are also available for a more targeted approach.

LEARN MORE - https://somalogic.com/somascan-assay

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QMS White Paper