Summary of Cytiva's Quality Management System

cytiva

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General

Cytiva has an established, documented, and implemented QMS in accordance with the appropriate requirements of regulations, standards, and stakeholder expectations.

Each site has a specific Site Quality Plan providing a cross- reference between the Global Quality Manual and the Quality Procedures and Work Instructions that define the site's QMS.

Internal audit programs are in place to ensure that the QMS complies to the requirements and is effectively implemented and maintained.

Documentation

Relevant documents are revision controlled, legible, readily identifiable, and accessible. Relevant records provide evidence of conformity to regulatory requirements and company procedures.

Documents and records are maintained and retained in accordance with applicable requirements and standards.

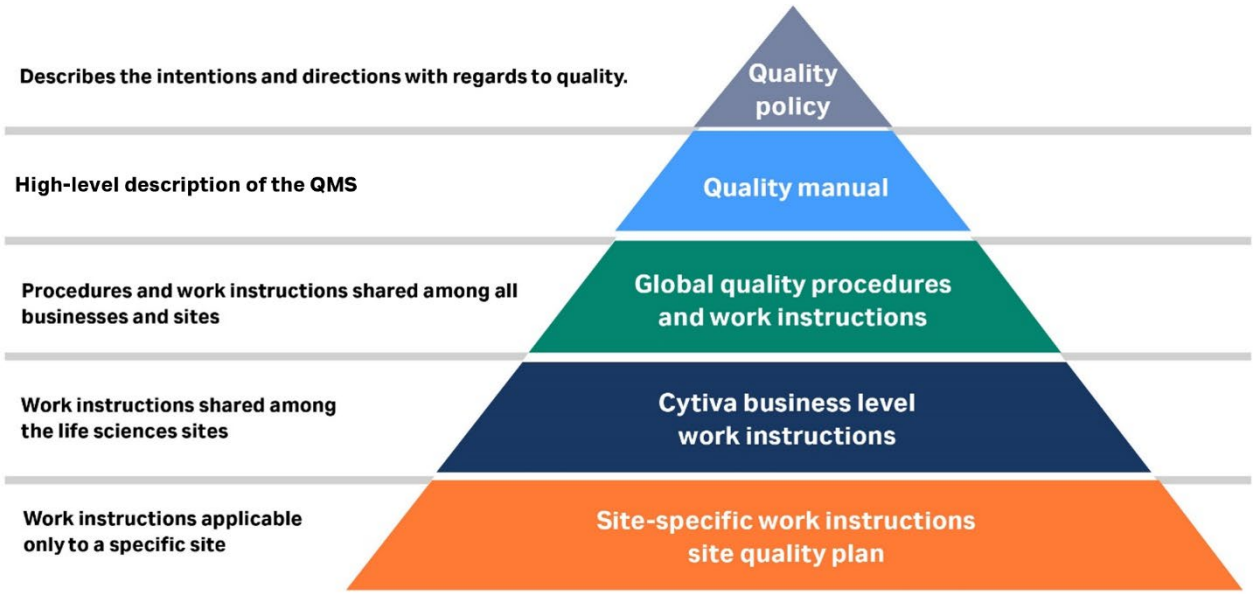

Figure 1 illustrates the various levels of QMS documentation.

Management responsibility

Management commitment

Cytiva is committed to a strong QMS that complies with appropriate regulatory requirements and standards. This is achieved by providing an adequate organizational structure and the necessary resources to develop and implement quality planning and objectives.

Customer focus

Management ensures that customer requirements are determined and met via marketing research prior to product release and post-market surveillance methods. Multiple methods are adopted to drive customer satisfaction including customer communications and customer feedback response.

Quality policy

There is one common Quality Policy across Cytiva. This policy has been documented and communicated throughout the organization. The Quality Policy is approved by the President and CEO and VP QA/RA and ensures commitment to improving customer satisfaction in our products and services, compliance with laws and regulations, continual improvement and maintaining the effectiveness of the QMS.

Resource management

Human resources

Cytiva ensures that personnel performing work directly or indirectly affecting product quality have the appropriate education, training, skills, and experience. Training requirements and results are documented.

Infrastructure

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

Work environment

Cytiva manages the work environment needed to achieve product quality and QMS requirements, which includes:

- The health, cleanliness, and clothing of personnel
- 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
- Control of the physical environment and other factors such as temperature and humidity

Product realization

Planning of product realization

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

The product realization procedures determine the following:

- Quality objectives and 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
- Records needed to provide evidence that the realization processes and resulting product meet requirements

Customer-related processes

Determination of requirements related to the product Cytiva determines:

- Requirements specified by the customer, including the requirements for delivery and post-delivery activities
- Statutory and regulatory requirements related to the product
- User training needed to ensure specified performance and safe use of the product
- Any additional requirements considered necessary by Cytiva

Review of requirements related to the product

Cytiva has processes for accurately reviewing the requirements related to the product. This review is conducted prior to a commitment to supply a product to the customer.

The controls include a process to evaluate and confirm the following:

- Product requirements are defined and documented
- Contract or order requirements differing from those previously expressed are resolved
- Cytiva can meet those requirements
- User training is available or planned to be available
- The results and actions arising from the review are documented and retained

Customer communication

Cytiva has processes to communicate with customers. These processes address:

- Product information
- Inquiries, contracts, order handling, including amendments
- Customer feedback, including appropriate handling, reporting, and investigation of customer complaints
- Notifications of quality issues for delivered products
- Change control notifications
- Definition of responsibilities for communication with customers and regulators

Design and development

Design planning

Cytiva has processes for the design and development planning for products.

Design and development plans include:

- Identification of relevant roles and responsibilities
- Identification of design and development stages and handoffs
- Design review of design inputs, design verification, design transfer, and validation prior to the product release

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

Cytiva has processes for the development of appropriate product design input requirements to address the intended use(s) of the device, including the needs of the user and patient.

Design inputs include:

- Product's functional, performance, and safety requirements
- Intended use and user needs (product usability)
- Applicable statutory and regulatory requirements
- Information derived from previous similar designs where applicable
- Other requirements essential for design, development, purchasing, manufacturing, installation, cybersecurity and service
- Output(s) of risk management

Cytiva'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

Cytiva 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. Design outputs shall:

- Be verified for conformance to design input requirements
- Include or reference acceptance criteria
- Identify characteristics of the product that are essential for its safe and proper use
- Provide information for purchasing, production, installation, and the provision of service

The final design output is the verified and validated finished product, including labelling, packaging, and the specifications for purchasing materials, manufacturing procedures, assembly drawings, software code, acceptance criteria, test procedures, service and installation manuals, and operator instructions.

Design and Technical reviews

Cytiva has processes that define the appropriate stages for systematic reviews of the design. Design reviews are planned and performed at appropriate stages and documented. Design reviews include:

- An evaluation of the design outputs to meet design inputs requirements
- Identification of potential problems and proposed necessary actions

Technical reviews are carried out to assess the adequacy and robustness of the design.

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

Design verification

Cytiva has design verification processes, which demonstrate that the design output meets the design input requirements.

Design transfer

Cytiva has design transfer processes 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 validation

Cytiva has design validation processes, which ensure that the product meets the user needs and intended uses.

Design validations are performed on production or production equivalent units, lots, or batches of the finished device.

Design validation is performed under actual or simulated use conditions representative of the environment in which the product will be used.

Design validation is completed prior to the delivery or installation of the product.

Design changes

Cytiva 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, 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 components.

Design records

Cytiva maintains a design history file in accordance with approved procedures for each product. The design history file contains records necessary to document that the design was developed in accordance with the approved integrated design plan.

Purchasing Controls and Supplier Management

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

The type and extent of control exercised to the supplier depends on product type, impact of the supplied product on the quality of the final Cytiva product, quality audit reports, and previously demonstrated capability and performance. Records related to suppliers, including evaluations, qualification activities, tendering, and any necessary actions arising from evaluations, are retained. Supplier performance is assessed and developed.

Production and service provision

Control of production and service provision

Cytiva has processes that address production and service provision under controlled conditions. These include:

- The availability of information that describes the characteristics of the product
- The availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary to ensure product quality
- The availability and use of suitable monitoring and measuring devices/equipment
- The implementation of suitable monitoring and measuring techniques
- The implementation of release of product, delivery, and post- delivery activities
- The implementation of labelling and packaging processes

Installation activities

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

Identification and traceability

Cytiva has processes for appropriate product identification and, as appropriate, isolation of returned products to prevent mix-ups with conforming products.

Where traceability is a requirement, Cytiva provides necessary controls to ensure traceability.

Preservation of product

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

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

Change management

Cytiva has a structured approach to evaluate changes to QMS processes, design, production and processes, manufacturing, testing, labelling, and the form/fit/function of products. Such changes are evaluated, actions identified for verification and validation of the change, implemented and communicated to the impacted stakeholders as identified (regulatory agencies for regulated products, customers).

Control of monitoring and measuring devices

Cytiva identifies the monitoring and measuring devices needed to provide evidence of conformity of products to predetermined requirements. Records of the results of calibration and verification activities are retained. When software is used in the monitoring and measurement of specified requirements, the ability of the software to satisfy the intended application shall be validated.

Measurement analysis and improvement

Cytiva has planned and implemented the monitoring, measurement, analysis, and improvement processes needed to demonstrate conformity to product requirements, ensure conformity of the Quality Management System and maintain the effectiveness of the Quality Management System. This plan includes determination of applicable methods, including statistical techniques, and the extent of their use. The company has established documented procedures for implementation and control of the application of statistical techniques and their results recorded and maintained.

Internal Audits

The company conducts periodic internal audits to evaluate that the organization:

- Conforms to applicable regulations, standards, other requirements and guidelines
- Conforms to Quality Management System requirements established by the company
- Ensures 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

The company has established and maintains procedures defining the controls and related responsibilities and authorities for dealing with 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.

The company takes one or more of the following actions where applicable to disposition nonconforming product:

- Rejection of the nonconforming product
- Taking action to address 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
- Taking actions appropriate to the effects or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started

Complaint Handling

The company 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
- Handling of complaint-related product
- Determining the need to initiate corrections or corrective actions

Improvement and CAPA

The company identifies and implements any changes necessary to ensure and maintain the continued suitability, adequacy, and effectiveness of the Quality Management System using the company 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.

The company has a nonconformity and corrective action framework. The company takes appropriate action to address the cause of nonconformities in order to reduce likelihood of recurrence.

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