Cytiva
Björkgatan 30
75184 Uppsala
Sweden

Dear Valued Customer:

Thank you for your interest in Cytiva. In order to contribute to the harmonization of industry practice Cytiva's is using standard questionnaire in the Rx-360 Consortium standard format, http://rx-360.org to respond on customer questionnaire.

The Rx-360 questionnaires are complemented with Cytiva documents and web links with more information about our company and products. To ensure that you will always have current information available, we strive to supply web-based information as much as possible. The "Document Index" (attached) summarizes available information and where it can be found.

We have developed several Rx-360 packages covering Cytiva's product lines. The documents and links in each Rx-360 package are compiled based on questionnaires from our customers and other biopharmaceutical manufacturers around the world.

Yours Sincerely,

DocuSigned by:
BA31FDD60C644A5...

Henrik Norberg
Customer Regulatory Support Leader

Document Index including attachments and links

Information	**Information available at**
Module 1 Rx-360 Cytiva Company Information - Quality management system	Attached
General Regulatory Statement	www.cytiva.com/RegulatoryStatements
ISO certificates	www.cytiva.com/qualitymanagement
Regulatory Support Documents Change Control Notifications	www.cytiva.com/rsf
Information about Cytiva Regulatory Support Documentation and web service.	www.cytiva.com/rsf

☒ Please check here if additional documents are attached.

Summary of Cytiva's Quality Management System.

SECTION 1. General Company Information	
1.1	Company Name: **Cytiva**
1.2	Company Address: **Cytiva has four main reginal addresses:** **Marlborough, USA:** **100 Results Way, 01752 Marlborough, Massachusetts, USA** **Amersham, United Kingdom:** **Amersham Place, Little Chalfont, HP7 9NA Buckinghamshire, United Kingdom** **Uppsala, Sweden:** **Björkgatan 30, 751 84 Uppsala, Sweden** **Shanghai, China:** **No.1, Hua Tuo Rd. Zhangjiang Hi Tech Park, 201203 Shanghai, China** GPS Coordinates:
1.3	Phone: **Please visit www.cytiva.com/support/contact-us**
1.4	Respondent or General Quality Department Email: **Please visit www.cytiva.com/support/contact-us**
1.5	Fax: **N/A**
1.6	Website: **www.cytiva.com**
1.7	Facility Establishment Identifier: **N/A**
1.8	DUNS Number: **N/A**

1.9	If there is an individual contact for the following areas, please provide name and preferred contact information *(at a minimum, name and telephone number or email)*: Quality: **Please visit www.cytiva.com/support/contact-us** Technical Services: **Please visit www.cytiva.com/support/contact-us** Commercial/Business/Sales: **Please visit www.cytiva.com/support/contact-us** Preferred Primary Contact: **Please visit www.cytiva.com/support/contact-us**
1.10	Please list other subsidiaries operating under the company: **Cytiva has over 16,000 employees and operations in 40 countries and is part of the Danaher Corporation.**
1.11	Is your company and affiliates willing to have Rx-360 conduct audits on behalf of your customers according to the Rx-360 audit programs? **Yes** *Learn more at http://rx-360.org/audit-programs/*
1.12	If Rx-360 has performed audits at your sites, please state site and date of the audit: **Many Cytiva sites have been audited by Rx-360, for more information please visit https://rx-360.org/audit-program/licensable-audit-reports/**
1.13	Please list the general product groups manufactured by the company: **Cytiva provide expertise and tools for a wide range of biotechnology, life sciences applications and laboratory products.**
Additional comments:	

SECTION 2. General Company Operating Information

2.1	What year was the company established? **Danaher acquired Pall (founded 1946) in 2015 and GE Healthcare Life Sciences' Biopharmaceutical business 2020 (Whatman™ founded 1733) and named it Cytiva. In 2023 Cytiva and Pall merged and are now doing business as Cytiva.**
2.2	Is the legal ownership structure of the company public or private? If other, please elaborate. **Cytiva is a wholly-owned operating company of Danaher Corporation. Danaher is a public company**
2.3	If public, what is the company's stock symbol and on which exchanges is it listed? **NYSE: DHR**

2.4	How many manufacturing sites does the company have? **Over 35 manufacturing sites** **See appendix 1**
2.5	Does the company have a corporate Quality Assurance Division? **Yes**
2.6	Does the company have any of the following written policies at the corporate level? If so, please provide policy number and title.
2.6a	Environmental? **EHS Policy please visit www.cytiva.com/rsf**
2.6b	Quality Assurance? **Quality Policy please visit www.cytiva.com/rsf** **ISO certificates please visit www.cytiva.com/rsf** **Summary of Cytiva's Quality Management System, attached**
2.6c	Health and Safety? **EHS Policy please visit www.cytiva.com/rsf**
2.6d	Global Citizenship / Corporate Responsibility? **https://sustainability.danaher.com/**

Additional comments:

I (Supplier) confirm that the information provided in this questionnaire is correct and can be verified.

Signature: DocuSigned by: BA31FDD60C644A5...

Printed Name: **Henrik Norberg**

Title: **Customer Regulatory Support Leader**

Date: 18 of April 2024

Telephone Number:

Email Address: **Please visit www.cytiva.com/support/contact-us**

Appendix 1

Cytiva manufacturing sites				
Country		**Scope of the site**	**ISO certification**	**Legal Entity**
Austria	Kremplstrasse 5, 4061 Pasching, Austria	Manufacture and distribution of consumable cell culture products (liquid and powder)	ISO 9001 ISO 13485 ISO 22301 ISO 14001	Global Life Sciences Solutions Austria GmbH & Co KG
Belgium	Reugelstraat 2, 3320 Hoegaarden, Belgium	Provider of single-use processing & packaging technology solutions for the biopharmaceutical, micro-electronic & related clean room environments.	ISO 9001 ISO 14001	Pall Life Sciences Belgium BV
Canada	4560 Tillicum St Burnaby, BC, V5J 5L4 Canada	Manufacture of aseptic filling units	ISO 9001	Vanrx Pharmasystems Inc.
Canada	655 W Kent Ave N Vancouver, BC, V6P 6T7	Design, Manufacturing and Sales and service of pre-clinical and clinical equipment and reagent product used in the production of biotechnology products in the field of nanoparticle drug delivery	ISO 9001	Global Life Sciences Solutions Canada ULC
China	Room 201, Building 22, No.12 Juyuan Middle Road, Shunyi District, 101300 Beijing, P.R. China	Design, Manufacturing and Sales of Pharmaceutical Single Use Systems Including Film, Bags and Related Manifolds; Manufacturing and Sales of Filtration Associated Accessories	ISO 9001	Pall Biotech (Beijing) Co Ltd
China	No.88, Daerwen Road, Pudong New District, Shanghai, China, 201203	Filter and single-use system validation services, filter application technical support. Design, project management and testing of filtration, separation, purificati on systems and equipment.	ISO 9001	Pall Biotech (Beijing) Co Ltd
China	No. 1568 Chunjiang East Road, 311500 Tonglu 33, China	Design and development, production of filter paper for medical use	ISO 9001 ISO 13485 ISO 14001	Cytiva Bio-technology (Hang Zhou) Co., LTD
Germany	Planiger Str. 137, 55543 Bad Kreuznach, Germany	Sales and testing of products and accessories for filtration, separation and purification & equipment technologies for detection and testing.	ISO 9001 ISO 50001	Pall Modultechnik GmbH
Germany	Rotlay Mühle 55545 Bad Kreuznach, Germany	Development, design, testing, manufacturing of products and accessories for	ISO 9001 ISO 22301 ISO 14001	Pall Modultechnik GmbH

		filtration, separation and purification for the food and beverage industry as well as for chemical and pharmaceutical products.	ISO 45001	
Germany	Hahnestraße 3, 37586 Dassel, Germany	Design and Development, Manufacturing, Development and Manufacturing Services and distribution of Sterile and non-sterile paper - and membrane products for separation and analysis purposes in medical device applications	ISO 9001 ISO 13485 ISO 14001	Global Life Sciences Solutions Germany GmbH
India	Survey No 275/2, 282/1, 283/1, Plot no. 4, Village Maan, Taluka- Mulshi, District – Pune- 412108, India	Design, project management, manufacture, assembly, testing installation, commissioning and after sales services of filtration, separation, purification systems and equipment.	ISO 9001	Cytiva India Pvt Ltd
Netherlands	Nijverheidsweg 1, 1671 GC Medemblik, The Netherlands	Manufacture and distribution of sterile and non-sterile containers and systems of polymer materials for storage and processing of substances for medical, (bio)pharmaceutical and veterinary applications.	ISO 9001 ISO 14001	Pall Medistad B.V.
New Zealand	433 Old Highway, RD8, Tauranga, North Island, 3180, New Zealand	Manufacture and distribution of New Zealand and Australian sourced Serum products	ISO 9001 ISO 13485 ISO 22301	Global Life Sciences Solutions New Zealand
Puerto Rico	194 Pall Boulevard, #99 & 100, Fajardo, 00738, Puerto Rico	Manufacture of Disposable Filter Cartridges for the Bio-Pharmaceutical, Health Care Products, Laboratory, Electronics, Food and Beverage, Single Use Technologies and General Industrial Processing Applications. Provision of Scientific and Laboratory Services.	ISO 9001 ISO 13485 ISO 14001	Pall Life Sciences Puerto Rico, LLC
Sweden	Mariehemsvägen 212, 906 52 Umeå, Sweden	Hardware manufacturing site for instruments, accessories, and spare parts	ISO 9001 ISO 22301 ISO 14001	Cytiva Sweden AB
Sweden	Björkgatan 30, 751 84 Uppsala, Sweden	Research, development and manufacturing of Resins and other chemical products Manufacturing of hardware (Customized Bioprocess	ISO 9001 ISO 13485 (Ficoll-paque PREMIUM) ISO 22301 ISO 14001	Cytiva Sweden AB

		Solutions) Research and development of software		
Singapore	Global Life Sciences Solutions Singapore Pte Ltd. 25 Tuas South Street 1, Singapore 638034, Singapore	Manufacture and Distribution of consumable cell culture products (dry powder media)	ISO 9001 ISO 13485 ISO 22301	Global Life Sciences Solutions Singapore Pte Ltd.
Switzerland	Route du Petit-Eysins 1 1262 Eysins Switzerland	Design and Development, Production, Distribution and Servicing of Equipment and Disposables for Processing Blood, Blood Derivatives and Cellular Products	MDSAP ISO 13485 ISO 14001	Biosafe S.A
Switzerland	3 Avenue de Tivoli, 1700 Fribourg, Switzerland	Design, project management, procurement, testing, manufacturing, sales, marketing and service of products, systems and accessories for filtration, separation and purification and equipment technologies for detection and testing – and oversight of these activities undertaken various toll manufacturing sites	ISO 9001 ISO 13485	Pall International SARL
Switzerland	Allée des moulins 3, 1274 Grens Switzerland	Design, development, manufacture and service of device and disposables for processing blood and cellular products	ISO 9001	Biosafe S.A
United Kingdom	Sovereign House Vision Park Cambridge CB24 9BZ, United Kingdom	Design, development, control of manufacture and service of Biopharma Equipment and Software	ISO 9001 ISO 13485	Asymotote LTD
United Kingdom	The Maynard Centre, Forest Farm. Estate, CF14 7YT, Whitchurch, Cardiff, United Kingdom	Sales and services of chemicals, manufacturing of devices and instruments for life sciences	ISO 9001 ISO 13485	Global Life Sciences Solutions Operations UK Ltd
United Kingdom	Station Road, Ilfracombe, EX34 8BH, United Kingdom	Manufacture of fine and ultrafine filters and accessories for gas, liquid and diagnostic product applications.	ISO 9001 ISO 22301 ISO 14001 ISO 45001	Pall Manufacturing UK Limited
United Kingdom	St Columb Major, TR9 6TT, United Kingdom	Manufacture of filtration products for use in medical applications. Manufacture of filtration media for use in healthcare and industrial applications.	ISO 9001 ISO 13485 ISO 22301 ISO 14001 ISO 45001	Pall Manufacturing UK Limited

United Kingdom	Walton Road, Farlington, Portsmouth, PO6 1TD, United Kingdom	Design, project management, manufacture and service of fluid filtration equipment, separation, purification and single use systems, including filter housings, filter elements, fermentation and monitoring equipment and associated accessories and cleaning services for gas and liquid applications. Calibration, service and repair of Palltronic Instrumentation.	ISO 9001 ISO 22301 ISO 14001 ISO 45001	Pall Manufacturing UK Limited
United Kingdom	5 Harbourgate Business Park, Southampton Road, Portsmouth, PO6 4BQ, United Kingdom	Design, Development, Testing, Validation, Sales & Marketing of Filtration, Separation and Detection equipment technologies. Provision of Technical Support and Laboratory Testing, including Validation Services to PALL Corporation and its Customers.	ISO 9001	Global Life Sciences Solutions Operations UK Ltd
USA	816 Berry Shoals Road, Duncan, SC, United States	Manufacture and distribution of sterile and non-sterile containers and systems of polymer materials for storage and processing of substances for medical, (bio) pharmaceutical and veterinary applications	ISO 9001	Cytiva US LLC
USA	225 Marcus Boulevard, Hauppauge, NY, 11788, United States	Manufacture of Surface Modified Materials, Lamination of Proprietary Membranes, Ultra-Filtration/Micro-Filtration Membranes, and Cassettes for Use in Life Science and Industrial Applications.	ISO 9001 ISO 14001	Cytiva US LLC
USA	925 West 1800 South, 84321 Logan, Utah, USA	Design, manufacture and distribution of consumable cell culture products	ISO 9001 ISO 13485 ISO 22301 ISO 14001	HyClone Laboratories LLC
USA	8780 Ely Road, Pensacola, FL, 32514, United States	Manufacture of Microporous Membrane and Melt Blown Media.	ISO 9001 ISO 14001	Cytiva US LLC
USA	800 Boston Turnpike Road 01545 Shrewsbury, Massachusetts, USA	Development and manufacture of Hardware	ISO 9001	Global Life Sciences Solutions USA LLC

USA	14 Walkup Dr Westborough, 01581 Westborough, Massachusetts, USA	Development and manufacture o filtration products, disposable bioreactor and mixing bags and their accessories	ISO 9001 ISO 22301 ISO 14001	Global Life Sciences Solutions USA LLC
USA	20 Walkup Drive, Westborough, MA, 01581, United States	The Design, Integration, Testing Service, Commissioning, and Servicing of Process Equipment for the Biotech and Pharmaceutical Industries.	ISO 9001	Global Life Sciences Solutions USA LLC
Service and other addresses				
Country		**Scope of the site**	**ISO certification**	
Australia	23-27 Chaplin Drive, Lane Cove West NSW 2066 Australia	Sales and Service of life sciences instruments	ISO 9001	Global Life Sciences Solutions Australia Pty Ltd
China	No.1, Hua Tuo Rd. Zhangjiang Hi Tech Park, 201203 Shanghai, China	Sales and services of chemicals, devices and instruments for life sciences in greater China region, including Hong Kong, Taiwan & Macau	ISO 9001	Global Life Sciences Technologies (Shanghai) Co., Ltd.
France	26-28, Avenue Winchester 78100 St Germain En Laye, France	Sales of filtration and separation equipments, analysis and associated technical support	ISO 9001	Pall France SAS
India	Galileo John F Welch Tchnology Center, 122 122, EPIP Zone, Phase II Hoodi Village, Whitefield Road, Bangalore 560066 India	Design, Development, sales and service of Life Sciences Instruments	ISO 9001	Hyclone Life Sciences Solutions India Private Limited
Italy	Via Emilia, 26, 20090 Buccinasco MI, Italy	Sales and after – sates service for standard and special filters and separation ststems. Analytical and performance qualification tests for filters and separation systems. Sales, calibration and repairing services of Pall´s instruments.	ISO 9001	Cytiva Italy SRL
Japan	3-25-1 Hyakunincho Shinjuku-ku, 169-0073 Tokyo, Japan	Service, Sales and Distribution	ISO 9001	Global Life Sciences Technologies Japan KK
Sweden	Björkgatan 30, 751 84 Uppsala, Sweden	Services of instruments for life sciences within the Benelux, DACH countries, Russia, Nordics, Poland,France, United	ISO 9001	Cytiva Sweden AB

		Kingdom and Ireland, Spain, Portugal and Italy		
Singapore	1 Maritime Square #11-01 Habour Front Center, 099253 Singapore Singapore	Sales and services of chemicals, devices and instruments for life sciences	ISO 9001	Global Life Sciences Solutions Singapore Pte. Ltd. (SGD)
South Korea	202, R&D Bldg., No. 2, 9, Songdomirae-rp Yeonsu-gu Incheon Republic of Korea	Sales and Service for South Korea	ISO 9001	Global Life Sciences Korea Limited
United Kingdom	Amersham Place, Little Chalfont, HP7 9NA Buckinghamshire, United Kingdom	With Management of Life Sciences. Marketing and sales within the United Kingdom	ISO 9001	Global Life Sciences Solutions Operations UK Ltd
USA	100 Results Way, 01752 Marlborough, Massachusetts, USA	Service and Sales, R&D, Product Management	ISO 9001 ISO 14001	Global Life Sciences Solutions USA LLC
USA	170 Locke Drive Marlborough, MA 01752 USA	Cleanroom activites	ISO 9001	Global Life Sciences Solutions USA LLC
USA	160 Locke Drive Marlborough, MA 01752 USA	Warehouse activities	ISO 9001	Global Life Sciences Solutions USA LLC
USA	9 Crystal Pond Road, Southborough, MA 01772 USA	Warehouse and Incoming Inspektion	ISO 9001	Global Life Sciences Solutions USA LLC

Summary of Cytiva's Quality Management System

cytiva

WWW.CYTIVA.COM/QUALITYMANAGEMENT

Summary of Cytiva's Quality Management System

Contents

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.

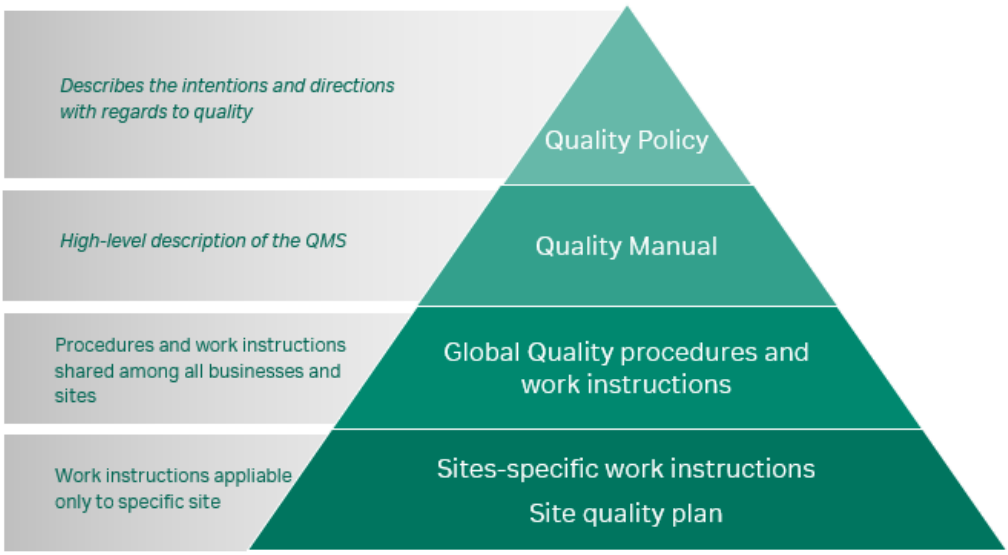

Figure 1 illustrates the various levels of QMS documentation.

Data integrity

Data integrity is the overall completeness, accuracy and consistency of data. Global Cytiva and Site Quality Management Systems ensure that systems for the creation and management of data are fit for their intended use and comply with applicable requirements. The holistic Quality management System approach ensures the data developed for the management of business processes and systems is accurate, consistent and does not adversely impact product quality, patient and consumer safety and related data integrity requirements.

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

A policy has been documented and communicated throughout the organization. The Quality Policy is approved by the management 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.

Responsibility and Authority

Roles, responsibilities, authorities, and accountabilities are defined and communicated through a combination of quality system documentation, organizational charts, job descriptions and other applicable procedures and instructions.

Management Review

The company has established and maintains Management Review processes. The Quality Representative and Management with Executive Responsibility review the organization's Quality Management System to ensure its continuing suitability, adequacy, and effectiveness and to drive actions, where needed. The review is planned and conducted in accordance with the Quality Management Review procedures.

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.