PHILIPS

Supplier Quality Manual

Together we are inspired to enable best in class value-chain partnerships to the delight of our customers

Philips Excellence

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Introduction

This manual details the internal set up, roles and responsibilities and Philips way of collaboration with suppliers. This provides guidance on how the supplier should operate to fulfill their obligation of supply.

We recognize that Philips has a wide variety of suppliers and technologies; the expectations stated in this manual may apply in different ways, depending on the product or service supplied.

The information provided in this Supplier Quality Manual is intended and shall be considered as supporting material used in customer supervision by Philips on its suppliers without prejudice to any existing agreement, purchase order, drawings specifications exchanged between Philips and suppliers.

Purpose and Scope

The purpose of this Supplier Quality Manual is to communicate base level Philips expectations and requirements. This Supplier Quality Manual is meant for potential or new suppliers to Philips with a focus on quality and product reliability. This includes, Philips' Purpose, Supplier Quality Mission, Environmental and Sustainability Policies, as well as supplier and product life cycles. This Supplier Quality Manual is not intended to elaborate on detailed supplier qualification requirements.

The expectations and requirement given within this Supplier Quality Manual are influenced by Philips' quality, regulatory, product, process, and customer requirements to ensure quality products. Suppliers are critical to Philips success in delivering quality products through their supply of materials, products, parts, and services. This Supplier Quality Manual delivers an overview of those expectations and requirements.

The Philips Supplier Portal, or Philips Supplier Representatives can provide further explanation and guidance on supplier requirements as set forth in existing agreements, purchase orders, drawings, and specifications. This Supplier Quality Manual does not replace or alter any existing contracts, purchase orders, drawings, or specifications.

Philips Purpose: Link to: About us | Philips

Philips Quality Policy

Placing the customer first and upholding patient safety, quality and integrity always, goes to the heart of Philips' purpose.

This is why we:

- Design and deliver safe, effective, and reliable products, solutions and services
- Adhere to and maintain the effectiveness of the quality management system
- Comply with applicable internal and external regulations and standards
- Take action to address internal and external concerns involving our products, solutions and services
- Practice continuous improvement in everything we do

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Philips Supplier Quality Mission

Together we are **inspired** to enable best in class value chain partnerships to the **delight** of our customers.

- ✓ To respond to changing environment we need to **improve** and implement new capabilities.
- ✓ **Single Ways of Working** to build clarity both within Philips and towards suppliers
- ✓ Critical product features are **defined and communicated** to suppliers
- ✓ Purchased part quality expectations are **clear and risk based**
- ✓ Supplier capabilities and performance are **measured, tracked and visible.**
- ✓ "**Right first time, every time**" to become the norm

Sustainability and Environmental Policy

Philips establishes technically and economically viable objectives to optimize the environmental performance of the organization's products, services, and activities:

- Our **Product Development Objectives** include evaluating the environmental impact over the total life cycle of a product, taking steps toward more efficient use of materials, including packaging; reducing or eliminating hazardous substances; reducing energy consumption; and contributing to improving recycling and disposal.
- Our **Manufacturing Objectives** include environmentally related activities such as emissions into air and water; use of energy and water; and waste disposal while preventing pollution within our community.
- Our **Supplier Sustainability Program** looks for Supplier Sustainability Performance, Responsible Sourcing of Minerals, Substance Management and Greening the Supply Chain.

  Link to: Philips Supplier Sustainability Programs
- We are committed to compliance and harmonization with all applicable laws and regulations and are prepared to enter into voluntary agreements.

  Link to: Philips Environmental, Social and Governance Policies
- Our **Supplier Sustainability Declaration (SSD) & Regulated Substances List (RSL)** are legal agreements between Philips and the supplier via which the suppliers are informed about and in which the supplier commits to achieve.

  Link to: Philips Regulated and Substances Compliance
- Our **Supplier Sustainability Performance (SSP) Program** is a collaborative systematic approach to improve sustainability of a supply chain through continuous improvements. We base our goals upon peer best practices to recognized and global references.
- We establish and maintain an environmental management system and audit by means of a systematic, documented verification process to ensure continuous improvement.

  Link to: Philips Expectations on Supplier Sustainability Performance

Philips Business Organization

Royal (Koninklijke) Philips has three Business Clusters: Diagnosis and Treatment, Connected Care and Personal Health. Within each Business Cluster are Business Groups. All Philips Business Groups share the same quality management system and business requirements. Business Groups operate in multiple markets that require several different supporting suppliers, including logistics, translation, service, etc.

Link to: [Philips Consumer Products]

	Focus areas	Products and solutions
 **Diagnosis & Treatment**	• Precision diagnosis • Treatment selection and planning • Image-guided minimally invasive therapy	• Diagnostic imaging and ultrasound • Digital and computational pathology • Informatics for Radiology, Oncology, Cardiology • Interventional imaging, navigation and devices • Services (managed services, consultancy, etc.)
 **Connected Care**	• Patient care and workflow management • Chronic disease management	• Telehealth, patient monitoring and analytics • Hospital and clinical informatics platforms • Emergency care and resuscitation • Sleep, breathing and respiratory care • Managed services
 **Personal Health**	• Healthy living and prevention • Personal care • Digital consumer engagement	• Oral care • Mother and childcare • Male grooming and beauty • Services (re-ordering, support, coaching, etc.)

Key Roles and Responsibilities

Philips builds strong partnerships with suppliers in many functional areas to ensure and maintain a focus on Quality. Philips understand our business segments are different in nature and, in some cases, have unique roles and responsibilities based on the business or market they represent. Within a partnership, it is important that the roles and responsibilities within Philips be defined. Key interfacing roles are:

Supplier

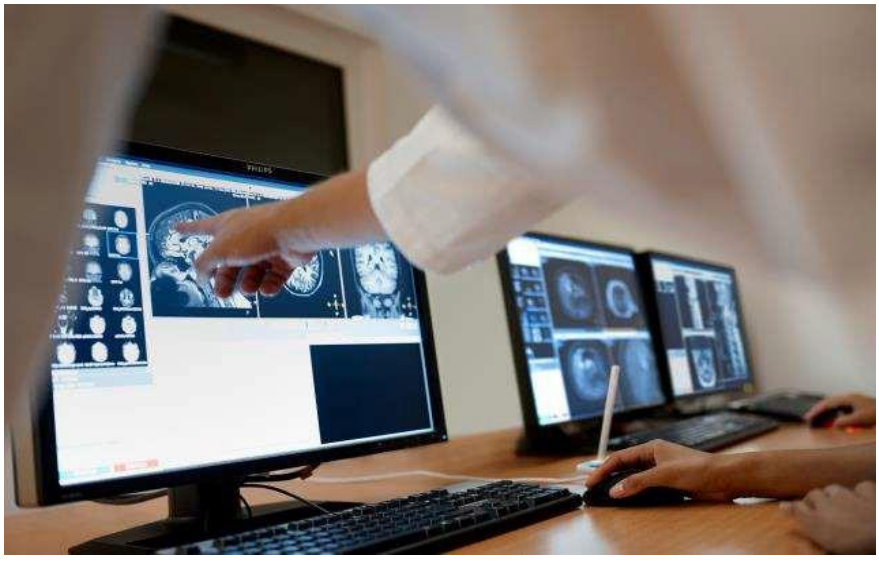
As a Philips supplier, your organization is responsible for developing and maintaining a quality management system to ensure consistent performance in order to deliver quality parts, products, and services. This includes the suppliers' responsibility for ensuring compliance to the contract and compliance to Philips specifications for the part, product or service provided. This includes compliance to Local and National Regulations/Law.

Procurement

Procurement is the primary integration point linking sourcing with technology, aligning Philips Product and Supplier Technology Roadmaps, and managing sourced components. Procurement coordinates parts specifications with R&D Engineering and the selection of potential suppliers according to predefined criteria. The selected suppliers must meet stringent quality requirements set by Philips.

Supplier Quality

Supplier Quality assures that the suppliers' Quality Management System (QMS) meets the applicable Philips' quality and regulatory requirement. There are processes in place to assure initial selection, evaluation, approval, and monitoring of suppliers. Philips utilizes PPQM (Purchase Parts Quality Management) to define these steps. Supplier Quality utilize APQP (Advanced Product Quality planning) to ensure the right level of risk mitigation is in place within the Supply chain. Supplier quality leverages Supplier Quality Improvement Programs & Supplier Improvement Process (SQIP & SIP). Both are in place to drive continuous improvement within Philips Supply chain. All these approaches are supported by the relevant IT infrastructure.



General Business Principals

Patient safety, Quality and Integrity always is at the heart of our culture and is part and parcel of our company's mission and vision. While pursuing our business objectives, we aim to be a responsible partner in society, acting with integrity towards our, customers, employees, business partners and shareholders, as well as the wider community in which we operate.

The General Business Principles set the standard for acting with integrity at Philips. They govern all our decisions and actions throughout the world and apply equally to our group actions and to our conduct as individuals. The General Business Principles are an integral part of Philips' labor contracts and are available in 30 languages.

Link to: General Business Principals

Purchased Parts Quality Management (PPQM)

Philips developed a comprehensive Supplier Management Approach Program called Purchased Parts Quality Management (PPQM). The PPQM method is used for the Quality Management processes related to purchasing controls, there are 5 Steps:

- Supplier Planning, Classification and Selection
- Supplier Audits and Certification
- Component Specification and Qualification, including Advanced Product Quality Planning (APQP), Receiving Inspection and Change Control
- Nonconformance monitoring, Corrective and Preventive Actions, including Supplier Corrective Action Request (SCAR)
- Supplier Performance Monitoring

The PPQM provides a systematic approach to purchasing controls at both the supplier and within Philips.

Philips utilizes PDLM (Product Development Launch and maintenance) as an infrastructure for the APQP process.

PPQM Approach

1. Supplier Planning, Classification and Selection

This procedure is about Supplier Selection, Classification, and Qualification and applies to all Philips organizations.

The process of selecting suppliers for materials, components, finished devices or services is an integral part of Philips commitment to the highest quality products and services to our customers. When Purchasing is pre-selecting the supplier, Supplier Quality will make a technical and/or a QMS assessment to ensure suppliers have the correct capability.

Each supplier must be qualified according to the Philips Selection, Classification, and Approval process before being added to the Philips Approved Supplier List (ASL). The process includes an audit, risk classification, and official approval by Philips. Suppliers are considered qualified once placed on the ASL.

Recognizing the degree of oversight and management within various industries, Philips has established a modified assessment process used to evaluate companies for inclusion within our ASL. **

**Out of scope of this procedure are suppliers of:

- Products purchased by R&D or other functional groups that will not be used in the manufacturing of Philips finished product or finished product qualification (including design verification)
- Prototype parts, tools, equipment (manufacturing aids)
- Non-production test equipment and supplies
- Part risk classification for it is a function of the Research and Development process

2. Supplier Audits and Certification

Philips has a global audit process in place and executes Quality Management System, Manufacturing Processes and Product Audits. An audit can be triggered by supplier qualification, surveillance, or for cause. Philips manages their audit schedule globally to leverage resources for both Philips and suppliers.

○ Auditing at Supplier

Supplier should ensure that the periodic reviews of the effectiveness of the Quality Management System are performed and documented. Suppliers should allow external audits, including unexpected audits from Philips or third-party agencies ensuring compliance with industry standards.

3. Component Specification and Qualification

Philips utilizes the Advanced Product Quality Planning (APQP) methodology to proactively provide visibility and improve communication between stakeholders during product development. This is a risk-based approach to ensure consistent product quality from the first production batches.

The scope of APQP applies to all Philips entities engaged in Product Development, Launch and Maintenance (PDLM) and all our suppliers of components and products intended to be used with, in, or as a Philips finished product.

The purpose of this process is to provide a clear and robust framework to control industrialization of new products and changes to existing products, within the supply base. It defines the activities, deliverables, acceptance criteria and responsibilities for both Philips and our suppliers (including identification of any documentation needed that support the process). The result is a product quality plan for manufacturing products, which consistently meet customer requirements.

The structured approach of APQP ensures our suppliers implement process controls and provide objective evidence to demonstrate that purchased parts consistently meet all Philips engineering design requirements and specifications. Early supplier involvement is a key enabler.

Through the correct application of APQP, we can ensure our products are **right first time, every time**.

4. Nonconformance, Corrective and Preventive Action

The following requirements Nonconformance and Supplier Corrective Action Reports applies to all Philips organizations.

Philips has methods in place to detect problems at an early stage when prevention has failed. Philips will work closely together with our supplier to correct any problems and to minimize the impact on our customers. The use of 8D and Plan-Do-Check-Act (PDCA) problem solving tools are expected from suppliers in these cases.

Suppliers listed on Philips' Approved Supplier List (ASL) are expected to have similar quality controls, corrective, and preventive action systems.

The web-based Philips SCAR IT tool provides access to the supplier so that they can update the status of their investigation, corrective, and preventive actions directly in the system. This enables the teams from Philips and the suppliers to focus on the effectiveness of the activity.

5. Performance Monitoring and Reporting

Philips continuously monitors and reviews the performance of the supplier through various methods, including Quality Notifications, PPM nonconformance and other running metrics.

Suppliers to Philips are required to have a comprehensive corrective and preventive action program and are required to allow Philips or third parties to perform an audit or inspection when indicated at any time (for Cause). Philips Audit Program audits suppliers based on their risk classification indicated on the Philips Approved Supplier List (ASL). Philips suppliers must be fully committed to maintain their Approved Supplier status by continuously demonstrating excellent quality performance.

Philips will communicate the results of Supplier Oversight Monitoring activities like quality performance, individual performance, and correlation between DPPM, Supplier QA, Philips Source Inspection, ORT (Ongoing Reliability Testing), CTX audit results, and SCAR responsiveness on a regular basis with the supplier.

Philips recognizes the need and highly appreciates the use of statistical data analysis in driving continuous quality improvements.

The Supplier Quality Improvement Program (SQIP) is a structured program offered to suppliers to boost their Quality Management System performance and drive consistency. It is aimed at augmenting a supplier QMS to ensure robust and sustainable quality management activities are taken.

The Supplier Improvement Process (SIP) is a structured process that helps suppliers get back on track with their operational Quality KPI's. Customer control points, pass throughs, DPPM/Internal Yields/ SCAR's/OEE are typically the focus of this kind of partnering activity.

Both SQIP and SIP are intended as a partnership between Philips and our supplier partners to ensure we can deliver the best quality, efficiently and effectively on a consistent basis.

Link to: Supplier Lifecycle Management

Supplier Initiated Changes

Supplier agrees to provide prior notification, at the earliest date possible, of any change in location/ manufacturing location, inspection/control plans including test methods, material composition, process methods and controls that the Supplier intends to implement, and which can affect the product(s) or service(s) provided to Philips or Philips finished devices.

Unless Supplier provides a Catalog Part, it is understood that Supplier shall not implement any such changes until Philips has determined the impact of the change(s) on product(s) or service(s) provided and approved the change in writing.

Changes to Catalog Parts require notification to Philips, but not prior approval before implementation. This includes, but is not limited to, the following types of changes:

- Product or service design changes
- Manufacturing process changes that may affect design and/or production specifications
- Change of manufacturing or service facility location
- Change of Supplier name
- Changes that have a significant impact upon your quality system
- Changes to regulatory status (including regulatory inspection findings impacting the product, the service or environmental compliance status)
- Change in Certification status
- Any changes, such as those outlined above, that are made by sub-tier suppliers.

Link to: Supplier Initiated Change Request (SICR)

Sub-Tier Supplier Controls

Suppliers are responsible to manage their sub-tier suppliers and supply chains to ensure that raw materials and components used in the manufacture of Philips products, parts or provision of services meet Philips specifications and comply with the requirements in the applicable agreement in relation to these sub-tier suppliers. As such, suppliers shall apply appropriate controls to ensure that their suppliers comply and are capable of meeting specified requirements. Suppliers are required to manage both directed and non-directed sub-tier suppliers and to maintain part qualification and quality for products purchased through them.

Philips' expectation is that the supplier has installed a formal purchasing and supplier control process to manage sub tier suppliers. These controls are expected to include:

- Supplier Planning, Classification and Selection
- Supplier Audits and Certification
- Component Specification and Qualification
- Nonconformance, Corrective and Preventive Action
- Performance Monitoring and Reporting, including sub tier auditing programs
- Change Control

Business Contingency Planning

Philips expects their suppliers to have a comprehensive crisis management approach to deal with potential disruptions. This approach should include a plan of action, communication plans, escalation procedures, and roles and responsibilities. The plan shall address the recovery time needed for a variety of business interruptions, contact information for key locations, supply chain risk assessment for equipment, material, supplied components and labor, etc. This shall be specific to Philips products and/or services provided.

Supplier Quality Agreements

Philips will determine if a Quality Agreement is needed. Once the need is determined, it is our expectation that the supplier will work with Philips to put this Agreement in place and always abide by it. A Change Notice Agreement can be used in lieu of the Quality Agreement when Philips deems this appropriate.

Escalation Process

Philips and the supplier shall hold each other mutually accountable to the highest quality standards and business practices. To that end, Philips has established an escalation process whereby we can assure such compliance. Escalation may include higher levels of action up to and including disqualification. The intent is to foster trust and a partnership based upon 2-way communication.

Purchasing Terms and Conditions

Philips often enters into a purchasing agreement with its suppliers. If a purchasing agreement is not in place, then purchases shall be covered by Philips General Conditions of Purchase.

Link to: General Conditions of Purchase

Supplier Quality Management System (QMS) Requirements

Suppliers shall have a Quality Management System (QMS) in place that is established according to applicable governing standards and regulations (e.g., ISO 9001 or equivalent). For suppliers who are certified, Philips requires that they maintain standard certification status. For suppliers who are not yet certified to the specified ISO standards, it is preferred that they have a plan in place to become certified. Should certification be suspended, expire, or change in status, Philips shall be notified. Philips may specify additional industry or performance standards to be achieved by its suppliers in alignment with current quality objectives.

Terms, Abbreviations and Definitions

Term	Definition
AOP	Annual Operational Planning
APQP	Advanced Product Quality Planning
Approved Supplier	A supplier who has been successfully evaluated and whose approval has been documented in the Approved Supplier List for the purpose of supplying specific goods and services.
Approved Supplier List	A list of suppliers who have been evaluated and approved to deliver devices, components, or services.
CAPA	Corrective Action Preventive Action: Corrective Action - Action taken to eliminate the cause of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence. Preventive Action - Action taken to eliminate the cause of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence.
cGMP	Current Good Manufacturing Practice
Commodity	A term used to describe a category of inventory items or services.
Control Plan	A document that identifies key manufacturing or service process steps or inputs and how those items will be sustained.
Cpk	Process Capability Index is a snapshot or a series of snap shots of a process at specific points in time and is used to assess the "local and timely" capability of a process. Process Capability is the comparison of the Voice of the Customer (Specification Requirements) and the Voices of the Process (Control Limits).
Corrective Action	Action taken to eliminate the cause(s) of non-conformities/failures in order to prevent recurrence.
CTX	Critical to Process (CTP), Critical to Safety (CTS) & Critical to Quality (CTQ).
DfX	Design for Excellence - The X in DfX stands for Value, Costs, Quality, Manufacturing, Logistics, Risk Management, Reliability and Sustainability.
EUMDR	European Medical Device Regulation
FDA	The United States Food and Drug Administration, authorized to conduct inspections on behalf of the United States government.
General Business Principles	Philips is committed to ensuring the highest standards of business conduct and has incorporated this commitment in its General Business Principles and underlying policies. General Business Principles set the standard for acting with integrity.
GDP	Good Documentation Practice.
GMP	Good Manufacturing Practice
NPI	New Product Innovation.
OEM	Original Equipment Manufacturer: Finished devices, drug, or biologics used or sold by an organization or establishment, in which the external supplier to an organization holds legal title, design, manufacturing, and regulatory responsibility.
ORT	Ongoing Reliability Testing
PDCA	Plan-Do-Check-Act, also known as the Deming Cycle, is a methodology for Continuous Improvement.

Term	Definition
PDLM	Product Development, Launch and Maintenance
PEPF	Philips Excellence Process Framework describes all business processes for Philips. The PEPF consists of three value chains forming the organizations end-to-end processes: Idea to Market (I2M), Market to Order (M2O), Order to Cash (O2C), supported with a set of management and enabling processes.
PPM	Parts Per Million
Ppk	Process Performance index (k) that incorporates and estimate of the long-term process standard deviation analysis. Process Performance index is an index of process performance related to both dispersion and centeredness.
PPQM	Purchased Parts Quality Management
Product	A product is a raw material, component, assembly, software, or service.
Preventative Action	Action taken to eliminate the cause(s) of potential non-conformities/failures to prevent their occurrence.
Quality Agreement	A document that defines the general relationship for quality activities between two entities.
Quality Risk	The potential for use or patient injury if a finished device contained or was manufactured using a supplier's nonconforming item, or if a service did not conform to Philips requirements.
SCAR	Supplier Corrective Action Request made to a supplier because of an identified quality issue. Response shall cover both corrective and preventive actions.
Services	Service Suppliers are Consultants, Contract Manufacturers, Distributors, R&D, Calibration, etc.
SICR	Supplier Initiated Change Request
SIP	Supplier Improvement Process
SLM	Supplier Lifecycle Management
SQIP	Supplier Quality Improvement Program
Sub-Tier Supplier	An organization or business entity that provides products or services to a Supplier.