Supplier Quality Manual

Together we are inspired to enable best in class value-chain partnerships to the delight of our customers
Table of Contents
Introduction .............................................................................................................................................. 3

SECTION 1 .................................................................................................................................................. 3
Purpose and Scope........................................................................................................................................ 3
Philips Mission .......................................................................................................................................... 4

Philips Supplier Quality Mission .............................................................................................................. 5
Our quality policy: ......................................................................................................................................... 5
With our hearts and minds we: .................................................................................................................... 5

Environmental Policy ................................................................................................................................ 6
Philips Business Groups ............................................................................................................................... 7
Key Roles and Responsibilities ..................................................................................................................... 9
Supplier ..................................................................................................................................................... 9
Procurement ............................................................................................................................................. 9
Supplier Quality......................................................................................................................................... 9
Supplier Requirements ............................................................................................................................... 10
Purchased Parts Quality Management (PPQM)............................................................................................. 11
PPQM Approach.......................................................................................................................................... 11
1. Supplier Planning, Classification and Selection ...................................................................................... 11
2. Supplier Audits and Certification ........................................................................................................... 12
3. Component Specification and Qualification ........................................................................................... 12
4. Non Conformance and Corrective and Preventive Action ....................................................................... 14
5. Performance Monitoring and Reporting ................................................................................................ 14
Supplier Change ........................................................................................................................................... 15
Sustainability and Environmental Compliance ............................................................................................. 17
Sub-Tier Supplier Controls .......................................................................................................................... 17
Business Contingency Planning .................................................................................................................. 18
Supplier Quality Agreements ....................................................................................................................... 18
Purchasing Terms and Conditions................................................................................................................ 18

SECTION 2 .................................................................................................................................................. 19
Management Responsibilities

General Expectations

Documentation Expectations

Quality Management System documentation should include:

Document Control

Control of Records

Retention

Product Identification

Traceability

Production and Process Controls

Acceptance Activities

Unexpected or Unannounced Auditing

Recalls

SCAR and Corrective Action and Preventive Action (CAPA)

Escalation Process

Training

Resource Management

Qualified Resources

Talent Management

Working Environment

Terms, abbreviations and definitions
Introduction

The first section of this handbook details the internal set up, roles and responsibilities and Philips way of collaboration with suppliers. The second section then provides guidance on how the supplier should to 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.

Section 1

Purpose and Scope

The purpose of this Supplier Quality Manual is to communicate and elaborate on Philips expectations and requirements to all potential and existing external suppliers to Philips with a focus on quality and product reliability. This includes, without limitation, suppliers of raw materials, components, Original Equipment Manufacturers (OEM), contract manufactures of finished devices, software, distributors, assemblies, and services suppliers associated with our products and services.

These expectations and requirements 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.

This Supplier Quality Manual provides further explanation and guidance on requirements as set forth in existing agreements, purchase orders, drawings and specifications between Philips and existing suppliers. It does not replace or alter any existing contracts, purchase orders, drawings or specifications.
Philips Mission

Philips has driven meaningful innovations to improve the quality of life for millions for over 125 years, creating strong and trusted Philips brand with market access all over the world.

Philips is committed to improving the quality of people’s lives. Improving the lives of 3 billion people, a year by 2025 drives Philips in the development and manufacturing of our products. Promoting acceptable working conditions, environmentally responsible management and ethical behavior is all part of this commitment.

Philips' Mission and General Business Principles (GBP) reflect Philips’s commitment to responsible corporate citizenship and the pursuit of a sustainable future – in economic, social and environmental terms. The Philips GBP set out guiding principles on integrity and ethics in business conduct, including those that help create a sustainable supply chain.

In short, Philips pursues mutually beneficial partnerships with its Suppliers and seeks to award business to those Suppliers who are committed to developing the highest quality, best-in-class products, to acting fairly, with integrity towards their stakeholders, and to observing the applicable rules of law and to supporting and respecting internationally proclaimed human rights.
Philips Supplier Quality Mission

“Together we are **inspired** to enable best in class value chain partnerships to the delight of our Customers“ in order to achieve this we need to:

Responding to changing environments, **improving** and implementing new **capabilities**

Implementing **Single ways of working** to build clarity both within Philips and towards suppliers, including the **definition and communication** of Critical product features

Ensuring purchased part quality expectations are **clear and risk based**, and that Supplier capabilities and performance are **measured, tracked and visible**,

Driving a “**Right first time, every time**” culture

Our quality policy:

With our hearts and minds we:

- delight our customers and deliver our brand promise
- design and deliver safe, reliable, and effective products and services
- drive a culture of continuous improvement
- comply with applicable internal and external regulatory and compliance requirements
- maintain an effective and efficient quality management system.

Our goal is to improve the lives of **3 billion people** a year by 2025
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.
- We establish and maintain an environmental management system and audit by means of a systematic, documented verification process to ensure continuous improvement.
- We are committed to compliance and harmonization with all applicable laws and regulations, are prepared to enter into voluntary agreements.

For more information on Philips sustainability, please visit:

[https://www.usa.philips.com/a-w/about-philips/sustainability.html](https://www.usa.philips.com/a-w/about-philips/sustainability.html)
Philips Business Groups

<table>
<thead>
<tr>
<th>Philips</th>
<th>Health Systems</th>
<th>Personal Health</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diagnosis &amp; Treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Connected Care and Health Informatics</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Health Systems</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Personal Health</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Domestic Appliances</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Health &amp; Wellness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sleep &amp; Respiratory Care</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Personal Care</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Coffee</td>
<td></td>
</tr>
</tbody>
</table>

### Diagnostic Imaging

(DI) sits at the very heart of the Philips strategy in the critical areas of Diagnosis and Treatment. It is the largest business group in Philips. In Diagnostic Imaging, we are empowering the people behind the image, so more patients can get healthier, faster. By expanding the boundaries of innovation, we provide solutions that seamlessly connect the people at the heart of imaging with the technology, software and data they need to get the right image the first time and to detect health events early.

### Ultrasound

Philips Ultrasound brings innovative solutions to clinical complexity while simplifying workflow. Our suite of systems is designed to meet the many unique challenges of clinical practice. Philips Ultrasound solutions bring excellent image quality and advanced, yet easy to use quantification, to improve upon the quality of care. Every image counts, because every patient matters.

### Image Guided Therapy (IGT)

Our vision is to provide integrated solutions that advance minimally invasive procedures by helping healthcare providers to decide, guide, treat and confirm the right therapy for the right patient at the point of care. Working together to realize this vision, we can save and improve lives and reduce the total cost of care by making therapy more efficient, more appropriate and more personal.

### Monitoring & Analytics / Therapeutic Care (MA & TC)

Connected Care & Health Informatics* businesses are characterized by a high degree of informatics and software-related competences, which go horizontally across the health continuum.

The Monitoring and Analytics (MA) business group resides in the Connected Care & Health Informatics business cluster. MA is a software and solutions business encompassing patient monitoring and its capabilities. Our MA solutions reach more than 370 million people every year. Our advanced intelligence platforms provide clinicians with the information when and where they need it so that they can make smart decisions. Our ultimate priority is to enable caregivers, administrators and patients to make decisions that support better health, increase efficiency and control costs.

Therapeutic Care, part of the Connected Care & Health Informatics business cluster, is expanding access to and quality of respiratory care, resuscitation, and emergency care solutions (including devices, services, and digital/data solutions). Our Hospital Respiratory Care (HRC) and our Emergency Care and Resuscitation (ECR) solutions are helping caregivers and lay responders both inside and outside the
hospital. We are the number one provider of therapeutic care solutions, saving and improving more and more lives every year

BG Healthcare Informatics

Philips Healthcare Informatics provides a robust portfolio of clinically rich, technologically sound healthcare informatics that connect people, technology, and data across the health continuum. Our intelligent, secure solutions help integrate systems, aggregate data, accelerate workflows, and inform decisions, giving clinical teams the insights, they need to make possible what matters most—healthier patients. Here is the link for further information:

https://www.usa.philips.com/healthcare/solutions/clinical-informatics

Domestic Appliances

Domestic Appliances aims to bring meaningful innovation to the home, enabling families and individuals to lead healthier and happier lives, every day. The business group, which is part of Personal Health, accounts for 11% of Philips’ health technology global sales (2017) and employs approximately 4,000 people. We make Philips the:

• world #1 brand in home cooking and food preparation devices
• world #1 brand in ironing
• #1 brand for air purification in China.

BG Sleep & Respiratory Care (SRC)

The global leader in sleep and respiratory, Sleep & Respiratory Care (SRC) exists to restore natural sleep and breathing. Our success spans more than three decades and can be attributed to our passion for deeply understanding the needs of the patients we serve. We leverage these insights to develop intuitive and seamlessly connected solutions that improve quality of life and help people rediscover their dreams. SRC is part of Personal Health and comprises the businesses of Sleep, Healthy Sleep Solutions, Respiratory Care and New Business Solutions.

Personal Care (PC)

The Personal Care business group, which is part of the health cluster Personal Health, aims to be the first choice for consumers and retailers by delivering innovative solutions that help people look and feel their best. We work hard to deliver insights in consumer, shopper, market and retail developments around the world, providing clear directions for business improvement by monitoring the position of brand, sales and products.

The PC businesses are Male Grooming and Beauty
Key Roles and Responsibilities

Philips builds strong partnerships with suppliers in many functional areas in an effort 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 both Supplier Quality Improvement Programs & Supplier Improvement Process (SQIP & SIP) are in place.
to drive continuous improvement within Philips Supply chain). All these approaches are supported by the relevant IT infrastructure.

Supplier Requirements

Philips strives to provide products and services of the highest quality whilst establishing world-class processes and procedures for all purchased materials, products and services. We are committed to developing and fostering supplier partnerships that will deliver industry-leading innovation, quality, reliability, and value to our customers.
Purchased Parts Quality Management (PPQM)

In pursuit of this mission, we have developed a comprehensive Supplier Management Approach Program called Purchased Parts Quality Management (PPQM). PPQM is used for the Quality Management processes related to purchasing controls: There are 5 bubbles: supplier planning, classification and selection, supplier audits, Advanced Product Quality Planning (APQP), Receiving inspection, change control, Supplier Corrective Action Request (SCAR) and supplier performance monitoring; it is the systematic approach to support purchasing control both at a supplier and at the product level.

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.
Therefore, 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 this and the degree of oversight and management within these industries, Philips has established a modified assessment process used to evaluate these 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). This includes prototype parts, tools, equipment (manufacturing aids), non-production test equipment and supplies. Part Risk classification, because it is a function of the Research and Development process.

2. **Supplier Audits and Certification**

Philips have 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 manage their audit schedule globally in order to leverage resource for both Philips and suppliers.

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.

Through the correct application of APQP, we can ensure our products are right first time, every time.
4. Non Conformance and Corrective and Preventive Action

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

Philips have 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 problem solving is mandatory for suppliers in these cases.

This is applicable for all suppliers listed on the Approved Supplier List (ASL)

The web based Philips SCAR IT tool provides access to the supplier so that they can update the status of their investigation and corrective action directly in the system, enabling 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 performance of the supplier through various methods, including PPM and other running metrics.

Suppliers to Philips are required to have a comprehensive corrective and preventive action program in place and is 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.

This is applicable for all suppliers listed on the Approved Supplier List (ASL)

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 and testing), CTX audit results, and SCAR responsiveness on a regular basis with the supplier.

Philips recognized the need and highly appreciates the use of statistical data analysis in driving continuous quality improvement

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 undertaken.

The Supplier Improvement Process (SIP) is a structured process that helps suppliers get back on track with their operational Quality KPI’s. DPPM/Internal yields/ SCAR’s / OEE and Customer pass through’s 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.
Supplier Change

Supplier shall not change, substitute or modify products, nor make any changes that may affect the specifications. Any changes proposed or intended to be made by Suppliers, or changes by Sub-tier Suppliers shall be submitted to Philips in writing for review and approval prior to implementing any such changes on Philips specified format. Further detailed information you will find in the Philips Quality agreement.

Philips personnel shall review and approve changes that may affect the Product(s), including and without limitation:

**Process:**
- Process method or technology
- Contamination Control
- Control Plan and / or Product incoming, in-process or final acceptance test
- Product performance
- Process Validation
- Temporary process change (Process deviation)
- Test Software which affects the product (e.g. programming MAC address change)
- Increased risk identified in Process Failure Modes & Effects Analysis (PFMEA)
- Supplier Manufacturing site transfers
- Sub-tier Supplier changes
- Transportation method

Any change in the Quality Control Plan including incoming, In-process and final acceptance test changes related to:
- Test specification
- Test acceptance requirements
- Test method Validation
- Products reviewed by Supplier MRB for “Use As Is” disposition
- Outgoing Inspection Plan
- Reduction in either 100% testing or sampling plans

**Material:**
- Changes to materials (including raw materials) and/or Components (BOM)
- Change in a supplier of a material or Component
Change to Manufacturing, test, or inspection equipment:
  - New or alternative equipment
  - Equipment Qualification or Validation
  - Change from manual to automated process

Facility Changes:
  - Relocation of Manufacturing equipment within the same Manufacturing facility
  - Facility to facility transfer of Manufacturing processes or technology.
  - Altering environment specs or conditions in areas used for Manufacturing, storage, or test (i.e. microbial/endotoxin/particulate monitor)
  - Change in clean room

Change in Component or Product requiring:
  - Updated Component Specification
  - Updated Product Specification
  - New or alternate Sub-tier supplier

Change in Product design:
  - Product
  - Product Software
  - Product Labeling
  - Packaging

Change in Supplier name and/or address:
  - Name
  - Address
  - Change to Product part number
Sustainability and Environmental Compliance

The 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 adhere to.

More information is available at https://www.usa.philips.com/a-w/about-philips/sustainability.html

Sub-Tier Supplier Controls

Suppliers are responsible to manage their sub-tier suppliers and any 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 Philips General Business Principles. 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.
Suppliers are expected to manage sub-tier Suppliers with controls commensurate with risk. Suppliers are responsible to ensure that product(s) manufactured utilize only authentic, conforming and specified material as stipulated in the specification.

Philips’ expectation is that the supplier has in place a formal purchasing and supplier control processes to manage sub-tiers. These controls are expected to include:

- Supplier planning, classification and Selection
- Supplier Audits and Certification
- Component Specification and Qualification
- Non Conformance and Corrective and Preventive Action
- Performance Monitoring and Reporting, including sub tier auditing programs
- Change control

Suppliers are responsible for ensuring and controlling the quality of all purchased components and raw materials to manufacture product for Philips.

Please Note: Prior to implementing sub-tier Supplier changes, Suppliers are expected to seek Philips consent

**Business Contingency Planning**

Philips expect our Suppliers to complete a formal business Disaster Recovery Plan to ensure no interruption in supply. While contingency plans cannot cover all potential scenarios, we expect our Suppliers to maintain robust plans to facilitate rapid response and recovery in the event of disruptions.

Philips expect 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. This plan is there to address the recovery time needed for a variety of business interruptions, contact information for key locations, supply chain assessment of risk for equipment, material, supplied components and labor, etc. and 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 abide by it at all times. There is a Change Notice Agreement, which is used in lieu of the Quality Agreement when Philips deems appropriate.

**Purchasing Terms and Conditions**

All purchases shall be covered at a minimum by the Philips General Conditions of Purchase. You can access the above via the following link: [https://www.philips.com/a-w/about/company/suppliers/working-with-philips/general-conditions-of-purchase.html](https://www.philips.com/a-w/about/company/suppliers/working-with-philips/general-conditions-of-purchase.html).

However, in most cases, Philips enters into a formal Master Purchase Agreement with its suppliers. All purchases shall be covered at minimum by Philips Purchasing Terms and Conditions.
SECTION 2

Management Responsibilities

A Philips’ Supplier should demonstrate commitment by their senior management to continuous improvement. Documented evidence of Management’s commitment to the development and improvement of the Quality Management System includes:

- Supplier senior management should ensure that the appropriate communication is established with Philips in order to be effective within the suppliers Quality Management System.

- The senior management within the supplier should be actively involved in their Quality Management System and to ensure their QMS addresses the managerial process of quality planning, quality control and quality improvement processes.

- Supplier Management to ensure adequate team with the appropriate competencies and succession for critical position deployed for operation sustenance and continuous improvements.

General Expectations

Suppliers should establish, document, implement and maintain an effective Quality Management System, which is required for the product and/or service provided to Philips. The purpose of a QMS is to provide a high degree of confidence that the material and services conforms to contract requirements and should be of the highest quality and free from defects. The Supplier’s management should ensure
that the Quality Requirements in their Quality Manual, including and without limit to, are thoroughly distributed, understood, and managed, and that adequate levels of authority have been established to ensure the continuous improvement of the Quality System.

Suppliers shall have a Quality Management System in place that fulfills Philips requirements; these are established according to applicable governing standards and regulations. (e.g., ISO 9001, ISO 13485, ISO 27001, EUMDR and others.) 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. Philips has a rigorous Supplier Quality Improvement program that can establish equivalence to certification standards. In addition, Philips may specify industry or performance standards to be achieved by its suppliers. For suppliers who are certified, Philips requires that they maintain standard certification status. Should certification be suspended, or expired, or any change in status, Philips should be notified.

Documentation Expectations

Quality Management System documentation should include:

- Documented statements of a Quality Policy and quality objectives
- Documented procedures as required by the Quality Management System
- Documents needed by the organization to ensure the effective planning, operation and control of its processes
- Records required by the Quality Management System

Document Control
The supplier should establish, maintain and document procedures to control all Quality Management System documentation and all data generated under the Quality Management System. The supplier should have current revisions of documents available at all appropriate locations.

Control of Records
The supplier should use Good Documentation Practices (GDP) when creating and maintaining records to ensure clear, complete and accurate information is recorded. Upon request, documents, which provide evidence that product, parts or services, conform to requirements. Specifications should be retrievable for review by Philips or any regulatory body within a reasonable timeframe.

Retention
A record retention policy should also be in place to ensure records are maintained in accordance with standards, regulations and agreements. Record retention should abide all applicable laws, regulations, standards and agreements.
Product Identification

Supplier should have a system in place to identify product during all stages of receipt, production, and distribution where specified. This system should also ensure that product in different stages of the manufacturing process is properly identified to avoid mix-ups.

Traceability

Suppliers should be responsible for setting up and maintaining controlled documentation of product traceability during all stages of receipt, product, and distribution, where required. Philips may specify for bar coding or other certifiers (e.g., unique device identifiers) where applicable for product and/or packaging.

Production and Process Controls

Each supplier should develop, conduct, control and monitor production processes to ensure parts are manufactured in conformance to Philips specifications. This includes documented instructions that define the production activities, approval of processes, and equipment validation, where specified. Documented instructions should also include any changes to critical-to-quality processes and equipment. Control and validation of critical Quality process parameters and component or device characteristics during production should be maintained.

Philips expects Suppliers to develop and maintain highly capable processes to produce quality Products and Services. Use of Statistical Process Control (SPC) for special part and process characteristics is recommended. SPC is expected for all Critical to Safety and Quality Characteristics. SPC data may be required with each shipment at the discretion of the receiving facility. Suppliers are expected to utilize indices such as Cp / Cpk / Pp / Ppk.

Acceptance Activities

The supplier should establish procedures for acceptance activities. These procedures should include inspections, tests and verification activities for raw material acceptance (incoming product), in-process
acceptance activities, and release of finished product as required (Software is included in this). In addition, procedures should ensure in-process product is controlled until required tests or approvals are performed demonstrating compliance to Philips specifications. These activities should be documented and available upon request for review. This also included design verification as well as process and process validation where applicable.

**Unexpected or Unannounced Auditing**

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.

**Recalls**

As part of a trusting partnership, if either party determines recall or other action involving a product or products, they will immediately notify the other party. Should any action such as a recall or other action be required per a regulatory requirement, Philips shall be notified and included in the final determination. The supplier should cooperate with Philips to implement the recall once a determination has been made. Supplier warrants may apply and this will be business unit dependent. In applicable cases, please follow the quality agreement guidelines.

**SCAR and Corrective Action and Preventive Action (CAPA)**

The Supplier should establish and maintain procedures for implementing a CAPA system in compliance with the industry standards and Quality Management System requirements. Philips may issue a Supplier Corrective Action Request (SCAR) to the supplier quality defects. The supplier should collaborate with Philips to determine the division of responsibility for implementation of the CAPA systems depending upon the nature of the quality problem and resolution.

**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.

**Training**

Suppliers should have a documented training program in place to ensure staff have the necessary education, skills and knowledge to implement the requirements of their role. Training should include training to the Quality Management System as it applies to the individual roles of the employees, and systems to ensure training effectiveness. All training records must be documented and maintained. All employees should be aware of key processes and any defects, which may occur from the improper performance of their roles.
Resource Management

Qualified Resources
A supplier needs to have adequate resources, including the assignment of trained personnel to manage and perform activities and internal quality audits to meet the requirements of the company QMS. Employees need to have equipment, facilities, training, and work environment conducive to producing high quality products that consistently meet the product specifications as required by Philips.

Talent Management
The Supplier should have sufficient personnel with the necessary education, background, training and experience to assure that all activities are correctly performed and knowledge and skills are sustained. In addition, procedures should be established to identify training needs. Training programs should be established to ensure all personnel are trained to adequately perform their assigned responsibilities. Personnel should be aware of device defects that may occur due to improper performance. All training must be documented and maintained as part of the employees’ personnel record. In order to ensure that products are developed according to Philips requirements.
Working Environment

The Supplier should ensure that the work environment conditions are properly maintained to not adversely affect product quality and compliance to applicable laws and regulations. All requirements for working procedures and environmental requirements should be documented and monitored. Personnel should be trained on environmental requirements. Please refer back to our sustainability policy (Environmental Policy section).
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AOP</td>
<td>Annual Operational Planning</td>
</tr>
<tr>
<td>APQP</td>
<td>Advanced Product Quality Planning</td>
</tr>
<tr>
<td>Approved Supplier</td>
<td>A supplier who has been successfully evaluated and whose approval has been documented in the Approve Supplier List for the purpose of supplying specific good and services.</td>
</tr>
<tr>
<td>Approved Supplier List</td>
<td>A list of supplier who have been evaluated and approved to deliver devices, components or services.</td>
</tr>
<tr>
<td>CAPA</td>
<td>Corrective and 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.</td>
</tr>
<tr>
<td>cGMP</td>
<td>Current Good Manufacturing Practice</td>
</tr>
<tr>
<td>Commodity</td>
<td>A term used to describe a category of inventory items or services.</td>
</tr>
<tr>
<td>Control Plan</td>
<td>A document that identifies key manufacturing or service process steps or inputs and how those items will be sustained.</td>
</tr>
<tr>
<td>Cpk</td>
<td>Cpk is a snapshot or a series of snapshots of a process at specific points in time and is used to assess the “local and timely” capability of a process</td>
</tr>
<tr>
<td>Corrective Action</td>
<td>Action taken to eliminate the cause(s) of non-conformities/failures in order to prevent recurrence</td>
</tr>
<tr>
<td>CTX</td>
<td>An abbreviation for Critical to Process (CTP), Critical to Safety (CTS) &amp; Critical to Quality (CTQ)</td>
</tr>
<tr>
<td>EUMDR</td>
<td>European Medical Device Regulation</td>
</tr>
<tr>
<td>FDA/DfX</td>
<td>The United States Food and Drug Administration, authorized to conduct inspections on behalf of the United States government. Design for Excellence - The X in DfX stands for Value, Costs, Quality, Manufacturing, Logistics, Risk Management, Reliability and Sustainability</td>
</tr>
<tr>
<td>General Business Principles FDA</td>
<td>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. The United States Food and Drug Administration, authorized to conduct inspections on behalf of the United States government.</td>
</tr>
<tr>
<td>GDP General Business Principles</td>
<td>Good Documentation Practice. 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.</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
</tr>
<tr>
<td>NPI/GDP</td>
<td>New Product Innovation. Good Documentation Practice</td>
</tr>
<tr>
<td>OEM/NPI</td>
<td>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. New Product Innovation</td>
</tr>
<tr>
<td><strong>PDLM</strong></td>
<td>Product Development, Launch and Maintenance</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------------------------------</td>
</tr>
<tr>
<td><strong>PEPFOEM</strong></td>
<td>Philips Excellence Process Framework 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.</td>
</tr>
<tr>
<td><strong>Ppk/PEPF</strong></td>
<td>Ppk is a short term analysis (mostly done with 50 or 100 samples measured). Ppk stands for Process Potential Capability. Philips Excellence Process Framework</td>
</tr>
<tr>
<td><strong>PPM/Ppk</strong></td>
<td>Parts Per Million - Ppk is a short term analysis (mostly done with 50 or 100 samples measured). Ppk stands for Process Potential Capability.</td>
</tr>
<tr>
<td><strong>PPQM</strong></td>
<td>Purchased Parts Quality Management</td>
</tr>
<tr>
<td><strong>Product PPM</strong></td>
<td>A product is a raw material, component, assembly, software or service. Parts Per Million</td>
</tr>
<tr>
<td><strong>Preventative Action</strong></td>
<td>Action taken to eliminate the cause(s) of potential non-conformities/failures in order to prevent their occurrence. A product is a raw material, component, assembly, software or service.</td>
</tr>
<tr>
<td><strong>Quality Agreement Preventative Action</strong></td>
<td>A document that defines the general relationship for quality activities between two entities. Action taken to eliminate the cause(s) of potential non-conformities/failures in order to prevent their occurrence.</td>
</tr>
<tr>
<td><strong>Quality Risk Quality Agreement</strong></td>
<td>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. A document that defines the general relationship for quality activities between two entities.</td>
</tr>
<tr>
<td><strong>SCAR Quality Risk</strong></td>
<td>Supplier Corrective Action Request made to a supplier as a result of an identified quality issue. 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.</td>
</tr>
<tr>
<td><strong>Services SCAR</strong></td>
<td>Service Suppliers are Consultants, Contract Manufacturers, Distributors, R&amp;D, Calibration, etc. Supplier Corrective Action Request made to a supplier as a result of an identified quality issue.</td>
</tr>
<tr>
<td><strong>SIP</strong></td>
<td>Supplier Improvement Process</td>
</tr>
<tr>
<td><strong>SQIP</strong></td>
<td>Supplier Quality Improvement Program</td>
</tr>
<tr>
<td><strong>Sub-Tier Supplier Services</strong></td>
<td>An organization or business entity that provides products or services to a Supplier. Service Suppliers are Consultants, Contract Manufacturers, Distributors, R&amp;D, Calibration, etc.</td>
</tr>
<tr>
<td><strong>Sub-Tier Supplier</strong></td>
<td>An organization or business entity that provides products or services to a Supplier.</td>
</tr>
</tbody>
</table>