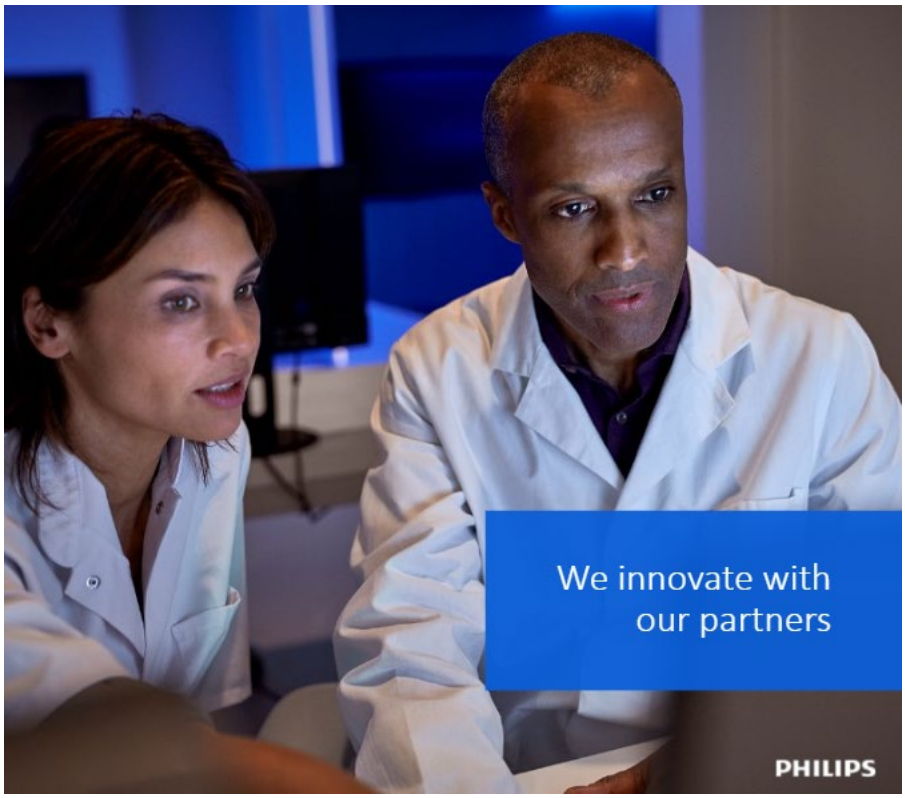
Supplier Quality Manual

Join Philips as a valued partner in our quest for excellence, where collaboration and steadfast dedication to quality pave the way for a thriving future together.



Dear Valued Supplier,

We are delighted to welcome you to the Philips family, where patient safety and quality is at the heart of everything we do. This manual serves as your guide, providing a warm embrace into our collaborative journey towards excellence.

Within these pages, you will find a detailed overview of our internal setup, clearly defined roles and responsibilities, and insights into the unique Philips way of collaboration. Our goal is to support and guide you in fulfilling your obligations to supply, ensuring a seamless and fruitful partnership.

We understand and appreciate the diversity of suppliers and technologies that join us in our mission. The expectations outlined in this manual are designed to be adaptable, acknowledging that they may apply differently depending on the specific product or service you provide.

The Supplier Quality Manual offers general guidance and is not meant to establish quality or commercial agreements. Please consider this information as a complement to any existing agreements (such as, but not limited to procurement and quality agreements), purchase orders, drawings, or specifications exchanged between Philips and you, our esteemed supplier.

At the same time please note that this Supplier Quality Manual does not affect the need for you, as our supplier, to be familiar with the details of all our existing agreements and exchanged documents in order to perform in accordance with the provisions thereof.

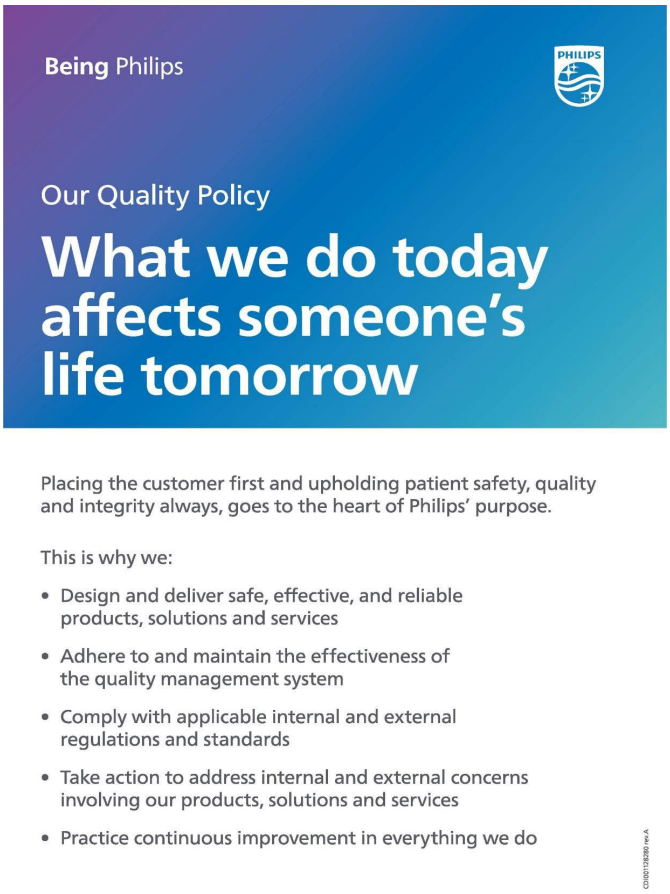
The support and information shared by Philips via this Manual does not limit Philips' right to, and Philips reserves the right, to hold Partner liable under the existing agreements.

As we embark on this journey together, we hope you feel a sense of warmth and support that underscores our commitment to safety, quality and collaboration. Welcome to Philips, where we strive for excellence in every product, every service, and every relationship.

If you have any questions regarding the information in this document, contact your local Supplier Engineer or Global Supplier Account Manager.

Warm regards,

The Philips Quality Team



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2. Preface

Maintaining exceptional quality is critical to the success of our organization. This manual serves as a comprehensive guide for suppliers, outlining essential practices and expectations to ensure quality excellence. It highlights interconnected pillars of supplier quality management; supplier evaluation and qualification, part qualification, supplier-initiated changes, nonconformance and corrective actions management, and supplier performance monitoring.

Supplier evaluation and qualification is the first step in Philips' supplier quality management, ensuring suppliers have the right capabilities to meet Philips' quality expectations. This process evaluates suppliers' compliance with requirements, including product quality, technical skills, and operational processes, before adding them to the Approved Supplier List (ASL).

Part qualification forms the foundation of supplier quality, ensuring that all components and materials meet established standards before being integrated into production. This proactive approach minimizes risks and ensures seamless operations.

Supplier-initiated changes emphasize the importance of collaboration and transparency in adapting to evolving requirements. Effective communication and adherence to change management processes protect patient safety and quality standards while fostering innovation.

Addressing non-conformities and corrective actions are vital for continuous improvement. By identifying and resolving issues swiftly and systematically, we uphold quality standards and prevent recurrence.

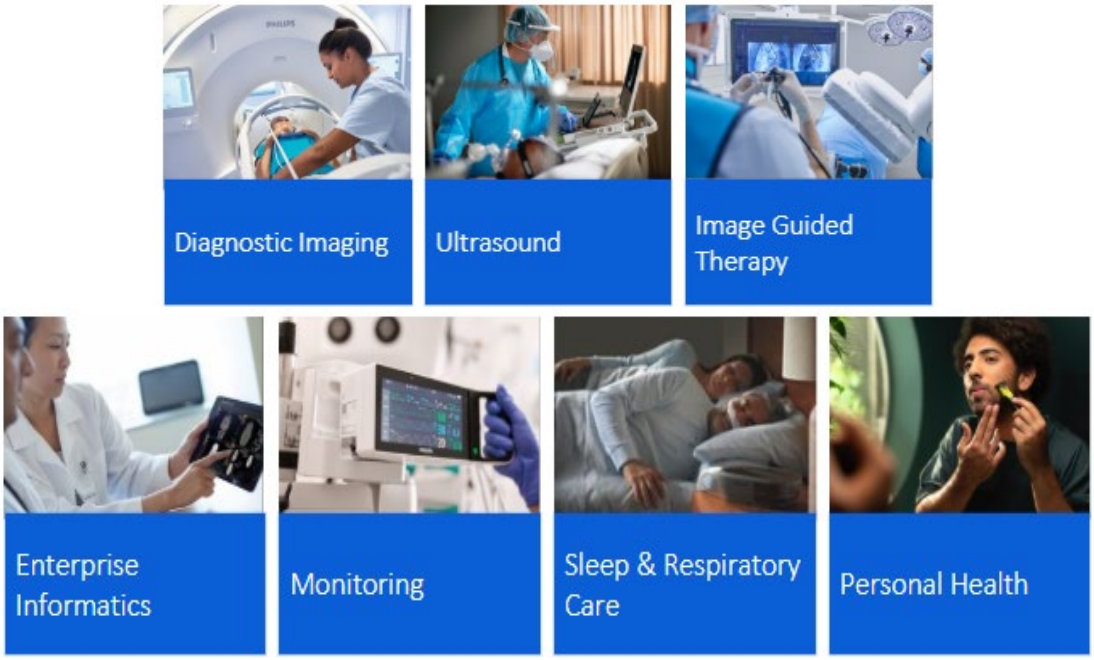
Lastly, supplier performance monitoring serves as the glue connecting these elements, enabling ongoing evaluation and fostering accountability. By leveraging performance metrics, organizations can build lasting partnerships with suppliers who consistently meet quality expectations.

Together, these principles form a cohesive framework for supplier quality management, demonstrating the interconnected nature of each element. As a partner in our shared pursuit of excellence, your commitment to these practices will ensure a sustainable and thriving collaboration.

3. Philips Ecosphere

Philips, a global leader in health technology, leverages a broad portfolio of innovative solutions designed to improve people's health and well-being. With a focus on Diagnosis and Treatment, Connected Care, and Personal Health, Philips aims to deliver advanced technologies that support seamless healthcare

experiences and empower personal wellness. Our structured approach allows suppliers to support multiple areas of our business, ensuring the collaborative delivery of these solutions, all driven by our mission to make life better through meaningful innovation.



4. Supplier Evaluation and Qualification

Philips evaluates suppliers based on their ability to meet company and regulatory standards, focusing on product quality, service, and technical capabilities. This qualification process involves assessments, certification reviews, contract establishment, and quality audits.

Once qualified, suppliers are added to the Philips Business Approved Supplier List (ASL). Due to the company's extensive scope, additional qualifications may be necessary when engaging with various Philips business units, with requalification required in cases of new business, increased risk or complexity, or varying quality performance.

5. Part Qualification - Advanced Product Quality Planning (APQP)

As a part of our commitment to patient safety, quality and our efforts to drive continuous improvement, our purchased materials are qualified via the *Advanced Product Quality Planning Process*.

For qualification, Philips employs APQP for supplied products which includes new product introduction and changes to existing products.

Philips requires APQP for all new purchased materials and changes affecting released materials, including at sub-tier suppliers (also referred to as sub-contractors, supplier contractors – see for more information the section below "Sub-Tier Supplier Management").

Philips conducts qualification through a Part Submission Warrant (PSW), incorporating various essential elements.

- **Design for Manufacturing, Assembly, and Test (DFM/A/T)** - This approach ensures product designs optimize manufacturing efficiency, simplify assembly processes, and facilitate easy and effective testing and validation.
- **Specification Review and Part Qualification Plan (SRPQP)** – A formal review of product specifications in their entirety to ensure alignment with design requirements and developing a plan for how the part will be manufactured and qualified, including steps for verification and validation.
- **First Article Inspection (FAI)** - Verification conducted on first production samples to ensure they fully meet all specified dimensions, materials, characteristics, and functional requirements before mass production begins.
- **Process Flow Chart** - A diagrammatic representation of the entire manufacturing process, illustrating each step in the sequence of operations, which helps identify key stages and dependencies in production.
- **Manufacturing Quality Control Plan** - A structured approach detailing how quality will be controlled and monitored during production, including specific procedures, inspections, control points, and tests to maintain product standards.
- **Process Failure Mode and Effect Analysis (PFMEA)** - A methodical approach to identifying potential failure points in the manufacturing process, evaluating their impact, and developing strategies to mitigate risks and enhance reliability.
- **Measurement System Analysis (MSA) / Test Method Validation (TMV)** - An evaluation of the measurement systems and test methods used during production to ensure they are capable of accurately assessing the quality of parts and materials.
- **Process Validation Plan and Report** - A plan to test and confirm that the manufacturing process consistently produces products that meet required specifications, documented through a report detailing validation activities and results. All non-verifiable processes require process validation (IQ, OQ, PQ). To support process validation efforts, Philips has published an External Supplier Process Validation Guidebook which outlines the minimum Process Validation expectations for you and your supply base. Supplier processes and tools | Philips. Plan and report should be supported by the SRPQP.
- **Line Readiness Assessment (LRA)** - An evaluation conducted prior to production to ensure the manufacturing line is fully prepared and capable, including equipment setup, personnel training, and procedural readiness.

- **Certificate Requirements (CoC, CoA, Regulatory Requirements)** - Documentation that confirms compliance with specified standards and regulatory requirements, including certificates of conformance and analysis that guarantee quality and traceability.

Sub-Tier Supplier Management

In alignment with the APQP process, suppliers to Philips are expected to independently manage their own suppliers, unless otherwise agreed to with Philips in writing. This includes overseeing relationships, qualifications, and performance to ensure materials used in Philips components and devices meet quality and compliance standards. By paying attention to the entire supply chain, suppliers play a crucial role in maintaining consistent quality control, compliance, and risk management, thereby contributing to the overall reliability of Philips products.

6. Supplier Initiated Changes

As a manufacturer operating in a highly regulated environment, Philips adheres to strict procedures to ensure all purchased products and services meet specified requirements. To facilitate this compliance, Philips establishes written agreements with suppliers that outline their responsibilities. These agreements clearly define the obligation of suppliers to notify Philips of any changes that may affect product and service conformity. To uphold product and service integrity, suppliers inform Philips of any potential changes via written notification at supplierchangerequests@philips.com, as early as possible. This includes modifications undertaken by the supplier, their affiliates, or their suppliers that may impact the products or services provided to Philips.

Some examples that might necessitate such a request:

- Alterations to product or service design
- Changes in manufacturing processes
- Installing, moving, or modifying manufacturing facilities or equipment
- Changes in regulatory compliance status
- Changes in software delivery methods
- Changes to software release schedules
- Changes to support duration for products or software

If there is ever uncertainty about whether a change requires notification, suppliers are encouraged to submit a change request to Philips.

Suppliers shall not implement any changes or ship product affected by the change until Philips has determined the impact of the changes on the product(s) or service(s) provided to Philips and approved the change in writing.

7. Non-conformance Management

Philips has a non-conformance management process designed to address quality issues effectively and at the source. When a non-conformance is identified and potentially requires notification or investigation from a supplier, Philips initiates communication with the supplier through either a Supplier Quality Notification (SQN) or a Supplier Corrective Action Report (SCAR). This approach ensures transparency and collaboration in resolving the issue and preventing future occurrences. All communication is managed and maintained through a supplier portal, ensuring streamlined interaction and data sharing.

In both cases, it is essential for the supplier to trigger the appropriate action within their own Quality Management System (QMS). We rely on their cooperation to effectively investigate and correct the issue, thereby preventing its recurrence. Timely acknowledgement and cooperation is crucial in establishing agreed upon timelines and ensuring the swift resolution of any non-conformance.

Philips is committed to working collaboratively with suppliers to maintain high-quality standards. Based on the nature of the event and impact, Philips will determine if containment, root cause, or corrective actions are required to be documented in the supplier portal. Our shared goal is to uphold excellence and reliability in our products and operations.

Philips will mutually agree with suppliers on SCAR timelines based on the event's complexity. Suppliers should use standard problem-solving methods like 8D or 5-Why and employ statistical methods when possible. Additionally, suppliers should ensure that measurable criteria are defined to confirm that SCAR actions effectively address the root cause of the issue.

Appian:

SQNs and SCARs are communicated and managed within Appian which allows for two-way communication and data sharing between Philips and the supplier. To enable usage, an account must be created by Philips and activated by the supplier.

Appian training material and specific access instructions and credentials can be provided by Philips upon request.

8. Supplier Performance Monitoring and Reporting

Philips evaluates supplier performance using predefined criteria, often including, but not limited to; supplier non-conformances, SCAR timeliness and effectivity, and audit performance. This assessment is conducted monthly and reported accordingly.

Trends in Supplier performance are evaluated to determine if additional actions are required, including but not limited to, audits, change in supplier status, supplier improvement programs. Supplier improvement programs promote active collaboration with managers, engineers, operators, and shift leaders to discover and apply solutions to correct discovered issues. If a supplier is placed into a probation status, no new business can be granted until probation status is lifted. Additional actions may also be required, for cause, at any time.

9. References

Philips Supplier Portal

Supplier processes and tools | Philips

About us | Philips

Supplier Lifecycle Management

Philips Supplier Sustainability Programs

Philips Environmental, Social and Governance Policies

Philips Regulated and Substances Compliance

Philips Expectations on Supplier Sustainability Performance

General Conditions of Purchase

Philips Consumer Products