sense and simplicity

Purchasing Process Overview for Suppliers PCCI Global Purchasing Organization

Introduction

We look forward to working together! The intent of this document is to explain Purchasing processes that you will be exposed to. Being in the highly regulated healthcare industry, there are quality, business and environmental requirements that must be met.

Content of this presentation includes:

- Philips Healthcare, Patient Care and Clinical Informatics (PCCI): Who are we?
- Supplier Selection, Qualification and Contracting
- Inbound Supply Processes
- Supplier Relationship Management and Business Reviews
- Product Lifecycle Data Management
- Change Management
- Quality



Philips Healthcare Guiding Statement

We are dedicated to creating the future of healthcare and saving lives. We develop innovative solutions across the continuum of care in partnership with clinicians and our customers to improve patient outcomes, provide better value and expand access to care.

Philips Healthcare

- A world leader in diagnostic imaging, patient monitoring, clinical information management and related services
- Healthcare Sales: ~40% of Royal Philips Electronics
- Active in healthcare for over 100 years
- Sales 2011 EUR 8.9 billion
- 37,000 people employed worldwide including
- More than 450 products and services offered in over 100 countries
- 8% of system sales reinvested in R&D
- Global manufacturing footprint

Philips Healthcare

Our offerings:

- Computed Tomography
- Diagnostic ECG
- Emergency Care & Resuscitation
- Clinical Informatics
- Interventional X-ray
- Magnetic Resonance
- Monitoring
- Mother and Child Care
- Nuclear Medicine
- Radiation Oncology
- Radiography
- Respiratory Care
- Ultrasound
- Women's Healthcare

















Patient Care and Clinical Informatics

Businesses



Cardiology Informatics



Enterprise Imaging Informatics



Enterprise Patient Informatics Solutions



Therapeutic Care



Patient Monitoring Systems



Specialty and Emerging Markets



Measurements and Monitors



Mother and Child Care

Supplier Selection and Qualification

- As a new supplier, please be aware that our requirements for you are based on the impact to the safety of our product.
- As a supplier of custom parts/products, you are required to complete the following:
 - Supplier Self Assessment: to better understand the quality, business and environmental systems within your organization.
 - Change Notification Agreement: to ensure we are notified of an changes so we can determine if the change may affect the quality of our devices.
 This is a Quality System requirement.
- Depending on our relationship, you may also be required to sign:
 - Sustainability Agreement
 - Quality Agreement
 - Business Contracts (eg., Umbrella Purchasing Agreement, etc)
- Finally, Philips may choose to conduct a more detailed assessment or Quality Audit of your site.

Inbound Supply Processes: Introduction

We use multiple methods of managing inbound supply

- Traditional PO's via email
- Purchase Orders via a secure Web site SNC PO Collaboration
- Supplier Managed Inventory via a web portal Nocturne

These are explained on the following pages.

Inbound Supply Processes (cont'd): SNC (Supplier Network Collaboration)

What is SNC – PO Collaboration?

- Purchase Orders are transmitted to a secured Web site.
- Supplier confirmation of the Purchase Order is entered on line and auto uploaded into our ERP system.

Benefits:

- Provide current open order list.
- Eliminate faxing of Purchase Orders.
- Eliminate order acknowledgement responses via Phone/E-Mail.
- Download the purchase order directly to your ERP system.

Inbound Supply Processes (cont'd): Supplier Managed Inventory Programs

What is SMI and SOI?

 Philips has both SMI (Supplier Managed Inventory) and SOI (Supplier Managed/Owned Inventory) programs for our suppliers. The diagrams below describe briefly how they work.

Supplier Managed Inventory (SMI) Supplier determines when PO to cover Supplier sends invoice. and how much to ship per Philips owns inventory 3 to 6 month upper and lower limits. requirement Supplier Owned Inventory (SOI) PO to cover Supplier determines when Philips creates Supplier owns inventor 3 to 6 month and how much to ship per (Converted to Philips self-billing requirement upper and lower limits. when needed.) invoice.



Inbound Supply Processes (cont'd): SMI and SOI Programs

Benefits:

- Real-time availability of forecast and consumption information via our Nocturne web portal
- Reduced administrative effort in terms of PO management and invoice processing
- Improved production utilization
- Local warehousing space and process support (SOI)
- Competitive advantage
- Solidifies relationship between Philips and the supplier

Inbound Supply Processes (cont'd): Packaging Requirements

Our Expectations:

 Philips expectation is to receive product that is bar coded and labeled and meets legal requirements.

Why do we require this?

- It is a legal requirement.
- Philips wants to process incoming material accurately and efficiently.

What standard does Philips use?

- For finished goods that are distributed within the health care industry:
 The Health Care Industry (HIBC) Supplier Labeling Standard.
- For all other materials: The Electronic Industries Association (EIA)
 Outer Shipping Bar Code Label Standard (ANSI/EIA-566-B).

All new suppliers receive the Philips' Packaging Requirements (A-Q2920-40552) which provides a full description of the requirements.

Rev. C Document Number A-Q2920-00088-F1

Page 12 of 20 Restricted

Business Reviews

Why does Philips conduct Business Reviews?

 We conduct regular Business Reviews with our key suppliers in order to evaluate your performance, as well as strengthen our relationship together. The frequency of these reviews is based on the business relationship that we have.

What can you expect?

- Regular <u>Business Review</u> of your supplier rating, contracts or certificates effectivity, our business roadmap together, etc.
- Global Supplier Rating System score on Quality, Delivery, Innovation, Cost, and Responsiveness.
- Audits and/or Assessments as determined by Philips.

Product Lifecycle Data Management

Philips works with many suppliers – who are also referred to as External Manufacturers (EM's). Therefore, it is critical that all EM's understand how we exchange Part Specification data and how to interpret and incorporate this data correctly.

<u>Mandatory Requirement:</u> The EM must correctly and completely implement this data in their systems, programs, tools, etc. according to its lifecycle status, without any addition or omission.

For more information,

 Philips' Materials Engineers (ME) can help explain key Purchasing and Product Lifecycle Data Management (PLDM) process models and collaboration principles between Philips and External Manufacturers.

Change Management

Philips to You

- When part/product specifications are released or changed, Philips will notify you via a Specification Change Notification (SCN).
- This will include the updated information with the expectation from you to confirm receipt, evaluate and accept the change.
- These SCN's must be acknowledged.

You to Philips

- If there is a potential need for you to change a process or specification, you must first request approval of this change from Philips.
 - This approval process is necessary because Philips must verify that the change does not impact the safety of our medical devices.
- You may send notification with the required information to the responsible Philips' Materials Engineer. The information will be reviewed by Philips. After review, Philips will respond as appropriate.

Quality

Our Objective:

 Philips' objective is to achieve a Zero Defect-level for all products procured, by focusing on product quality and reliability improvement

Processes:

- Along with the items mentioned so far, other processes used in the area of purchased part/product quality to support this objective are:
 - Performance measurement, including a quality score
 - Supplier Corrective Action Request, and Supplier Quality Notice
 - Supplier Audits (QMS, Process focused)

Conditions:

- In order to achieve this objective, Philips has the following conditions:
 - All Preferred and critical part suppliers must have a Quality Agreement
 - All Preferred suppliers are monitored via GSRS
 - For all underperforming suppliers, performance improvement will be driven through an improvement plan

Quality (cont'd): Supplier Corrective Action Requests

- Philips monitors your quality at Receiving, Incoming Inspection,
 Production Line, and from the Field.
- For Supplier Caused Issues, Philips Materials Engineering will send you a Supplier Action Request (SCAR), or Supplier Quality Notice (SQN):
 - SCAR. In these cases, Philips requires you to respond to the SCAR with a root cause analysis and corrective and preventive action plan in a timely manner.
 - SQN: Supplier Quality Notices do not require a response from you. We provide the defect information to you so you are aware of failures for trending purposes and you can determine the need to conduct an investigation.

Quality (cont'd): Supplier Corrective Action Requests

- Methodology: PCCI expects you use a recognized methodology for your analysis, and then reply on the SCAR form using the 8D (8-Disciplines) Methodology
 - 8D is a problem-solving methodology for product and process improvement. More information is readily available on the Internet or can be obtained by contacting a PCCI Materials Engineer.
 - You will be sent a Supplier Corrective Action Request Process External Quick Reference Card, Document Number A-Q2920-00224-F4 which explains our response content expectations in more detail.
- Response Time: PCCI expects you to complete your investigation by the Response Requested Date.
 - If you are not able to complete your investigation within this timeframe, please notify the Engineer listed in the SCAR with additional detail.
- Questions or Problems?: If you believe that PCCI has incorrectly identified an issue as supplier-owned, please notify PCCI. Rev. C Document Number A-Q2920-00088-F1

Title: Purchasing Process Overview for Suppliers

Quality (cont'd): Performance Metrics

Parts Per Million

- PPM = (reject quantity / Used Quantity)*1000000
- Your PCCI Commodity Manager will work with you to define an Agreed PPM level that you will be measured against.

Lot Acceptance Rate (LAR)

- Lot Acceptance Rate (LAR) measures your ability to deliver defect free lots to us. This metric is used to quantify the general issues associated with incoming rejects.
- PCCI expects you to ship us 100% defect free lots.

Number of Complaints (CMP)

- Number of Complaints (CMP) is the total number of Supplier Corrective Action Requests (SCARs) that are the triggered as a result of a CAPA, Field Return, Customer Return, or Supplier Evaluation.
- PCCI expects zero number of complaints because these types of issues can affect our product's performance at our customer's sites.



Thank You

At Philips, we constantly strive to improve our relationships with suppliers. We achieve this by involving suppliers early in the NPI process and providing suppliers with as much information as possible to ensure efficiencies in our products and processes. The result is a win-win for each organization.