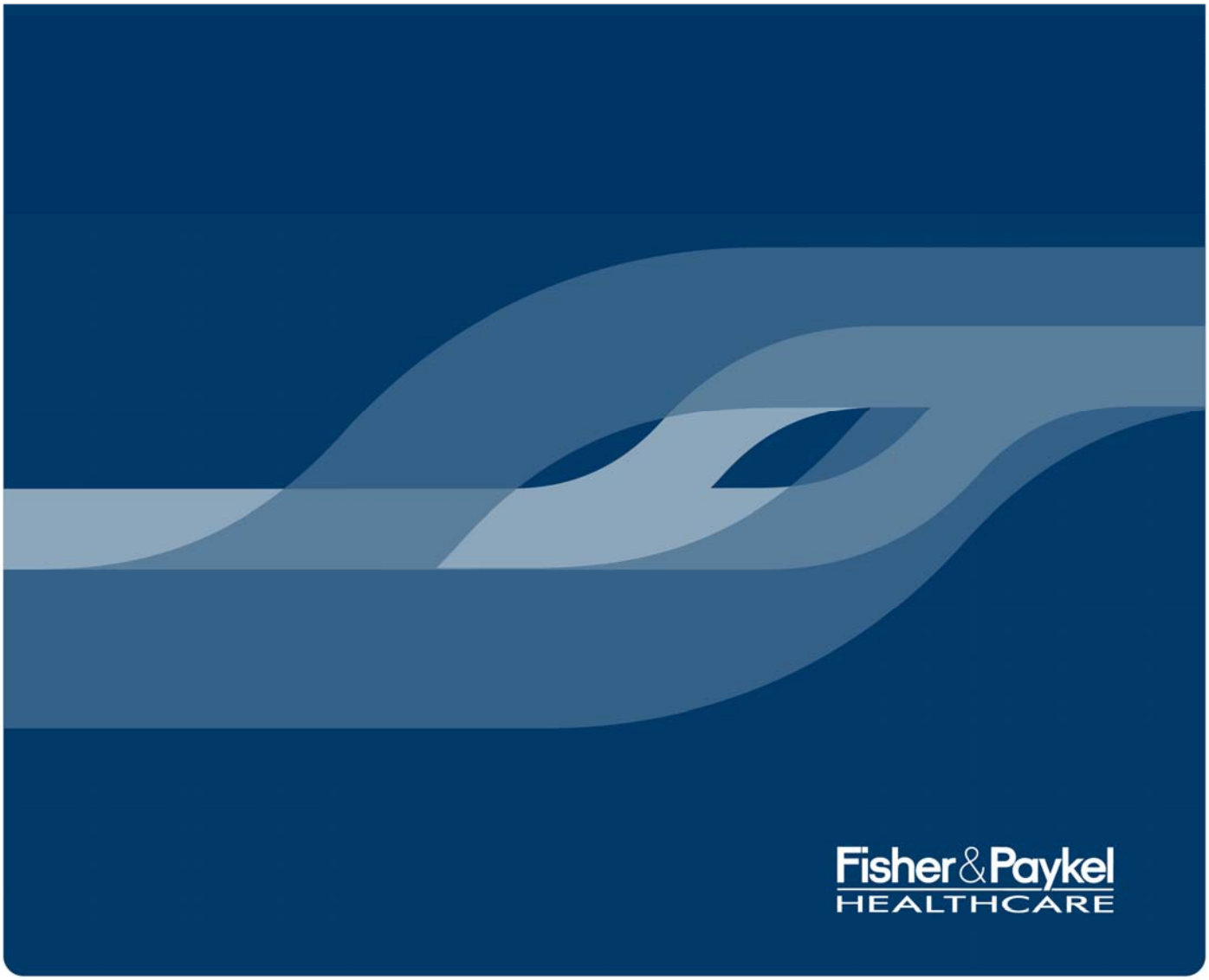
Supplier Quality Manual

Supplier Quality Manual | Revision A



Fisher & Paykel HEALTHCARE

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COMPANY INTRODUCTION

FISHER & PAYKEL HEALTHCARE

We are a leading designer, manufacturer and marketer of products and systems for use in respiratory care, acute care, and the treatment of obstructive sleep apnea.

We manufacture our products at facilities in New Zealand and Mexico and sell them in more than 120 countries worldwide. We sell our products through direct sales offices operations in most of our major markets, and a network of distributors that sell to hospitals, homecare providers and other manufacturers of medical devices. We employ more than 2,750 people around the world including over 325 staff dedicated to research and development.

Fisher & Paykel entered the respiratory care market in 1971 with the development of a unique respiratory humidifier system for use in critical care. We now offer a broad range of products and systems for use in respiratory and acute care and in the treatment of obstructive sleep apnea (OSA).

With the healthcare device industry regulated worldwide, the ability to meet stringent standards is vital to ensuring market acceptance of our products. We assist our compliance with these standards by operating a quality management system certified to a range of international standards which apply to both our manufacturing facilities and our sales network.

We manufacture, assemble and test our complete range of products, including many components, in our facilities in New Zealand and Mexico. Our facilities incorporate controlled working environments and our manufacturing and design processes are certified to meet international standards including ISO9001 and the medical device quality standard ISO13485.

VISION

Our vision is to increase shareholder value by profitably designing, developing, manufacturing, marketing and selling healthcare devices worldwide that improve patient care and outcomes. Our consistent growth strategy is to provide an expanding range of innovative medical devices which can help to improve outcomes and efficiency of care for patients in an increasing range of applications, both in hospital and homecare settings.

KEY PRODUCT GROUPS

We have two major product groups, Respiratory and Acute Care and Obstructive Sleep Apnea.

RESPIRATORY & ACUTE CARE

We offer a broad range of heated humidification products and systems for use during the treatment of respiratory conditions by ventilation or oxygen therapy, which form part of a comprehensive family of solutions for all therapies in the F&P Respiratory Care Continuum.

Incorporating patented and other proprietary technologies, our respiratory devices are designed to overcome many of the challenges of effectively creating, controlling and delivering gases to a patient's airway at close to physiologically normal levels of temperature and humidity.

Our therapy solutions incorporate technologies designed to benefit both the clinician and the patient, translating to efficient delivery of care and improved patient outcomes.

Our products include respiratory humidifiers, single-use and reusable chambers and breathing circuits, infant resuscitators, infant warmers and accessories. We also offer humidification systems for use in surgical procedures to condition dry carbon dioxide gas to normal physiological levels of temperature and humidity.

OBSTRUCTIVE SLEEP APNEA

Fisher & Paykel Healthcare is a leading innovator that excels in the treatment of obstructive sleep apnea (OSA). We entered this market with the introduction of a heated humidifier, adapted from our sophisticated ICU technology, as a simple adjunct to continuous positive airway pressure (CPAP) therapy. The aim was to improve patient comfort and compliance to a treatment, which was at the time not very well tolerated. Heated humidification has since become a widely accepted part of CPAP therapy. Today, we offer a comprehensive range of CPAP devices, masks and humidifiers that deliver the best in sleep performance for an energized lifestyle.

SUPPLIER QUALITY MANUAL OVERVIEW

PURPOSE AND SCOPE

The purpose of this Supplier Quality Manual is to communicate Fisher & Paykel Healthcare's expectations and requirements to all potential and existing external suppliers to Fisher & Paykel Healthcare. This includes all suppliers of product, parts or services to Fisher & Paykel Healthcare including, without limitation, suppliers of raw materials, components, assemblies, printed material, custom applications or embedded software, Original Equipment Manufacturers (OEMs), contract manufacturers of finished products and service suppliers associated with our products.

These expectations and requirements are based on Fisher & Paykel Healthcare's regulatory, quality, product, process and customer requirements to ensure quality products are manufactured. As suppliers are critical to Fisher & Paykel Healthcare's success in delivering quality products through their supply of product, parts and services, this Supplier Quality Manual delivers an overview of those expectations and requirements.

The requirements within this Supplier Quality Manual are provided as a supplement to existing agreements, purchase orders, drawings and specifications between Fisher & Paykel Healthcare and existing suppliers and do not replace or alter any existing agreements, purchase orders, drawings or specifications.

KEY ROLES AND RESPONSIBILITIES

As part of a working relationship, it is important that the roles and responsibilities are defined. This is to ensure that each party understands their role in ensuring success for both parties. As you may deal with various individuals within our organization, their defined roles and responsibilities are outlined below. These represent the core roles and responsibilities within our business although titles may differ slightly.

SUPPLIER:

As a supplier to Fisher & Paykel Healthcare, your organization is responsible for developing and maintaining a quality management system to ensure consistent performance in delivering conforming products, parts or services to Fisher & Paykel Healthcare. This includes responsibility for ensuring compliance to Fisher & Paykel Healthcare requirements and specifications for products, parts or services rendered, including those requirements provided in this document.

FISHER & PAYKEL HEALTHCARE:

Supplier Quality:

Supplier Quality personnel are responsible for the evaluation and approval of potential suppliers, and liasing with suppliers to ensure quality systems, products, parts or services conform to requirements and specifications. This includes process requirements to ensure consistent manufacture of supplier products, parts or services and resolving non-conformances with the supplier. As part of ensuring these expecations and requirements are continually met, they are also responsible for ongoing monitoring of supplier

performance. This includes engaging suppliers to continuously improve process capability, reduce waste and variability, and providing input for changes to a supplier's approval status.

Purchasing:

Purchasing is the primary contact for all production-related purchases to ensure production material requirements are met. Purchasing is also involved in the approval of any new business with existing suppliers. The supplier must inform the Purchasing group through the relevant Materials Controller for any delivery related issues for existing products, parts or services. This includes any changes that may be made to your packaging, process, product or facility that may impact the form, fit or function of the purchased product, part or service.

Procurement:

Procurement are the primary contact for all commercial and business aspects of the supply chain. This includes any changes in pricing, business structure, supply agreements or for any new potential business or technology. They are also involved in the selection and evaluation of all new suppliers and form the link between new suppliers and product development.

Development Engineering:

The Product or Process Development teams are responsible for defining requirements and specifications for supplied product, part or services. They are also responsible for the assessment and approval of any new, or changes to, outsourced products, parts or services.

Operations Engineering:

The Operations teams are responsible for ensuring ongoing production requirements are met during the manufacture of our devices. This includes the implementation of a new product design into production and implementation of changes to existing outsourced products, parts or services. They are also involved in improvement initiatives to existing products, parts or services within the manufacturing environment.

QUALITY MANAGEMENT SYSTEM

MEDICAL DEVICE REGULATIONS

As a medical device manufacturer distributing to markets worldwide, Fisher & Paykel Healthcare is required to comply with many regulations. These include the United States Food & Drug Administration's (FDA) 21 CFR Part 820, Europe's Medical Device Directive (MDD 93/42/EEC), Japan's Pharmaceutical Affairs Law (JPAL) and Canada's Medical Device Regulations (SOR 98/282). These regulations form the basis of the Quality System requirements we place on our suppliers.

The Quality System requirements we place on our suppliers ensures ongoing compliance to these regulations as well as ensuring systems are in place to support the manufacture of quality products and parts and delivery of quality service.

QUALITY SYSTEM REQUIREMENTS

Each supplier shall develop and maintain a quality management system to assure supplied product, parts or services consistently meet Fisher & Paykel Healthcare requirements and specifications. A quality system that conforms to ISO 9001:2008 or equivalent establishes a baseline Quality Management System. Although a certified Quality Management System is not required, suppliers are encouraged to have their Quality Management System confirmed by an independent audit such as third party certification.

Management responsibility and review:

Suppliers shall ensure that management responsibility and authorities are clearly defined, documented and communicated within its organization. Management shall ensure sufficient resources for an effective quality management system.

Internal Audits:

Suppliers shall ensure that periodic review of the effectiveness of the quality management system is undertaken and documented.

Training:

Suppliers shall 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 conducted should be documented and include training to the Quality Management System as it applies to the invidual roles of the employees.

All employees should also be made aware of defects which may occur from the improper performance of their specific roles.

DOCUMENT CONTROL & RECORDS

The supplier shall have a process in place to control documents and records relating to the Quality Management System including manufacturing and distribution data. This should include storage conditions to prevent the deterioration, damage or loss of documents. This process shall also ensure documents are approved before use and outline how the documents are distributed.

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 and specifications should be able to be retrieved for review by Fisher & Paykel Healthcare or any regulatory body within a reasonable timeframe.

Examples of records a supplier should retain, to demonstrate its conformance to requirements, include test results, equipment verification records and calibration records. This includes dates of manufacture, quantity manufactured, quantity released for distribution, part and lot identification, and data demonstrating conformance.

A record retention policy should also be in place to ensure records are maintained in accordance with standards, regulations and agreements. A supplier should determine its record retention period to be equivalent to the lifetime of the product. Any record retention period has to be compliant with the applicable laws, regulations, standards and agreements.

PURCHASING CONTROLS

Suppliers are responsible for their direct suppliers and supply chains to assure that raw materials and components used in the manufacture of their products, parts or provision of services meet Fisher & Paykel Healthcare specifications. As such, suppliers shall apply appropriate supplier controls to ensure that their suppliers comply and are capable of meeting requirements and specifications.

IDENTIFICATION & TRACEABILITY REQUIREMENTS

Supplier shall have a system in place to identify product during all stages of receipt, production, and distribution. This system shall also ensure that product in different stages of the manufacturing process is properly identified to avoid mix ups. This includes any raw materials, in-process materials, inspected product, nonconforming product and product ready for shipping or storage.

The system shall also ensure that the raw material and components used to manufacture the product or part shipped to Fisher & Paykel Healthcare can be traced through their system throughout the production process from receipt to shipping. A unique traceability identifier, such as a lot or batch number should be included on the product labels. For all custom components, the label must also include the Fisher & Paykel Healthcare part number and revision.

PRODUCTION & PROCESS CONTROLS

Each supplier shall develop, conduct, control and monitor production processes to ensure parts manufactured conform to specifications. This includes documented instructions that define the production activities, approval of processes and equipment and any changes to those processes and equipment, monitoring and control of process parameters and component and device characteristics during production.

Environmental Controls:

Suppliers shall ensure product or parts are manufactured in an environment to reduce contamination. This may include applying environmental controls and processes for maintaining cleanliness and separation between areas where controls are in place and uncontrolled areas. This may also extend to personal

protective equipment (PPE) for employees within defined areas of the production environment, and design of buildings to ensure sufficient space and suitability for use.

Equipment:

Suppliers shall ensure adequate equipment is available and adequate for the manufacture of products to meet specifications. This includes ensuring equipment is maintained periodically, documenting activities performed and by whom and when the activites are performed.

Suppliers shall ensure that all measuring equipment, used for testing and inspection of components are calibrated or otherwise verified to a national or international standard. A process should be in place to ensure that equipment is routinely inspected, calibrated and maintained to ensure its accuracy is maintained. Equipment should also be identified with its status and protected from any unintended alteration. The limits of accuracy and precision should also be known, to ensure the correct equipment is used for the appropriate measurements. Records of these activities shall be maintained.

CHANGE NOTIFICATION

Suppliers shall ensure adequate notification is provided to Fisher & Paykel Healthcare for changes which may affect the form, fit, function, reliability, serviceability, performance, functional interchangeability, regulatory compliance, safety or interchangeability of the product, part or service. This includes changes made by sub-suppliers. This is to allow us to assess whether the change may affect the overall quality, safety, performance or effectiveness of the affected devices. Notification of changes must include description of the change, proposed implementation date, and affected products, parts or services. Notification must be in writing and should be addressed to a Purchasing representative. For suppliers of custom products, parts or services, all changes must be approved by Fisher & Paykel Healthcare prior to implementation. A minimum of six months' notice is required prior to implementing a change.

ACCEPTANCE ACTIVITIES

Suppliers shall establish and maintain procedures for acceptance activities. This includes inspections, tests and verification activities for raw materials acceptance (incoming product), in-process acceptance activities, and release of finished product. This includes procedures that ensure in-process product is controlled until required tests or approvals are performed demonstrating compliance to specifications. These activities shall be documented and available upon request for review.

The release of product shall also ensure that associated data and documentation is reviewed and approved prior to release, to ensure that each production lot, run or batch meets acceptance criteria and is authorised by designated personnel. Product shall be held in quarantine or otherwise adequately controlled until released. The product's status shall be identified to indicate its acceptance status. This status shall be maintained throughout production to distribution.

PACKAGING & LABELING

Suppliers shall package products appropriately for shipping to preserve the product's integrity throughout the shipping process within the supply chain. Suppliers must also ensure that labeling and marking of shipped products are sufficient to enable adequate identification and traceability back through the supplier's systems. This includes ensuring the labeling and marking maintains its integrity and remains affixed throughout the shipping process.

SUPPLIER & PART APPROVAL PROCESS

PROCESS OVERVIEW

All suppliers must be evaluated and approved prior to use within our business. The process for all potential suppliers, involves evaluation of the supplier's business systems and their ability to meet requirements and specificiations for the product, part or service. This forms the basis of Fisher & Paykel Healthcare's Supplier & Part Approval Process (SPAP). This process is intended to ensure that those suppliers can consistently meet requirements our specifications.

Fisher & Paykel Healthcare uses a classification system based on the product, part or service being supplied and its impact on the finished product being manufactured by Fisher & Paykel Healthcare. This classification then enables suppliers to be grouped into categories which determines the level of approvals and ongoing controls required.

The Supplier & Part Approval Process can be considered in two parts:

- Supplier Approval: Evaluation of the supplier's business systems against internal requirements.
- Part Approval: Evaluation of the supplier's process capability in consistently meeting specifications.

SUPPLIER APPROVAL

As part of the approval process, the following documents may be requested depending on the level of approvals required. These documents will be sent to your identified contact and should be completed and returned to a representative of the Supplier Quality team within 10 working days.

- **Confidentiality Agreement (CA):**
  This is an agreement between Fisher & Paykel Healthcare and the potential supplier wherein the supplier agrees not to disclose any confidential information that it receives in the course of providing products or services to Fisher & Paykel Healthcare.

- **Vendor Questionnaire (VQ):**
  This is a set of questions structured in such way to provide Fisher & Paykel Healthcare with an overview of the supplier's general operations, quality management system and inventory practices. This provides an initial indication of the supplier's business systems.

- **Self Assessment Scorecard (SAS):**
  This is a questionnaire evaluating the implementation of the supplier's Quality Management System (QMS). The SAS is a guide intended to provide an initial understanding of the Supplier's Quality Management System as part of the Supplier Approval Process.

- **Supplier Quality Agreement (SQA):**
  This is an agreement between Fisher & Paykel Healthcare and the supplier covering specific quality requirements related to the component, products or services being supplied and the supporting Quality Management Systems implemented by the supplier. The SQA details the nature of the relationship and outlines the responsibilities of both the supplier and Fisher & Paykel Healthcare and specifically focuses on quality requirements. Once signed, it documents the

commitment of both the supplier and Fisher & Paykel Healthcare in meeting these quality requirements. It is our expectation that the supplier will work with Fisher & Paykel Healthcare to put this agreement in place.

- **Supplier Audits (SA):**
  For any supplier determined to be Sole Source[1] or a Contract Manufacturer[2], an audit is required and will be performed as part of the Approval process. An audit may also be performed for other suppliers as considered necessary by Fisher & Paykel Healthcare. Refer to the Supplier Audit section of this Supplier Quality Manual for more information on the Supplier Audit process.

Once you have completed these documents and submitted them to a Supplier Quality representative, they will be reviewed to ensure your business and quality systems meet our requirements.

PART APPROVAL

The Part Approval process determines the supplier's process capability in meeting the specifications for a product or part being supplied and manufactured into or sold as a finished product. This process applies:

- For any new part or component manufactured into a finished device for distribution.
- Where there is a change to the specification of a part e.g. a material change.
- Where there is a change to the suppliers manufacturing process e.g. a new tool is required.
- Where the process output can not be fully verified by subsequent inspection or testing.

In the absence of the above conditions, Part Approval may still be performed for business reasons.

Part Approval includes:

- training of personnel;
- the execution of production runs;
- measurements of key dimensions;
- inspection of product, part characteristics; and
- documentation of the above results.

Prior to performing Part Approval and initiating production, the manufacturing process should be documented in a work instruction, standard operating procedure or equivalent and the specifications have been determined and communicated. A protocol outlining the requirements for production, inspection and

[1] *Sole Source:* Specific products or services available from only one source, also called sole provider, sole supplier, sole vendor, or sole distributor.

[2] *Contract Manufacturer:* Manufactures a finished device to another establishment's specifications.

testing equipment as well as acceptance criteria must be established before the production run is initiated. This protocol must be approved by Fisher & Paykel Healthcare before execution of the production run.

During Part Approval, any measurement equipment used for inspection and testing must be calibrated. Any deviations from the approved protocol must be reviewed and approved by Fisher & Paykel Healthcare prior to execution of the deviation.

The level of confidence and reliability required to be achieved in the process will vary depending on the impact of the supplier product or part on the finished product. The minimum process capability index (Cpk) required to be met for any process is 1.33.

Before a product or part is approved, a report detailing the outcome of the production runs, inspection and testing will need to be reviewed and approved by Fisher & Paykel Healthcare.

Where Part Approval is not required, a First Article Inspection may be performed. This involves verification of key dimensions or characteristics from a single batch against requirements and specifications.

APPROVED SUPPLIERS

Once the Supplier Approval and Part Approval has been performed and successfully completed and documented, the supplier and part will approved. Approval of the supplier and part involves the establishment of the supplier in our approved supplier list. As an approved supplier, purchases may be made of the approved product or part, and further business may be sought for new products, parts or services.

If the Supplier Approval or Part Approval is unsuccessful, the potential supplier will remain unapproved for the supply of the part under evaluation until the requirements have been met and a reevaluation has been undertaken.

SUPPLIER AUDITS

PROCESS OVERVIEW

As part of the Supplier and Part Approval process as well as ongoing monitoring of supplier performance an audit of the supplier's Quality Management System and production processes may be required. This is to verify compliance to applicable standards, regulations, agreements, requirements and specifications. It will also involve a review of processes and procedures in place to assure quality product is manufactured and delivered to Fisher & Paykel Healthcare.

The audit will be conducted by a Supplier Quality representative and may involve a Procurement, Purchasing, or Product Development or Operations representative from Fisher & Paykel Healthcare. The audit will usually involve a visit to the supplier's facility where an on-site audit is conducted and the manufacturing activities and documentation is reviewed against set requirements. Alternatively, a desk audit may be performed whereby documents are submitted for review. It may also include interviews using video or telephone conferencing. A contracted audit may also be performed, whereby a contracted organization may perform the audit on Fisher & Paykel Healthcare's behalf.

Audit Plan

Prior to the audit, an audit plan will be issued outlining the areas to be audited and overall schedule for the audit. The supplier's feedback will be sought on the audit plan. This is to ensure arrangements can be made to enable all required personnel and documentation to be available during the audit.

Audit Execution

During the audit, the process, procedure, personnel and documentation may be reviewed for areas identified in the audit plan. This may involve the collection of objective evidence and interviews of personnel to support implementation and effectiveness of the supplier's Quality Management System.

Areas that are found to be non-compliant against a standard, regulation, agreement, requirement or specification, will be noted as findings and classified depending on their severity. These findings will be discussed at the close out meeting with the supplier's representatives.

Supplier Audit Corrective Action Plan (SACAR)

Following the completion of the audit, any findings noted will be documented in a Supplier Audit Corrective action report. This report will be issued to the identified quality contact for the supplier.

A response is due from the supplier within 10 days of receipt, with a proposed corrective action plan and estimated completion date provided. This will be reviewed by the Supplier Quality representative and feedback provided. As the corrective actions are completed, the Supplier Audit Corrective action report should be updated and returned to the Supplier Quality representative for review.

Audit Closure

Once all corrective actions have been completed and objective evidence provided demonstrating implementation and effectiveness, the supplier quality representative will review to ensure all corrective action has been adequately addressed. Once this review has been completed, and deemed to be adequate, the Supplier Audit will be closed and the supplier notified.

SUPPLIER NON-CONFORMANCE REPORTING

PROCESS OVERVIEW

All suppliers shall define processes to control product that does not conform to Fisher & Paykel Healthcare specifications. This is to ensure that any identified supplier nonconforming product will be documented and appropriately addressed and corrected. A non-conforming product is any supplied product or part that has not met requirements or specifications.

Any non-conforming product identified by Fisher & Paykel Healthcare and communicated to the supplier should have appropriate containment, correction and corrective actions taken and the supplier should confirm that the actions taken have been verified as being effective.

INITIATION OF A SUPPLIER NON-CONFORMANCE REPORT

Where Fisher & Paykel Healthcare has identified non-conforming supplied product, a Supplier Non-conformance Report (SNCR) may be issued to the supplier. This may be identified at any stage of the manufacturing process, anywhere from receipt of the goods through to finished product inspection, distribution and sale. Samples of the defective product may be requested from Fisher & Paykel Healthcare for investigation by the supplier.

RESPONDING TO SNCRs

The supplier shall use the SNCR form provided by Fisher & Paykel Healthcare or supplier's internal non-conformance report equivalent to SNCR to document subsequent actions taken to respond.

The SNCR shall document the minimum as follows:

- Supplier Containment & Correction Action: Supplier shall complete an investigation to determine the extent of the nonconformance, complete the containment of identfied nonconforming product and implement a correction within three working days from the issuance of the SNCR. Containment is an action taken to prevent a non-conformance spreading or continuing (ie. Quarantine) and a Correction Action is an action taken to eliminate the non-conforming product. This may include repair, modification, adjustment, relabeling, destruction or re-inspection of a product. The first lot or batch on which these actions are implemented shall be communicated in the SNCR.
- Root Cause Analysis & Corrective Action Plan: Suppliers shall complete a Root Cause Analysis (RCA) and determine a corrective action plan to address the root cause(s) of the problem within 10 working days from the date of SNCR issuance. Root Cause analysis involves identifying the primary causes of nonconforming product rather than addressing their symptoms. Corrective Action is an action taken to eliminate the cause of an existing non-conformance in order to prevent recurrence, ie. change in process, equipment or procedure.
- Corrective Action Implementation: Suppliers shall implement the corrective action plan within 20 working days from the date of SNCR issue OR until the agreed planned implementation date. The first lot or batch on which these actions are implemented shall also be communicated in the SNCR.

CLOSURE OF A SUPPLIER NON-CONFORMANCE REPORT

As each step in the SNCR process is completed, the documentation shall be sent to the Supplier Quality representative, where it will be reviewed for adequacy and effectiveness. This includes verification that the first good lot or batch after containment and correction is free from the original non-conformance. Once the corrective actions have been implemented, verification of the actions will also be undertaken on the post corrective action lots or batches.

If the verification activies deem the actions to be effective, the SNCR will be closed by the Supplier Quality Representative and communicated to the supplier.

SUPPLIER PERFORMANCE MONITORING

PROCESS OVERVIEW

The performance of all suppliers to Fisher & Paykel Healthcare is monitored on a regular basis to ensure suppliers' ongoing commitment and ability to meet business requirements. This review includes various indicators of supplier performance. Performance is measured using both quality and delivery performance indicators.This performance may be communicated to suppliers on a periodic basis.

PERFORMANCE INDICATORS

Quality: This is to measure conformance of supplied parts, products, components and service to Fisher & Paykel Healthcare's requirements and specifications . It is monitored through the following processes:

- Incoming Goods Quality Control Acceptance (IGQCA) . This is the measure of the number of units accepted in IGQC, as a percentage of total number of units delivered.
- Line Acceptance (LA). This is the measure of the number of units accepted in production, as a percentage of total number of units consumed.
- Supplier Non-conformance reports (SNCR). This is the number of SNCRs issued against a supplier.

Delivery: This is to measure the continued ability of a supplier to meet Fisher & Paykel Healthcare business inventory delivery requirements.

- On-time Delivery (OTD). This is a measure of the number of deliveries received on time as a percentage of total deliveries expected.

Additional performance indicators may be added at the discretion of Fisher & Paykel Healthcare.

SUPPLIER RATINGS

A supplier is given an overall performance rating, based upon a cumulative score of the weightings. The cumulative weighting score is between 0-100% and the resulting performance rating will be an indication of a supplier's performance as measured against the supplier performance indicators. This will be used as an indication of business impact and ability to meet set requirements.

PERFORMANCE MONITORING OUTCOMES

The supplier's performance is reviewed periodically to assess trends in quality and delivery performance. As a result of a supplier's performance, subsequent actions may be deemed necessary to improve the performance which may include but not limited to supplier audits, corrective and preventive actions through supplier development projects. Suppliers who repeatedly fail to deliver satisfactory products or do not deliver on time despite earlier requests for corrective actions may be denied the opportunity to quote new business or may be removed from the Approved Supplier List and business discontinued. A supplier's performance may also drive a change in the inspection performed on the supplier's product, part or service. In the same way, suppliers with consistent and excellent performance may be identified for further business.

APPENDIX: ACRONYMS & DEFINITIONS

CA	Confidentiality agreement - also known as a non-disclosure agreement
FPH	Fisher & Paykel Healthcare
FDA	Food and Drug Administration - the United States regulatory body responsible for food and drugs, including medical devices
GDP	Good Documentation Practices - General guidelines for maintaining quality records
IGQC	Inwards Good Quality Control - Fisher & Paykel Healthcare process for inspecting supplied product before release into production
JPAL	Japan Pharmaceutical Law - Japanese regulations covering medical devices
LA	Line acceptance - number of parts that are conforming as measured against total number of parts consumed in production
MDD	Medical Device Directive - European regulations covering medical devices
OEM	Original Equipment Manufacturer - a supplier that manufactures and provides a finished medical device for sale under its own brand name
OSA	Obstructive Sleep Apnea - a sleeping disorder for which a product group within Fisher & Paykel Healthcare is specifically focused on providing medical solutions for
OTD	On Time Delivery - the number deliveries on time against total number of deliveries
PPE	Personal Protective Equipment - tools, equipment, clothing issued for health and safety requirements
QMS	Quality Management System - set of structures, processes, and procedures defininining an organisations' system for assuring product safety and efficacy
RAC	Respiratory & Acute Care - product group within Fisher & Paykel Healthcare which manufactures medical devices for treating patients with respiratory conditions
RCA	Root Cause Analysis - process for determining the primary causes of a non-conformance
SA	Supplier Audit - an assessment of a supplier's Quality Management System through the review of process, procedures, personnel and practices
SACAR	Supplier Audit Corrective Action Report - a document issued upon completion of a supplier audit detailing the findings and corrective actions
SAS	Self Assessment Scorecard - Quality Management System-based questionnaire for the evaluation of a supplier's Quality Management System
SNCR	Supplier Non-Conformance Report - a document issued upon receipt and confirmation of non-conforming supplied product for documentation and approval of subsequent actions
SQA	Supplier Quality Agreement - specific quality agreement identifying quality requirements for supplied product, parts or services
VQ	Vendor Questionaire - set of questions intended to provide an overview of the supplier's business systems.