



Pall Corporation

## Pall Corporate Quality Manual

### Approvals:

A handwritten signature in black ink, appearing to read "Jennifer Honeycutt".

07 Nov 2017

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**Jennifer Honeycutt**  
President and CEO Pall Corporation

Date

A handwritten signature in blue ink, appearing to read "H. Idink".

21 Nov 2017

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**Dr. Heike Idink**  
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Date

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## 1.0 Purpose

The purpose of the Corporate Quality manual is to offer guidance to individual Business Units on what the minimum corporate quality requirements are, including details of the corporate procedures against which each Business Unit must comply.

## 2.0 Scope of the Corporate Quality Manual

The overarching Quality Manual covers all BUs, encompassing their products and services.

## 3.0 References

The Corporate Quality Manual sets the general direction such that the product or service to be provided shall adopt the ISO 9001 Standard (current revision) and the Corporate requirements. Each BU shall identify, document and maintain the specific statutory, regulatory, and customer references that are required in the specific industries and markets in which they conduct business.

## 4.0 Abbreviations

- BU – Business unit
- QARA – Quality Assurance and Regulatory Affairs
- PEC – Product Environmental Compliance
- KPI – Key Performance Indicators

## 5.0 Quality Policy

The Pall Leadership Team has established a quality policy that is appropriate to the BU Centric Organization and provides a framework for setting goals and objectives that satisfy applicable requirements and show a committed focus on continual improvement. Pall assures that the quality policy is communicated, understood and applied throughout the organization and is available to relevant interested parties, as required. Pall Quality Policy Statement can be found in **Appendix B**

## 6.0 Understanding the context of the Pall Corporation

Pall Corporation (Pall) is an operating company of Danaher Corporation. It is a global filtration, separation and purification company providing solutions to meet the critical filtration management needs of customers across a broad spectrum of life sciences and industrial applications.

As part of the Danaher family of companies our shared purpose is “Helping Realize Life’s Potential”. Our process and product enabling technologies help make good products better, safer and even possible.

We are committed to effective quality management, continual improvement and assure that all products and services meet the general quality requirements as established in this manual by our Corporate Quality Assurance and Regulatory Affairs (QARAQARA) group. In developing this Corporate Quality Manual consideration was given to the risks and opportunities that needed to be addressed based on business requirements and the ISO 9001 Standard (current revision).

Pall Corporation is a Business Unit (BU) centric organization that specializes in the design, manufacture and support of technologically advanced filtration, separation and diagnostic equipment and devices targeted to meet specific market requirements. When developing the quality management system, Pall Corporation considered the impact of internal and external issues arising from the following as applicable: legal, technological, competitive market, cultural, social, environmental, economic, internal values, cultural knowledge and overall performance of the organization. Interested parties and their requirements have been identified and continue to be monitored as they relate to the quality management system.

## 7.0 Interested Parties

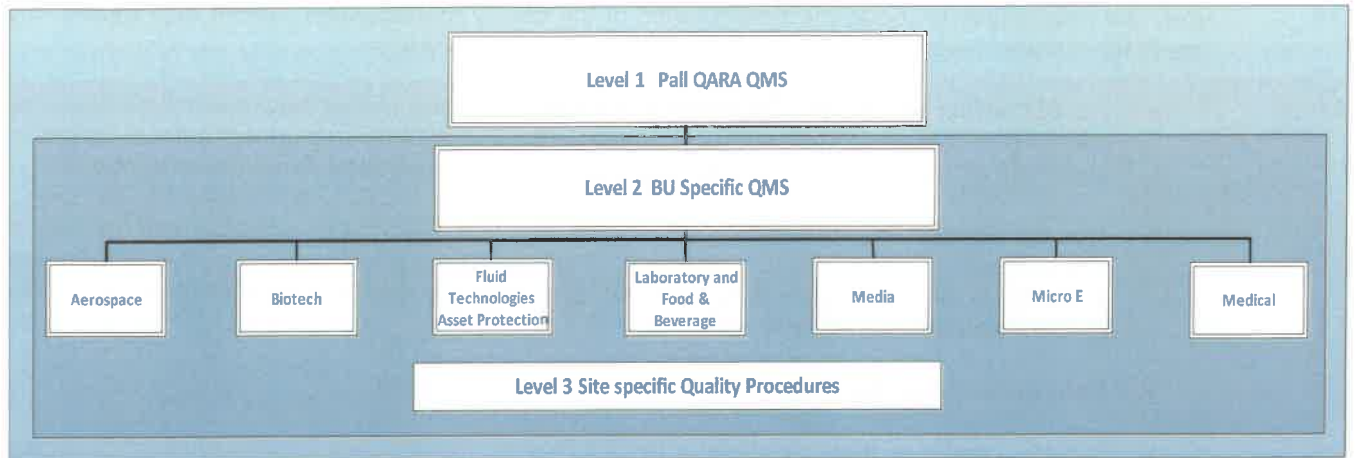
There are a number of interested parties which are reliant and dependent on the existence of the organization. Those interested parties needs and requirements are broadly described as:

- **Customers** – Customers are seen as interested parties as they rely on Pall manufacturing sites to supply them with finished product. In the event of an identified Quality concern, consideration would need to be made to communicate with key customers. On time delivery and **external ppm KPI's are established and monitored as a key customer deliverable**
- **Suppliers** – Suppliers provide the raw materials to enable the site to continue to produce product and supply customers. Suppliers may also supply key components, such as machinery, equipment and provide a range of services enabling the business to operate. Supplier performance KPI's are established and monitored.
- **Utility providers** - Utility providers supply the means necessary to keep a site functioning in regards to power and its distribution. Utility providers typically consist of facility (electric, water, gas, etc.) and IT (land lines, cell phones, etc.) Where applicable, specific contracts are established with service providers to ensure levels of service meet business expectations.
- **Employees** - Employees would be considered interested parties in terms of being competent to perform their role and understanding quality requirements specific to their role. Pall Corporation recognizes employee engagement is a major factor in achieving business objectives and as such monitors the level of engagement through surveys and feedback sessions and focusses on continually improving employee engagement.
- **Contractors** – Contractors would be considered interested parties in terms of services that they provide to each site. Where applicable, individual contracts are provided which determine service level requirements to achieve business needs.
- **Shareholders** – Shareholders would be considered interested parties as the performance of the organization has a direct impact on the share price. It is therefore imperative Pall Corporation continually invests in continual improvement activities and identifies and mitigates threats that could impact the organization with the aim of consistently improving business performance and ensure on-going share value stability.
- **Pall Group** – As a collective group, Pall Corporation would be considered an interested party. There are interactions between sites where one pall site may supply one or more other Pall sites.
- **Regulatory bodies** – Regulatory bodies may be considered interested parties in that communication may need to be made in the event of a breach of regulatory requirements. Depending on the magnitude of an event and/or risk, regulatory/legal bodies may have the authority to levy fines, sanctions, etc., ultimately impacting the business and the ability to continue operations. Information related to contacting regulatory bodies may be found in associate QARA procedures. Pall Corporation has established and implemented measurements to determine the effectiveness of regulatory control

The procedure for the establishment of quality metrics is CQP0019, Quality Assurance KPI's. Risks and opportunities associated with interested parties are described in paragraph 25.0 of this document

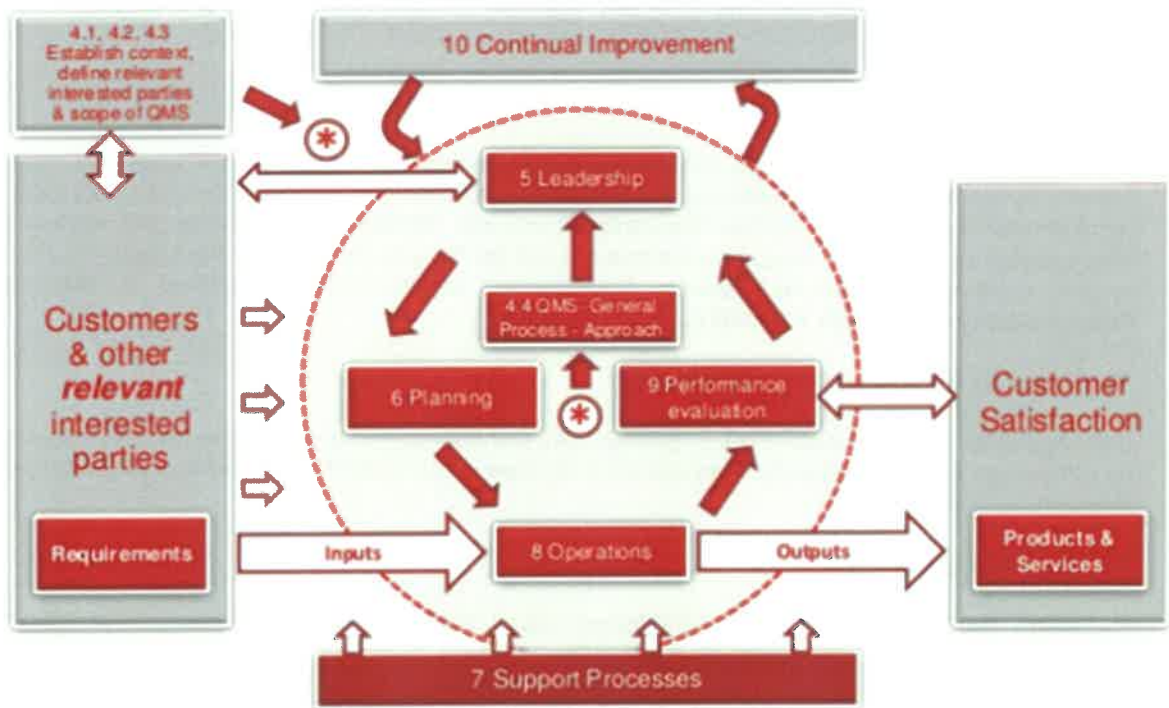
## 8.0 Quality Management System

The Quality Management System will be managed according to the Quality, Business Unit and Site requirements. The diagram below depicts the quality management systems structure and the flow down of corporate QARA requirements. The quality management system takes into consideration any risks and opportunities that need to be addressed. The BUs shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this manual.



### 9.0 Quality Management Process

Below depicts how Pall adopts the Process Approach to the overall Quality Management System / Continuous Improvement in accordance with the principles of ISO 9001. Pall will utilize the Plan-Do-Check-Act Cycle to manage and improve key business processes.



### 10.0 Organizational roles, responsibilities and authorities

Pall's Leadership Team has assigned the responsibility and authority for the Pall Corporate Quality System to the VP Quality Assurance and Regulatory Affairs.

The Corporate QARA group has established the general requirements in this manual, designed the document structure, created necessary Corporate Documents, details of which are referenced in this document. In addition, Corporate QARA will continually monitor these requirements at the BU Level and will assign responsibility and authority to the BUs to ensure that these requirements are cascaded down through their organization(s).

The BU Leader or designee assures that the roles and responsibilities necessary to achieve these Quality requirements in this manual are established and communicated throughout their organization.

They are responsible to report the performance of the quality management system and identify any needs for improvements to the BU. Additional BU responsibilities are:

- The BU Leader will assign a Quality Representative and ensure that they have the competence and skills necessary to implement and maintain the BU quality management system, details of which can be found in the **Training Awareness and Competence Procedure CQP0002**
- The BU Quality Representative will ensure that the BU quality management system is established, implemented and maintained. They are responsible for reporting the performance of the BU quality management system and identifying any needs for improvements to the BU Leader (management review).
- Escalate to the QARA group deficiencies requiring rectification.
- The BU Leader or their designee is responsible for creation and maintenance of controlled document(s) defining the scope of activities and quality management system that will be required for their products and services based on their customer, market, corporate, regulatory and other needs of relevant interested parties.
- Maintain documented information to the extent necessary to provide confidence that the processes are being carried out as planned.
- The BU Leader or their designee will ensure that the requirements have been defined and documented when sourcing products, services or components from any suppliers including another BU's.

#### **11.0 Quality Management System Leadership and Commitment**

Pall Corporation Leadership Team has demonstrated commitment to the overall Quality Management System by establishing and reviewing the Strategic Plans for the organization and integrating these requirements into the BU Centric Business Processes. Continual monitoring and review of the effectiveness of the quality management system will be done to ensure that the quality management system achieves its intended results. Management responsibility is defined in **Management Responsibility Procedure CQP0012**.

#### **12.0 Training Awareness & Competence**

It is imperative those undertaking key quality roles are competent to do so, the minimal requirements for achieving and demonstrating competence is defined in the **Training Awareness and Competence Procedure CQP0002**.

#### **13.0 Quality Objectives**

Corporate Quality Objectives are established based on the Strategic Planning Process and are deployed within the BU's and sites as applicable.

All objectives are consistent with the quality policy, measurable via KPI's, considering applicable requirements, be relevant to product and service conformance and customer satisfaction, be periodically monitored and communicated and updated as appropriate. The method for measuring KPI's is defined in **Quality Assurance KPI's CQP0019**.

## 14.0 Communication

It is important aspects of the Quality Management System are communicated to ensure the requirements of internal and external expectations are understood and those of interested parties. Appendix C contains the minimum requirements of what will be communicated.

## 15.0 Design & Development of Products and Service

Pall Corporation defines the expectation and implements controls for each of our QMS processes. The planning of controls is required to ensure consistent acceptability of products and services and compliance with regulatory requirements. Planning processes include the definition of quality objectives, development for required processes, establishment for appropriate verification programs and the requirement for records necessary to demonstrate the process and products conform to intended requirements. Operational planning and control is required prior to new and/or revised products or processes being implemented. During the planning phase, management will identify:

- Requirements for the products and services;
- Criteria for the processes and the acceptance of products and services;
- Resources needed to achieve conformity to the product and service requirements;
- Control of the processes in accordance with the criteria;
- Documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products and services to their requirements.

The output of operational planning and control includes documented quality plans, resource requirements, processes, equipment requirements, procedures, test data, and design outputs

## 16.0 Management Review

Management reviews are conducted to ensure the continued development and assess effectiveness of the Quality Management System; Management Reviews will be conducted at a site level and consolidated at a BU level. Each BU will complete a minimum of one Management Review per calendar year with the annual management review being completed during Q1

## 17.0 Operation Planning & Control



The above mentioned activity shall be maintained in order to ensure;

- The output of the planning remains suitable for Pall Corporation operations
- Planning activity ensure changes are adequately controlled to prevent any unintended changes taking place and adverse effects from such changes are avoided.

The governing document which details the process to be followed is the **Design Control Procedure CQP0007**.

## 18.0 Legal & Regulatory Requirements

Pall Corporation has established, implemented and maintains procedures to ensure the applicable legal and regulatory requirements are met and adhered to. Pall Connect has a dedicated Legal Centre portal which contains guidance documents and links to other intranet pages where useful supporting information can be located. The Legal Center can be found by following the link below:

<http://connect.pall.net/SitePages/LegalCenter.aspx>

## 19.0 Computer Validation

The QARA function has established corporate procedure for computer validation requirements and assessment of risk with regards to Pall Corporation's computerized systems and software to ensure compliance with 21 CFR Part 11, where applicable. The procedure which details the process is the **Computer Validation Procedure CQP0015**.

## 20.0 Validation of Final Product Test Methods

It is imperative that any method for testing final product is validated. Test method validation provides documented evidence, with a high degree of assurance, that the test methods in use consistently verify product specifications and functional requirements. **Validation Procedure CQP0016** outlines the process that must be used to validate final product test methods, this includes the associated test equipment used to assure that product made at Pall facilities has met requirements prior to distribution.

## 21.0 Product Labels and Labelling Material

It is the responsibility of each BU to ensure Product Labels and Labelling of Material complies with customer and / or regulatory requirements, the process of how this is achieved must be documented at a BU level. **Procedure CQP0003** details the process for labelling products and material

## 22.0 Customer Complaints

The process for managing customer complaints when received is detailed in **Customer Complaint Handling and Trending Procedure CQP0004**.

## 23.0 Product Recall

Where there exists the need to recall products the process to be followed is detailed in the **Recall Procedure CQP 0006**.

## 24.0 Nonconformance & Corrective Action

It is the responsibility of each BU to implement a Non Conformity & Corrective Action Process, the process to be implemented is detailed in the **Nonconformance procedure CQP 0008 and Corrective Action procedure CQP 0001**.

## 25.0 Management of Risk and Opportunities

Pall Corporation uses a number of methods which are collectively used for assessing risk and opportunities the purpose of which is to minimize risk to the interested parties defined in this document. At a strategic level the risks and opportunities that have the potential of impacting on the long term viability and success of the operation are identified through the level 1 leadership team **reviews**. The strategic planning activity takes place at planned intervals the results of which are disseminated down to BU and site level and the results of the planning activity are made available to all interested parties. At a functional / tactical level there are a number of processes that collectively used to manage risk and opportunities, those methods are captured in:

- QARA Risk Assessment Procedure CQP0005
- Control of Changes CQP0010
- Health Safety risk assessments – managed at a site level



- Environmental Impacts and Aspects Assessment (those sites with a documented Environmental Management System)
- Annual Supplier Evaluation & Business Continuity procedure is SSP001
- Business Continuity Threats, BR-003 (those sites with a documented Business Continuity Management System)
- Internal audit program CQP0009
- Design Control CQP0007
- Non Conformity and Corrective Action procedure CQP0001 & CQP0008
- Computer Validation Procedure CQP0015

## 26.0 Documented Information

Corp QARA has developed a documented structure that ensures that the necessary requirements for a quality management system is created and understood. There are a number of mandatory procedures which each BU must comply, details of which is contained within this document.

**Document Control and Good Documentation Practices Procedure CQP0011** outlines the minimum document control requirements. **Record Management Policy LC-003** describes the minimum requirements for retention of records; LC-003 can be located on the Legal Centre which can be accessed by following link [http://connect.pall.net/SitePages/Records\\_Management\\_Center.aspx](http://connect.pall.net/SitePages/Records_Management_Center.aspx)

## 27.0 Changes to the Quality Management System

Pall Corporation has a change management system that assures that all changes are documented and assessed in a planned and systematic manner. The change process includes as a minimum, risk assessments and planning activities including resources and deliverables that would be necessary to carry out the change. All planned changes are controlled and unintended changes are reviewed to assure that actions are taken to mitigate any adverse effects, as applicable. Consideration is given to the integrity of the quality management system and the availability of resources. The minimum requirements are outlined in **Change Control Requirements Procedure CQP0010**

## 28.0 Corporate Audit Program

To ensure the ongoing effective deployment of corporate procedures and also for the purpose of identifying areas of best practice the QARA will execute a corporate audit program, the requirements for developing and executing the program are detailed in **Corporate Auditing – Pall Sites CQP0009**. The results of audit will be reviewed during the corporate Management Review.

## 29.0 Business Unit / Site Specific Audit Schedule

Each BU and or BU site will develop and implement an internal audit schedule and conduct audits in line with planned intervals to ensure the Quality Management System conforms to:

- Corporate procedures
- The sites own Quality Management system
- The requirement of ISO9001

The audit schedule must be developed using a risk based approach taking into consideration:

- Results from corporate audits
- Results from customer audits
- Results from internal audits
- Customer complaints (Inter Company and external customers)
- Performance Against Key Performance Indicators

The development of the audit schedule must be documented. Those performing audits must be competent to do so, the **Training & Competence procedure CQP0002** details those competence requirements

### 30.0 Supplier Management

Pall Corporation maintains responsibility for the quality of all products purchased from external providers, including customer designated sources. Processes ensure products and services being provided by external sources will conform to our customers' requirements. The minimum requirements for Supplier Management is outlined in **Supplier Management Procedure CQP0014**.

### 31.0 Customer Audits / 3<sup>rd</sup> Party Assessments Management

The effective and professional management of audits by customers, regulators or assessment bodies is essential for maintaining the reputation of Pall Corporation **3<sup>rd</sup> Party Audit Procedure CQP0018** describes the minimum requirements.

### 32.0 Regulatory Agency Inspections

Where individual sites manufacturing processes are highly regulated, i.e. Medical or Aerospace products those sites must develop and document their process for handling regulatory agency inspections. When documenting the process consideration must be given to those elements referenced in **Corporate Procedure CQP0018 3<sup>rd</sup> Party Auditing**:

### 33.0 Product Environmental Compliance

Product Environmental Compliance (PEC) broadly relates to the requirement for Pall products to comply with a multitude of legal and regulatory requirements and directives. Pall maintains information relating to PEC on the Pall.Com website. Specific information pertaining to REACH and ROHS can be located on:

<https://www.pall.com/en/about-pall/quality.html>

The screenshot shows a portion of the Pall website's quality page. It features four main sections, each with a blue arrow pointing to the right:

- Pall Site Certifications**: "Locate the certificate needed for your facility" with a "Learn More" button.
- Product Conformance Information**: "View and download documents relating to Pall product Quality and Regulatory requirements conformance. Please check this section periodically for new content." with a "Learn More" button.
- REACH Statement**: "Download" with a dropdown menu showing "English".
- RoHS Statement**: "Download" with a dropdown menu showing "English".

Corporate procedure **CQP0017, Evaluation, Registration and Reporting Under US Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)** has been written to provide direction on the FIRA regulation.

### 34.0 Intercompany Complaints

**CQP0020 Inter Company Complaints** describes the process for managing Inter-company Complaints, the procedure provides guidance on the documenting, investigation, management to closure, tracking and trending of an alleged deficiency reported from another Pall site for product that has not left Pall's control. It is the responsibility of the BU lead to ensure the requirements of **CQP0020** is communicated and understood by the sites under their responsibility.

### 35.0 Product Certification

There may on occasions be the need to manage customer requests for manufacturing product certification.

Procedure **CQP0021 Handling Customer Requests for Product Certification made at Order Entry** describes that process from the time of customer order placement up to and including the provision of the requested item by Pall Customer Services or the relevant Dispatch department.

Requirements for certification identified post order entry may be addressed by the customer, through use of information provided via the 'Quality at Pall' web page. Or, if specific part number / batch number certification is requested post order entry this shall be communicated through Customer Services / Sales and addressed by the Quality site representative for the product manufacturing facility.

### 36.0 Quality Web Page Requirements:

The Pall.com web page contains customer facing information as such it is imperative the information is up to date and correct. Where 3rd party site certifications exist it is the responsibility of the BU lead to ensure those certifications related to sites under their scope of control are up to date.

## Appendix A

### Supporting Corporate Procedures

CQP0001	Corrective Action
CQP0002	Training Awareness & Competence
CQP0003	Product Labels and Labeling Material Review
CQP0004	Customer Complaint Handling and Trending
CQP0005	Risk Assessment
CQP0006	Recall Procedure
CQP0007	Design Control Procedure
CQP0008	Nonconformance's Requirements Procedure
CQP0009	Corporate Auditing - Pall Sites
CQP0010	Change Control Requirements Procedure
CQP0011	Document Control and Good Documentation Practices
CQP0012	Management Responsibility
CQP0014	Supplier Management
CQP0015	Computer Validation Procedure
CQP0016	Validation Procedure
CQP0017	Evaluation, registration and reporting under US Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
CQP0018	3rd Party Auditing Procedure
CQP0019	Quality Assurance KPI's
CQP0020	Intercompany Complaints
CQP0021	Handling Customer Requests for Product Certification made at Order Entry

*Pall Corporation provides filtration, separation and purification solutions to meet industry wide fluid management needs.*

*For each of our products and services, we will meet the requirements of our customers in all areas of the world. We will always ask what can be done better - for our customers, our distributors, our suppliers, our shareholders, our associates and the general public. Our personal commitment is to continually advance our processes by establishing quality objectives as part of our strategic planning process delivering sustained measurable improvements.*

**Appendix C – Communication Matrix**

<b>Requirement</b>	<b>Method of communication</b>	<b>Who from Pall is responsible</b>	<b>When to communicate</b>	<b>With whom to communicate</b>	<b>Who / Governing procedure / process</b>
Quality Policy	Intranet, Pall.com, Corporate quality manual, Policy posters displayed at a site	VP Corporate QARA, Director for Corporate QMS, BU Quality leads, Site level Quality Managers	Continuously displayed and when updates are made	Internal and external interested parties	Corporate Quality Manual
Quality Objectives and targets & performance against objectives	Level 1 leadership communication, Monthly management meetings, Management review, daily visual management boards	As above including site directors / general managers	On release of objectives and on-going reviews	Pall employees	Quality Assurance KPI's CQP0019
Information related to product and service	Service level agreements, purchase orders, complaints process, surveys, design specifications	Multiple persons	Communication take place on an ongoing basis in line internal procedures	Suppliers and customers	Sales, R&D, quality function, Supplier management, legal representatives
Changes to Corporate Quality Manual and procedures	Updates are via Pilgrim	Corporate quality team	When updates are made	Those impacted by the changes, as identified in Pilgrim	Corporate Quality Manual Doc control & good doc practices CQP0011

Appendix D - Revision History

Revision No.	Requested By	Revised By	Description of Change	Effective Date	Change Order Number
004	QARA Group	A. Gill	<p>Changed from QA&amp;RA to QARA.</p> <p>Procedure title added to CQP0009 paragraph 28.0</p> <p>Removed reference to E962 from paragraph 33.0. Title added to procedure CQP0017</p> <p>Paragraphs 34.0 Intercompany Complaints &amp; 35.0 Product Certification added</p> <p>Added paragraph 36.0, Quality Web Pahe Requirements</p> <p>Removed CQSM001 from Communications Matrix in appendix C</p> <p>Removed "Interested Parties" from Communication Matrix in appendix C "with whom to communicate" in respect of performance against KPI's</p> <p>Appendix D added – revision history</p>	See header	DIV CO 34005

