



Status CURRENT

| | | | | |
|--|--|--|------------------------------------|------------------------|
|  Pall Corporation | DOC TYPE DIV - REFERENCE DOCS | DOC NUMBER QARA Survey/Questionnaire Responses | EFFECTIVE DATE 9/14/2017 | REVISION 001 |
| DEPARTMENT Corporate QARA | TITLE Pall Corporation General Quality Systems Survey/Questionnaire Responses | | | PAGE 1 of 4 |

Pall is committed to effective quality management and continual improvement. Central to this strategy is the establishment and maintenance of a documented system of quality management, extending from the supply chain through design, manufacturing, sales, marketing, service, and finally distribution to the customer. The Quality Management System framework is based on ISO 9001:2015.


| | |
|---|---|
| General Quality Systems Topics: | Response (s) |
| Corporate Address | 25 Harbor Park Drive Port Washington, NY 11050 |
| Phone Number: | (516) 484-5400 |
| Type of Business | Manufacturer of various Filtration Products and Systems |
| Regional Pall Corporation Offices | Pall International Sarl Avenue de Tivoli 3, CH-1700 Fribourg, Switzerland Phone Number: +41 26 350 53 00 Pall Singapore 1 Science Park Drive, #05-09/15 East Wing The Capricorn, Singapore Science Park II Phone Number: +65 6389 6500 |
| General Markets | Life Sciences and Industrial |
| Corporation has been in existence since (year) | 1946 |
| Other Pall Locations | See www.pall.com for other Pall locations |
| ISO 9001, ISO 13485 and AS9100 Certifications | See www.pall.com on the Quality Page for actual copies of the ISO certifications. |
| Major Quality System Management Standards | ISO 9001 (All manufacturing sites meet this standard.) ISO 13485 (Specific to those manufacturing sites that require this standard.) AS9100 (Specific to those manufacturing sites that require this standard.) |
| Additional Product Standards and Regulations | Pall holds additional standards needed for specific product based on the needs of the industry it serves. Some examples would be products manufactured for the Aerospace, Nuclear, Industrial, Medical and Automotive sectors. |
| Quality Reporting | The Pall Corporation Quality Assurance and Regulatory Affairs Group reports to the Vice President Corporate Quality Assurance and Regulatory Affairs. The Vice President Corporate Quality Assurance and Regulatory Affairs reports to Pall |

Status CURRENT

| | | | | |
|--|--|--|------------------------------------|------------------------|
|  Pall Corporation | DOC TYPE DIV - REFERENCE DOCS | DOC NUMBER QARA Survey/Questionnaire Responses | EFFECTIVE DATE 9/14/2017 | REVISION 001 |
| DEPARTMENT Corporate QARA | TITLE Pall Corporation General Quality Systems Survey/Questionnaire Responses | | | PAGE 2 of 4 |


| General Quality Systems Topics: | Response (s) |
|--|---|
| | Legal and Compliance. |
| Corporate Quality Manual | See https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/CQSM.pdf on the Quality Page for an actual copy. |
| Corporate Quality Policy | See section 5.0 in the Corporate Quality Manual located on www.pall.com . |
| Quality Authority | The Quality Representatives have the authority and responsibility to approve and reject all products manufactured for Pall Corporation. |
| Management Representative | The Vice President of Global Regulatory Affairs and Quality Assurance or designee is the Management Representative for Pall Corporation. |
| Management Reviews | Pall Management Review Teams review the quality management system and its performance trends as an essential part of the continual improvement process. Some of the inputs that are required to be reviewed are results of internal audits, quality objectives, process performance and product conformity, status of corrective actions and changes that could affect the quality management system. |
| Pall Quality System Requirements | Pall Corporation has an established, documented, implemented and controlled Quality Management System that is continually improved to assure its effectiveness in accordance with the requirements of ISO 9001 as well as other applicable regulations and standards. |
| Specific Documentation Requirements: | Pall Corporation has a documented Quality Policy, Quality Objectives, Quality Manual, Policies/Methods, Product Work Instructions and Drawings as is required to meet the requirements of ISO 9001 and other applicable standards and regulations. These documents are controlled and formally approved. |
| Training | Pall Corporation has determined the necessary competence for personnel performing work affecting product quality, provides training to satisfy these needs, ensures that personnel are aware of the relevance and importance of their activities and maintains appropriate records of education, training, skills and experience. |
| Internal Audits Program | Internal Audits are performed at planned intervals to determine whether the quality management system conforms to the ISO 9001 standards, the quality management system as well as Pall and industry requirements. |
| Supplier Evaluation and Purchasing | Pall Corporation ensures that purchased raw materials and/or product conforms to specific requirements. Evaluation of suppliers will be based on their ability to supply product in accordance with the established requirements. Suppliers will be selected, evaluated, reviewed/audited and re-evaluated based on criticality of the supplier. |
| Product Identification and Traceability | All Pharmaceutical Grade Filter Cartridges have traceability to a specific lot number. All other products should be reviewed to determine the level of traceability. |
| Non-conformances | All nonconformities are reviewed, the cause of the nonconformity is determined, |

Status CURRENT

| | | | | |
|--|--|--|------------------------------------|------------------------|
|  Pall Corporation | DOC TYPE DIV - REFERENCE DOCS | DOC NUMBER QARA Survey/Questionnaire Responses | EFFECTIVE DATE 9/14/2017 | REVISION 001 |
| DEPARTMENT Corporate QARA | TITLE Pall Corporation General Quality Systems Survey/Questionnaire Responses | | | PAGE 3 of 4 |

| General Quality Systems Topics: and Corrective Actions | Response (s) |
|---|--|
| Change Control | Pall Corporation reviews all proposed changes to manufacturing processes and products to assess the requirements for advanced customer notification. Our change management system includes risk assessments, determining criticality change levels, planning the activities and deliverables that will be necessary to carry out the change and assuring proper approvals are documented using our change management system. Any changes that affect form, fit or function of the product will be considered worthy of customer notification. Pall's change management system allows us to manage change within our own operations to assure the efficient availability of quality products to the industries that we serve. |
| Customer Complaint | All Customer Complaints for a potential product quality concern are reviewed and processed using our Customer Complaint SmartSolve System. The cause of the complaint will be assessed and analyzed and reports will be sent back to the customer if required. |
| Calibration | All necessary measuring equipment is calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. The status of the calibration will be identified and the measuring equipment will be protected from damage and deterioration during handling, maintenance and storage. Records of the results of calibration and verification will be maintained. If any measurement equipment is found not to conform to requirements, then appropriate action will be done on the equipment and any product affected. |
| Process Controls | All Pall manufacturing sites must develop, conduct, control and monitor production processes to ensure that the product conforms to specifications. Documented and approved procedures and specifications that define and control the manner of production are required. |
| Preservation of Product | Pall shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall apply to the constituent parts of the product. |
| REACH Compliance | See https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/REACH_Pall.pdf for a statement on REACH Compliance. |
| RoHS2 Compliance | See https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/RoHS%20Statement%20for%20the%20Web%202022%20July%202017.pdf for a statement on RoHS2 Compliance.. |
| Electronic and Electrical Waste | Pall promotes reduction of waste, and aims to assist users of Pall electronic or electrical equipment in identifying suitable recycling facilities in a number of |

Status CURRENT

| | | | | |
|--|--|--|------------------------------------|------------------------|
|  Pall Corporation | DOC TYPE DIV - REFERENCE DOCS | DOC NUMBER QARA Survey/Questionnaire Responses | EFFECTIVE DATE 9/14/2017 | REVISION 001 |
| DEPARTMENT Corporate QARA | TITLE Pall Corporation General Quality Systems Survey/Questionnaire Responses | | | PAGE 4 of 4 |

| | |
|--|--|
| General Quality Systems Topics: | Response (s) |
| (WEEE) | countries as shown at: https://www.pall.com/en/about-pall/corporate-sustainability/weee-compliance.html |

Pall has a dedicated Quality Assurance and Regulatory Affairs (QARA) Group available to answer all of the concerns of our customers, review our products against regulatory changes and assist in ensuring that new products developed via R&D are also compliant with current regulations before production commences. We hope that this document has assisted in answering your question about Pall Corporation and we look forward to working with you on your specific needs. If you have any questions, please contact your Pall Representative.

Prepared by: Pall Corporation Quality Assurance and Regulatory Affairs
Date of Issue: September 2017

To the best of our knowledge this information is accurate as of the date of issuance. However, these statements are subject to change as new information becomes available. We recommend that you periodically confirm this information.

© Copyright 2017 Pall Corporation. All rights reserved.