Pall Corporation

Subject: Pall Corporation General Quality Systems Survey/Questionnaire Responses

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.

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, 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, AS9100 and ISO/TS 16949 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.) ISO/TS 16949 (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 Group reports to the Senior Vice President Global Regulatory Affairs and Quality Operations. The Senior Vice President Global Regulatory Affairs and Quality Operations reports to the CEO.
Corporate Quality Manual	See www.pall.com on the Quality Page for an actual copy.
Corporate Quality Policy	See section 3.0 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 Senior Vice President of Global Regulatory Affairs and Quality Operations 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

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	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 9001as 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. All of 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.
Nonconformances and Corrective Actions	All nonconformities are reviewed, the cause of the nonconformity is determined, and an evaluation is performed to see if an action is needed to ensure that nonconformities do not recur.
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 are reviewed and processed using our Customer Complaint SmartSolve System. The cause of the complaint will be assessed and analyzed and the results communicated back to the customer as 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

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	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 www.pall.com for a statement on REACH Compliance.
RoHS Compliance	See www.pall.com for a statement on RoHS Compliance.

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. It you have any questions, please contact your Pall Representative.

Prepared by: Pall Corporation Quality Assurance and Regulatory Affairs

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