 PALL CORPORATION

Subject: Pall Corporation General Quality Survey / Questionnaire Responses

Pall Corporation

"Pall Corporation provides filtration, separation, and purification systems to meet industry wide fluid management and analysis 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 Quality Management System and processes by establishing quality objectives as part of our strategic planning process delivering sustained measurable improvements."

1. COMPANY INFORMATION	
Corporate Name	*'Pall Corporation'*
Global headquarters	*Pall Corporation* *25 Harbor Park Drive, Port Washington, New York 11050, USA* *Phone number: +1 516 484 5400*
Internet Address	www.pall.com
Name of Parent Organization	*Danaher Corporation*
Legal status	*'Pall' is an Operating Company and wholly owned subsidiary of Danaher Corporation, within its Life Sciences platform.*
Foundation date	*1946*
Locations of the company (countries)	*Global company. See www.pall.com for company locations*
Business	*Pall Industrial (Energy+, Micro-electronics, Nuclear, Industrial, Aeropower, Food & Beverage).*

Pall Corporate Quality Authority;

Vice President Quality Assurance and Regulatory Affairs or designee is the Quality Management Representative for Pall Corporation.

The Pall Corporation Quality and Regulatory Affairs group reports to the Vice President Global Operations, reporting to the President and CEO, Pall Corporation. Providing Corporate focus on:

- *The Quality Management System*
- *Customer Complaint*
- *Supplier Quality Management*
- *Quality Information Systems*
- *Product Regulatory and Environmental Compliance*

Providing Corporate Quality objectives and targets, standard work and training to all of Pall's Business Units (BU) - reflecting Danaher's and Pall's imperatives on Quality and Compliance. Where the Pall Corporation business structure is based on a number of market focused Business Units – each with a cognizant Quality structure and responsible BU Quality Lead.

Each BU Quality Lead is responsible for implementation of Pall Industrial standard work, training and KPIs within their BU.

Each Pall manufacturing plant has a Quality Lead in the facility, responsible for the implementation of all quality and regulatory requirements at that site.

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, service, and finally distribution to the customer. The Quality Management System framework is based on ISO9001:2015.

Pall assures the products it supplies at the time of delivery shall conform to the mutually agreed requirements with its customers. Where the release specifications shall conform in all material respects to the appropriate industry standards and claims for the applicable product.

Pall further assures that, as of the date of each shipment of any product, such product shall not, when shipped, be damaged or mislabeled within the meaning of any applicable law, or be an article which may not, under the provisions of applicable law, be sold in the territory.

The BU Quality Leads and site Quality Leads have the authority and responsibility to accept or reject products manufactured by or on behalf of Pall prior to release to the market.

2. QUALITY MANAGEMENT SYSTEM

The Pall Corporation Quality Policy:

The Pall Corporation Quality Policy is available to download at
https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/Pall-Corp-Quality-Policy-2021-Letter-Size-en.pdf

The Pall Corporation Quality Manual:

The Pall Corporate Quality Manual is available to download at
https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/CQSM.pdf

Quality System Topics:

Pall Quality System is structured to meet the requirements of ISO 9001 and other applicable customer and regulatory requirements. The Quality System topics include but not limited to are Internal audits, quality objectives, process performance and product conformity, status or corrective actions and changes that could affect the Quality Management System.

Pall Quality System Requirements:

Pall 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.

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 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.

Specific Documentation Requirements:

Pall has a documented Quality Policy, Quality Objectives, Quality Manual, processes / methods, standard work instructions and drawings as is required to meet the requirements of ISO 9001 as well as other applicable regulations and standards. All of these documents are controlled and formally approved in the 'SmartSolve' documentation system.

Training:

Pall has determined the necessary competence for associates performing work affecting product quality, provides training to satisfy these needs, ensures that associates are aware of the relevance and importance of their activities and maintains appropriate records of education, training, skills and experience.

Internal Audit Programs:

Internal Audits are performed at planned intervals to determine whether the quality management system conforms to ISO 9001 standards, quality management requirements as well as Pall Corporate Quality Management System and industry requirements.

3. 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 is assessed and analyzed, and the results communicated back to the customer as required.

Pall undertakes to acknowledge the receipt of a complaint within five (5) business days, provided sufficient information related to the complaint has been received.

Within thirty (30) business days of receipt of the complaint sample, Pall will communicate an interim status or final report on the complaint investigation to the customer detailing a lot file review, scope analysis, identifiable root cause(s), and Corrective and/or Preventive Action(s), where applicable.

In the event that Pall determines that a recall of the Pall product(s) may be necessary or appropriate, Pall will notify customers in receipt of scope items, and the two parties will take joint decisions for product disposition or user information, where required. With the Customer responsible for notifying of any disposal he has undertaken in respect of recalled product, such that Pall may reconcile scoped product numbers.

4. SUPPLIER QUALITY MANAGEMENT

Pall ensures that purchased raw materials and/or product conforms to specific requirements. Evaluation of suppliers is based on their ability to supply product in accordance with the established requirements. Suppliers are selected, evaluated, reviewed/audited and re-evaluated based on criticality of the supplier.

![PALL PALL CORPORATION]

Pall wishes to control or limit use of various substances, either in, or in contact with articles and materials used in the manufacture of the products Pall supplies. Suppliers are therefore requested to advise Pall if they know certain substances of interest are present in the items they supply to Pall.

Pall employs an information gathering program through the use of a document reference E-962, This document contains the substances of current interest. These lists can change. Therefore, Pall has made available this website copy of the latest listings. In this way Pall hopes to ensure Suppliers are kept informed of our current requirements. To download the current version of E-962 see:
https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/E962.pdf

5.   QUALITY INFORMATION SYSTEMS

Pall employs various critical platforms for documentation control, routing and approvals, such as the SmartSolve system for Compliant management. Each of these critical platforms is supported by procedures on training, access control, maintenance, monitoring and backup, deviations, changes and periodic review.

6.   PRODUCT ENVIRONMENTAL COMPLIANCE

REACH Compliance	*Pall's general position of compliance to European REACH Substance of Very High Concern (SVHC) requirements is available at:* *https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/REACH_Pall.pdf*
RoHS Compliance	*Pall's general position of compliance to European Restriction of Hazardous Substances in Electrical and Electronic Equipment (ROHS) requirements is available at:* *https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/RoHS%20Statement%20for%20the%20Web%2022%20July%202017.pdf*
California Prop-65 Compliance	*Pall's general position of compliance to US California Safe Drinking Water and Toxic Substances (California Prop-65) requirements is available at:* *https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/Cal%20Prop%2065%20statement%20July%202018.pdf*
Persistent Organic Pollutants	*Pall's general position of compliance to is available at:* *https://www.pall.com/content/dam/pall/pall-corp/literature-library/non-gated/POPs-statement.pdf*

Safety Data Information	*Pall provides safety data information and labelling for substances, mixtures and articles considered as 'hazardous' under GHS Classification, Labelling and Packaging (CLP) requirements. Copies of documents can be downloaded at: https://www.pall.com/en/about-pall/quality/ssdi.html and https://www.pall.com/en/about-pall/quality/psdi.html*
Recycling	*Pall promotes reduction of waste and aims to provide information to facilitate recycling or re-use of the materials and components it supplies. However, due to contaminants present on the product as the result of use, the product should be disposed of in line with local and federal regulations and legislation.*
Waste Electronic and Electrical Equipment (Europe) provisions	*Pall aims to assist users of Pall electronic or electrical equipment in identifying suitable recycling opportunities. It provides suitable recycling facilities in a number of countries as shown at:* *https://www.pall.com/en/about-pall/corporate-sustainability/weee-compliance.html*

7. PLANT CERTIFICATIONS AND REGISTRATIONS

Pall holds ISO 9001 certification for facilities across the world – please see
https://www.pall.com/en/about-pall/quality/pall-site-certifications.html

Pall holds ISO 14001 certification for various facilities across the world – please see
https://www.pall.com/en/about-pall/quality/pall-site-certifications.html

Pall holds ISO 45001 / OHSAS 18001 certification for various facilities across the world – please see
https://www.pall.com/en/about-pall/quality/pall-site-certifications.html

Pall holds ISO 22301 certification for various facilities across the world – please see
https://www.pall.com/en/about-pall/quality/pall-site-certifications.html

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7. PLANT CERTIFICATIONS AND REGISTRATIONS

Various Pall Corporation facilities are registered with the US EPA as establishments for the production of 'pesticide devices' under the US EPA Establishment under Federal Insecticide, Fungicide and Rodenticide Act.

Pall FilterSystems GmbH, Bad Kreuznach, Germany, Est. numbers 92462-DEU-1
Pall Corporation, Cortland, NY, USA, Est. number 92464-NY-1
Pall Aeropower Corporation, New Port Richey, FL, USA, Est. number 92659-FL-1
Pall Europe Limited, Redruth, UK, Est. number 92658-GBR-1
Pall do Brasil LTDA, Sao Paulo, Brazil, Est. number 93533-BRA-1
Pall Poromembrane GmbH, Schwaikheim, Germany, Est. number 94619-DEU-1

Various Pall facilities are Kosher certified for the production of various food contact filtration products:

Pall FilterSystems GmbH, Bad Kreuznach, Germany
Pall Exekia, Bazet, France
Pall Corporation, Cortland, NY, USA
Pall Corporation, Timonium, MD, USA

Please see - Kosher Certifications (pall.com)

Various Pall facilities are Halal certified for the production of various food contact filtration products:

Pall FilterSystems GmbH, Bad Kreuznach, Germany
Pall Exekia, Bazet, France
Pall Corporation, Cortland, NY, USA

Please see -Halal Certified Filters | Pall Corporation

The Pall FilterSystems GmbH, Bad Kreuznach, Germany facility is NOT certified under cGMP (EU GMP part I, EU GMP part II (ICH Q7, US cGMPs / 21 CFR), nor to Regulation 2023/2006 related to food good manufacturing practices, but the site works to the principles of these requirements in respect of traceability of materials and products.

Pall Europe Ltd., Redruth, UK is certified to AS9100

7.   PLANT CERTIFICATIONS AND REGISTRATIONS

Pall holds additional standards needed for specific products based on the needs of the industries it serves. Some examples would be products manufactured for the Aerospace, Nuclear, and Industrial sectors.

8. NONCONFORMITIES AND CORRECTIVE ACTIONS

All nonconformities are reviewed the cause of the non-conformity is determined. And an evaluation is performed to see if an action is needed to ensure that nonconformities do not recur.

If equipment and instruments malfunction or are determined to be defective, they are immediately taken out of use.

9. CALIBRATION

All necessary measuring equipment is calibrated or verified ay specified intervals, prior to use, against measurement standards traceable to international or national measurement standards. The status of 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 product affected.

10.   CHANGE CONTROL

Pall 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 systems allow us to manage change within Pall's own operations to assure the efficient availability of quality products to the industries that it serves.

Prepared by: Pall Corporate Regulatory Affairs

Date of Issue: 25th January 2024

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.