PALL Life Sciences

QUALITY AGREEMENT

This Quality Agreement is made between

_____

(Customer Name)

And

Pall Corporation (through its division Pall Life Sciences)

(Hereinafter called Pall)

1. Table of Contents

1. Table of Contents
2. Scope of the Agreement
3. Purpose
4. General Requirements
5. Regulatory Requirements
6. Manufacture
7. Quality Assurance and Quality Control
8. Quality Data and Records
9. Audits
10. Change Control Procedure
11. Customer Notification
12. Complaint and Recall Handling
13. Confidentiality
14. Final Provision
15. Signatures

2. Scope of the Agreement

This Agreement shall apply to any Pall Life Sciences products that are manufactured by Pall Life Sciences' manufacturing facilities.

3. Purpose

This Quality Agreement serves to define and establish the obligations and responsibilities of the parties as related to the Quality Standards required for all products delivered by Pall Life Sciences.

This Agreement does not intend to be all inclusive in relation to legal and commercial issues, which may be covered under separate agreements.

4. General Requirements

Pall assures the products supplied to our customers at the time of delivery shall conform to the mutually agreed requirements, where applicable.

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.

Pall shall maintain and apply throughout the term of this Agreement, a quality system in accordance with the applicable ISO standards.

Pall is responsible to review and oversee the quality related activities of their suppliers, sub-contractors, service providers, and/or material sources.

5. Regulatory Requirements

If applicable to product, Pall is responsible to provide the Customer information to support regulatory submission.

6. Manufacture

Pall will be responsible for assuring that the standards and operations of its facilities, equipment, personnel, personnel training, systems, and procedures comply with a recognized quality system, applicable to the supplied product (e.g. ISO 9001, ISO 13485).

Pall will assure that the product is stored properly prior to delivery and shall deliver the product(s) in accordance with the conditions as agreed with the Customer, where applicable.

7. Quality Assurance and Quality Control

Pall shall be responsible for the purchase, storage, testing, and release of raw materials used in the manufacture of the product(s) and for ensuring suppliers for such materials comply with the current specifications and procedures.

Pall shall comply with (mutually agreed) requirements and shall deliver product in suitable packages with labeling containing product(s) information and appropriate caution and warning information, as applicable.

8. Quality Data and Records

A Certificate of Conformance, Certificate of Quality, and/or Certificate of Test will be issued as per the applicable product purchased.

Quality Records will be maintained as per the record type and the requirements of the product purchased.

9. Audits

Upon prior notice and approval, Pall will provide access to the premises in which the product(s) are manufactured and tested. A mutually signed confidentiality agreement will be required to access a Pall Facility. As deemed necessary by Pall, access to some proprietary information and/or processes could be restricted.

A mutually agreed upon audit agenda will be required.

10. Change Control Policy

Pall will review all proposed changes to manufacturing processes and products.

All changes will be based on a risk assessment approach where the project team will fully define the scope of the change, determine the criticality level, and plan validation activities and deliverables necessary to carry out these activities.

11. Customer Notification

A customer notification will be sent for any critical changes that affect form, fit, or function of the product.

Customer notification will be sent prior to implementing the planned change.

12. Complaint and Recall Handling

Pall will record and investigate all quality-related customer complaints.

Pall will 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 the Customer. The two parties will take joined decisions for product disposition or user information, where required.

The Customer will be responsible for returning to Pall all unused, recalled product(s) in their possession at the time the notification of the recall is received.

13. Confidentiality

Pall and the Customer understand and agree that any information of a confidential nature provided to each other pursuant to this Agreement shall be treated by the recipient in the strictest confidence.

The information in this Quality Agreement must be treated strictly confidential.

Disclosure of its content to any third party is prohibited unless agreed by authorized persons of both parties in written form.

14. Final Provision

This Agreement shall become effective at the latest date of the signature and will stay valid until both parties decide and agree upon a change of the content.

Any modification or amendment of this Agreement or waiver of any of the terms thereof requires written confirmation by both parties. Should individual provisions of this Agreement be or become invalid, the remaining provisions will not be affected in their validity.

If this Quality Agreement is pursuant to any other agreement, this Quality Agreement will terminate simultaneously with the governing agreement.

This Agreement will be replaced if the Customer and Pall agree upon a more current Agreement regarding the product(s).

15. Signatures

This Quality Agreement **SHALL** be approved by a Quality function only.

Pall Quality Representative Print Name Title		Customer QA Print Name Title	
Date		Date	
Signature		Signature	