Lifecore Biomedical, LLC. Change Notification Policy

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Purpose

To define the Change Notification requirements for Lifecore Biomedical's suppliers.

Scope

This document pertains to all suppliers, or sub tier suppliers of Lifecore Biomedical, LLC.

Responsibilities

Who	Responsibility
Lifecore Biomedical, LLC Supply Chain	Ensure that change notification policy is appropriate, and published revisions are up to date.
Lifecore Biomedical, LLC Suppliers	Ensure understanding of and compliance to the policy.

Definitions

N/A

Equipment/Materials

N/A

Safety

N/A

Policy

Lifecore Biomedical, LLC (Lifecore) manufactures and markets regulated medical devices and pharmaceuticals that fall under the purview of the Food and Drug Administration (FDA). Our products require various levels of approval and review by the FDA. For the sake of patient safety, and compliance to FDA regulations, Lifecore must be notified prior to process and material changes made by our suppliers or sub-tier suppliers. Please submit change notification to mailto:purchasing@lifecore.com

Written approval from Lifecore is required before changes can be implemented. At a minimum, prior notification and written acceptance is required in the following cases:

- The change affects or alters compliance to a Lifecore drawing or print requirement. This applies even if the Supplier creates their own drawing or print based on Lifecore requirements.
- A change in manufacturing and/or testing location – even if the new location is owned and/or managed by the original Supplier.
- Modification of material grade, quality, or characteristics, whether in the raw or finished state.
- Change in raw material supplier by either Lifecore supplier or sub-tier supplier.
- A change to "in process" specification(s) outside previously validated process parameters.
- Changes to any process and/or testing documentation previously approved by Lifecore. Typically, this will be process or testing documentation developed or written specifically for Lifecore product.
- A change to surface cleanliness or surface coatings; examples include mold release agents, cutting oils, cleaners, sterilization or packaging etc.
- Drawings, specifications or prints with Critical-to-Quality (CTQ) features identified, will receive a higher level of scrutiny. Similarly, processes or materials that affect CTQ features will also receive increased scrutiny
- Any move or changes to equipment, machinery or processes. For instance, changing a manual process to an automated process, or changing a soldering operation to a welding operation.
- Changes to release specifications for materials, chemicals, and/or parts.
- Changes to test methods
- Lifecore requires that all palletized deliveries be on clean, functional and appropriate weight bearing plastic pallets

Any risk arising from changes made by Suppliers or sub-tier Suppliers without Lifecore written approval is solely the responsibility of Lifecore's Supplier or sub-tier Supplier. The most effective method to eliminate risk is to contact Lifecore via written "change notice" and receive written approval of the change PRIOR TO IMPLEMENTATION.

References

N/A

LIFECORE BIOMEDICAL

Summary of Revision Changes

Rev.	Change
01	Initial Release.