Kenvue Companies Quality Requirements For Suppliers

Suppliers to wholly owned subsidiaries of Kenvue, Inc. ("Kenvue Company/Companies") are expected to provide goods and services (hereafter Product(s)) that consistently meet customers' needs, are safe and effective for their intended use, and perform as intended. Therefore, in addition to meeting the Product/service specifications agreed upon in the applicable agreement, purchase order, or other contractual relationship, suppliers must also meet certain quality requirements including compliance with regulations where their Products are manufactured and where Products may be sold.

The Kenvue Companies Quality Requirements for Suppliers, listed below, comprise the primary criteria under which products/ services will be provided and against which Kenvue Companies will audit Supplier. If Supplier fails to comply with these criteria, the Kenvue Companies may terminate any existing contractual relationship with such supplier, subject to the terms of such contractual relationship.

1. Maintain all applicable licenses, site registrations, certifications and permits required to supply the Product(s),
2. Permit the relevant Kenvue Company and/or an authorized delegate to conduct Quality audits of the facilities, systems and/or documents related to the goods and services provided. Supplier will promptly provide responses and take corrective actions to remedy any observations cited,
3. Notify the relevant Kenvue Company of Health Authority inspections and regulatory issues such as: warning letters, observations, seizures, and injunctions, including any observations related to the products of a Kenvue Company and/or the Quality Management System (QMS) on which they are provided,
4. Provide performance metrics, when requested, for purchased products and their processes, and Quality System performance,
5. Establish and maintain Quality processes and controls to protect the integrity of the Product/ including but not limited to quality processes and controls for laboratories, production, facilities, equipment, materials, packaging and labeling. Also including:
    a. Current Good Manufacturing Practices according to the applicable standards of Product(s) provided,
    b. Good Documentation Practices,
    c. Data Integrity processes that ensure collecting, analyzing, reporting and retaining information and data in a manner that accurately, truthfully and completely represents the activity that occurred and that ensures the data is safe from manipulation or loss,
    d. Documented change control processes to ensure visibility to and review of changes for impact on quality of goods and services provided to a Kenvue Company and regulatory requirements,
    e. Written notification to the relevant Kenvue Company of proposed changes that may impact product quality or regulatory filings and requirements including but not limited to changes to: specifications, test methods, suppliers, materials/components, chemicals, material grade, reduced testing/test frequency, manufacturing/supply process, manufacturing location, equipment, or tooling in order for the Kenvue Company to determine impact on the Kenvue Company's product. Changes impacting the quality or regulatory requirements of a Kenvue Company's Product shall not be implemented without prior written consent of the Kenvue Company,
    f. Documented training of personnel to perform their job functions,

g. Qualification and management of suppliers for all goods provided to a Kenvue Company and notification to the Kenvue Company of changes to these suppliers and the materials they provide,

h. Documented processes for prevention of cross-contamination and mix-up throughout the process,

i. Documented processes outlining requirements for investigating and documenting quality related complaints applicable to the products manufactured by or for the Kenvue Company utilizing the goods and services,

j. Documented processes for the control of a service which leads to the generation, collection, assessment, investigation, and/or monitoring of data on behalf of a Kenvue Company that may result in the identification of an Adverse Event, special reporting situation e.g. regulatory reporting, Pharmacovigilance related Complaint, and/or new safety signal,

k. Documented processes for logging and trending of non-conformances, and the associated investigations, bounding and containment, and disposition decisions,

l. Notification to the relevant Kenvue Company of non-conformances and quality issues which may impact Product(s) provided to the Kenvue Company,

m. Equipment, environment, and test method qualification/validation appropriate to the Product(s) supplied,

n. Documented procedures for the control of storage areas,

o. Storage and shipment of goods and raw materials in accordance with the manufacturer's recommended conditions,

p. Retain original GxP records per defined procedures and provide records upon request.

q. All pallets used to supply goods to a Kenvue Company comply with Kenvue's pallet policy, including, but not limited to the following requirements:
   i. Minimize the potential for mold, pest and other contamination including control of pallet storage conditions and the use of softwood construction,
   ii. Certification that tribromophenol (TBP) treated wood pallets are not used,
   iii. Comply with International Standards for Phytosanitary Measures Publication No. 15,
   iv. Fumigation with Methyl Bromide is prohibited,
   v. Display an approved heat treatment mark,
   vi. Non-wood pallets shall be certified that they are free of polybrominated diphenyl ethers (PBDEs) flame-retardants.

r. Notify the Kenvue Companies of any materials used in the manufacture, delivery, or storage of the product or service supplied to the Kenvue Company that are animal-derived and ensure the materials comply with all bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE) applicable regulations.

s. Notify Kenvue Companies in advance of the potential presence of any hormones, cytotoxins, or penicillin that are in the same facility as the manufacture, delivery, or storage of Product(s) supplied to the Kenvue Companies.

t. Supplier shall not process, store or expose Product(s) in the same building as penicillin, cephalosporins, beta lactams, herbicides, pesticides/fumigation, rodenticides, and/or agrochemicals.

u. Oversight, qualification and management of sub-tier suppliers for all goods provided to the Kenvue Companies.

v. Established change notification process with sub-tier suppliers to ensure that changes made by sub-tier suppliers (process, equipment, materials, business entity) can be assessed and communicated via the normal change notification process to relevant Kenvue Companies.

w. Returned product, in any condition, will not be supplied to Kenvue Companies without Kenvue Companies advance written approval.

x. Supplier shall supply a Certificate of Analysis (COA) or Certificate of Compliance (COC) with each batch. The COA or COC should contain at a minimum the following information per applicable regulations:

- Lot or batch number
- Product specification reference
- Tests performed for the specified lot or batch and their respective results and their corresponding release criteria, to demonstrate full compliance with the current GMP/ manufacturing requirements (for COA only)
- Specifications for each test (for COA only)
- Method description or reference for each test (for COA only)
- Date of manufacture, along with retest or expiry date (where applicable) of the lot or batch
- Name and address of the original manufacturer and distributor or re-packager (where applicable), if the re-packager is not the same party as the distributor
- Approved by the competent person, such as Qualified Person or designee

y. For Supplier notifications, send notification to Kenvue Companies contacts with a copy of the notification to the relevant e-mail address listed below (based on category of Product):

Notification of Changes	Email Contact Information
Chemicals (for all sites/regions, including Excipient, Chemicals)	RA-CONUS-RawMatCente@kenvue.com
Packaging Materials (for all sites/regions)	RA-CPCUS-PKGCHGNOTIF@kenvue.com
Fibers & NonWovens (for all sites/regions)	RA-CONUS-RawMatCente@kenvue.com; ra-conbr-fnwrmcqual@kenvue.com
US sites	RA-MCCUS-MCPRO@kenvue.com

By supplying products under the relevant Award Letter, Supplier agrees to these Kenvue Quality Requirements for Suppliers (and if requested by the relevant Kenvue Company, will sign a copy of these Quality Requirements to confirm agreement, which may include electronic signature if approved for use by the Kenvue Company).

*******END OF DOCUMENT*******