



CONSUMER COMPANIES, INC.

Date: **31 January 2017**
Subject: **Foundation for Strategic Sourcing – AuditOne Initiative**

Dear Trusted Supplier to Johnson & Johnson Consumer Companies:

Please accept this letter as notification that the Johnson & Johnson Consumer Companies are **now expecting your participation in the F4SS AuditOne Program** as meeting our supplier assessment requirements, effective immediately. For all future contracts with J&J, Audit One participation will be a requirement.

As soon as you register for the program, it is our expectation that you will make every effort to engage and post a completed audit meeting our annual audit schedule.

The *F4SS AuditOne* program has been developed through collaboration with the *Foundation for Strategic Sourcing (F4SS)*, *Johnson and Johnson Consumer Companies*, *Procter and Gamble*, *Unilever*, *L'Oréal*, *Kimberly Clark* and *Estee Lauder*. This industry standardization initiative focuses on improving compliance to quality standards and Agency regulations, while reducing supply chain burden and consumer risk.

As a supplier to the global consumer products industry, you are expected to implement and maintain effective quality systems. You are continuously under the scrutiny of multiple customers, with their expectations that your systems result in the delivery of quality materials produced in a compliant manner.

Today, you likely host multiple customer audits each year, consuming significant time and resources in preparation, execution, observation closure, follow-up, and paperwork. Also, it is likely, that this process is burdened by the need to manage the many unique expectations of the customers you service. The F4SS AuditOne program is designed to streamline and simplify this customer audit process, freeing up your valuable time and resources.

The consumer products companies participating in the F4SS-sponsored program have agreed to a set of single audit standards. These are published standards, generated by known quality standard organizations. In select cases, the standard will be coupled with an addendum detailing expectations not specifically called out in the standard.

The program has been designed to use 3rd party audit firms to conduct the required audits. Audit firms were selected and vetted by the consumer products companies that collaborated in the development of this initiative. The firms were chosen based on experience, geographic coverage, and the robustness of their internal quality systems. The audit firm will work directly with you, the supplier, to fully understand any observed gaps and to develop a holistic and sustainable CAPA plan. The audit results and CAPA plan are owned by you, the supplier. You decide which of your customers may have access to them via a secure and interactive web portal. As your customer, we expect these reports to be made available to J&J.

To better describe how the program works, please review these steps:

STEP		WHO
1	Register for inclusion in the F4SS AuditOne Program at www.F4SS.org -registration details are located under the AuditOne tab in the tool bar	Both participating customer and supplier
2	Select the applicable audit standard for business based upon the product type being manufactured. If multiple product types are manufactured, the standard selected will be to the highest standard available.	Supplier
3	Determine the audit cost from the list of approved audit firms. Make a selection based upon cost, timing, geographic coverage, and capability to perform audit against the standard selected.	Supplier – <i>this is a supplier-funded program.</i>
4	Notify customers participating in the program that an F4SS-sponsored audit has been scheduled, indicating exact date(s) or month/year. Also supply name of audit firm and auditor (if known at time).	Supplier
5	Based on STEP 4 notification, customers may conduct a pre-audit conference with the auditor to communicate any Customer-specific audit requests.	Customer and Audit Firm
6	Conduct a pre-audit conference with auditor to: <ul style="list-style-type: none"> • review the Quality Standard selected for the audit • align on audit process expectations • detail supplier’s responsibilities to prepare required documentation 	Supplier and Audit Firm
7	Conduct the audit. Ensure the quality systems are both well designed and effective. Effectiveness is determined through objective evidence gathered from interviews, reports, and observation. The F4SS program utilizes in-depth evaluation, that assess both the robustness of the system design and the successful integration and application of the system within the operation.	Supplier and Audit Firm
8	Complete final audit report and post to F4SS-sponsored interactive web portal.	Audit Firm
9	Develop a CAPA plan, inclusive of immediate corrections, any mid to long-term preventive actions, and associated due dates.	Supplier and Audit Firm
10	Approved CAPA plan posted to F4SS-sponsored interactive web portal.	Supplier
11	Notify participating customers that the audit and approved CAPA plan are posted and available for review.	Supplier
12	Update CAPA plan with milestone activities and status to F4SS-sponsored interactive web portal.	Supplier

The list of AuditOne harmonized standards, with links to the actual standard, can be found at www.F4SS.org under the AuditOne tab.

These are now the standards against which you will be audited, whether or not you engage in the AuditOne initiative at this time.

At this site, you will also find step by step instructions, registration process, and the opportunity to execute a request for quotes directly to the participating audit firms.

As a participant of this innovative and valuable initiative, the Johnson & Johnson companies are delighted to bring this opportunity to our supplier base. We are certain this program will bring resource optimization to our extensive supply chain, while improving the compliance level that regulators demand.

Ultimately, we wish to shift our focus to collaborating with suppliers to improve and reduce customer risk rather than conducting excessive and repetitive site audits.

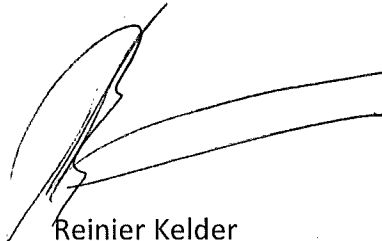
Should you have any specific questions regarding the mechanics of the program, please feel free to reach our the F4SS project manager – Dave Hempson at dave.hempson@f4ss.org

Thank you for your attention and partnership

Respectfully submitted,



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