

Supplier Evaluation and Selection

The Context

Device manufacturers must evaluate and select suppliers based on their ability to satisfy defined requirements. The manufacturer keeps records of the evaluation and selection process. This applies to suppliers, contractors, and consultants whether they provide a product or a service.

The Warning Letter

FDA sent a March 2, 2016 Warning Letter to Innovative Sterilization Technologies, LLC, a specification developer of the ONE TRAY Sealed Sterilization Container, located in Dayton, Ohio. The Warning Letter resulted from an FDA inspection.

The Issue Cited

The Warning Letter includes a citation about failure to evaluate a contractor to provide a service.

The Warning Letter says, “[Y]our Supplier Selection Process procedure ... does not address that services are evaluated and approved prior to use. For example, the firm contracted to validate the shelf-life and sterility results of the ONE TRAY were not evaluated or approved under your purchasing controls”.

FDA acknowledged that the company’s corrective action response appears adequate.

The Requirement

The Quality System Regulation requires, in §820.50(a), “Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.”

Recommendations

Supplier evaluation and selection applies to twelve possible combinations.

Firm Type: supplier, contractor, or consult

Ordered: product or service

Financial: purchased or otherwise received

Before evaluating a supplier, document what you would order, the firm’s type, and your financial relationship with any potential supplier. Use these to determine the requirements on both the potential firm and the product or service.

Identify a set of potential firms, evaluate each one on the ability to satisfy the requirements, and select one.

Document the process and results, including any firm evaluated and not selected.