CPG Sec. 100.550 Status and Responsibilities of Contract Sterilizers Engaged in the Sterilization of Drugs and Devices

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U.S.Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Enforcement
Division of Compliance Policy

Compliance Policy Guide
Guidance for FDA Staff and Industry
Sec. 100.550 Status and Responsibilities of Contract Sterilizers Engaged in the Sterilization of Drugs and Devices (CPG 7150.16)

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thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidance means that something is suggested or recommended, but not required.

BACKGROUND:

Questions have been raised as to the responsibilities of a contract sterilizer under the *Federal* Food, Drug, and Cosmetic Act *(the Act)*. The questions concern registration requirements under Section 510 *of the Act, the Food and Drug Administration's (FDA's)* inspectional policy, documentation and validation requirements, and responsibilities of the parties to the contractual agreements.

DEFINITION:

For the purposes of this guide the following definition will apply:

Contract Sterilizer - An establishment that provides a contractual service intended to sterilize an FDA regulated product.

POLICY:

1. Responsibility of Contract Sterilizers:

   Contract sterilizers are responsible for conformance with the portions of the current Good Manufacturing Practice (CGMP) regulations that pertain to the services they provide. *The applicable regulations are the Drug (21 CFR Parts 210 and 211) and/or Device (21 CFR Part 820) CGMP depending on the products sterilized.*

2. Registration:

   Each contract sterilizer of a drug or device ** must register as set forth under Section 510 of the Act *except for the following situations. If a contract sterilizer only distributes sterilized devices to the manufacturer or other registered firm and does not ship the sterilized devices into commercial distribution, then it is not required to register with the Center for Devices and Radiological Health (21 CFR 807.20(c)(2)). Additionally, a contract sterilizer located in a foreign country is only required to register if it imports or offers for import the sterilized devices into the United States (21 CFR 807.40(a)).*

3. Documentation:

   The finished drug or device manufacturer should maintain, as part of the master production and control record, or reference, written process specifications and documentation of the validation of the sterilization process conducted by the contract sterilizer. The finished drug or device manufacturer should also maintain, or have readily available, copies of the contract sterilizer's batch production records.

   The contract sterilizer must maintain documentation of validation and the written process and production specifications and procedures necessary to assure the process is adequately completed. Contract sterilizers are also responsible for completing and maintaining batch records of all operations performed.

4. Inspections:

   Contract sterilizers, as drug or device processors, are subject to the *inspectional* requirements of the Act.

5. Contractual Agreements:

The contractual agreement should specify which establishment will execute various functions. In general, the establishment which executes a given function will be primarily responsible for the *CGMP* which apply to that function.

6. Sterilization Process Validation:

   Sterilization processes are required by the *CGMP regulations* to be validated *(21 CFR 211.113(b) and 21 CFR 820.75). Either the finished drug or device manufacturer or the contract sterilizer would conduct the validation of the contract firm's process.* The finished drug or device manufacturer has ** responsibility for assuring that the finished drug or device meets sterility specifications and is processed under adequate CGMP controls **[1]**. The *contract sterilizer* has responsibility to assure ** that adequate *CGMP* controls * (e.g. equipment qualification, written procedures)* are established and *consistently* implemented. Therefore, both parties are responsible for validation and *any possible deficiencies; bearing in mind that the contract sterilizer is responsible for only those CGMP areas that its operations cover. Neither party can waive this responsibility in an agreement. Moreover,* the absence of an agreement does not remove this responsibility for either party.

NOTE: For licensed *biological products*, the Center for Biologics Evaluation and Research *or the Center for Drug Evaluation and Research, as appropriate,* holds the final manufacturer responsible for all production processes, including validations of sterilization performed under contract, whether or not the contract so states.

REGULATORY ACTION GUIDANCE:

If *significant* adverse findings are encountered during an inspection, the appropriate Center should be notified. In addition, the districts that have firms using the services of *contract sterilizers* outside the district should be advised of any *significant* adverse finding.

In considering regulatory, voluntary, or administrative action, the agency will regard the manufacturer as primarily responsible for assuring the compliance of the *drug or device*. However, the contract sterilizer and the manufacturer will be held jointly responsible for those processes performed by the *contract sterilizer*. Performance of each party will be considered in determining whether one or both parties are subject to regulatory action for failure to comply with *CGMP. The extent of the contract sterilizer's operation will be taken into consideration.* Should regulatory or *administrative* action be generated as a result of *an* inspection of the contract sterilizer, both parties should receive copies of all correspondence.

Material between asterisks is new or revised

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[1]*In some instances, the owner of a finished drug or device may not be the manufacturer. If this is the case, the owner would also bear responsibility to assure that the finished drug or device meets sterility specifications and is processed under adequate CGMP controls.*

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