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| YOU CAN REFER BACK TO ANY OF THESE DEFINITIONS BY CLICKING THE “DEFINITIONS OF KEY TERMS” LINK AT THE TOP OF EACH SURVEY PAGE. YOU DO NOT HAVE TO READ THEM ALL NOW.  DEFINITIONS OF KEY TERMS FOR FDA SURVEY | |
| TERM | **DEFINITION** |
| Audit [of suppliers of components and container/closures] | Supplier auditing is the systematic inspection and evaluation of a supplier's quality management system, including their practices, products, and documentation. Supplier audits often require site visits. |
| Drug product | For this survey, “drug product” includes the following types of products *in their final marketed form:* prescription drugs, biological products, over-the-counter drugs, and other products that are:   1. Intended to diagnose, cure, mitigate, treat, or prevent disease in animals or humans; *or* 2. Non-food products intended to affect the structure or any function of the body of humans or other animals.   Some products meet this definition of drug products because they are intended to treat a condition and/or are intended to affect the structure or any function of the body. For example, an antidandruff treatment is a drug because its intended use is to treat dandruff. Other products that fall into this category are toothpastes that contain fluoride, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun-protection claims. |
| Drug product processing facility | A drug product processing facility is any facility that manufactures, packs or re-packs, labels or re-labels, tests, or sterilizes any prescription or OTC drug for use by humans or animals. |
| Drug product component | Each active pharmaceutical ingredient and inactive agent (including fillers and coloring agents) that are combined to form a drug product. |
| Drug product container and closure | The packaging that contains and protects the drug product as it is marketed and delivered to end-user health care providers. |
| Established supplier (of drug components or containers and closures) | A company that has supplied your facility with specific drug components or containers and closures in the past and has been qualified by your facility or parent company as a supplier of those previously shipped products. |
| Gross revenue | The total earnings of a company through sales, services, and any other income generating activity, before expenses such as labor and material costs, taxes, interest, etc. are deducted. |
| Joint review meetings | Meetings scheduled between members of facility executive management, departmental managers, and shop floor personnel meant to discuss, anticipate, and inform everyone about current and potential issues. |
| Labeling | Any written, printed, or graphic material containing drug information that is affixed to or accompanies any drug product or any of its containers or wrappers. |
| Management with executive responsibility | Any employee who has the authority to provide resources, to establish or make changes to organizational structure, buildings, facilities, equipment, or the manufacture, processing, packing, or holding of a drug product. |
| New drug product component | A “new drug product component” shipped from a “qualified supplier” is the first time you receive a shipment of a specific drug product component from a supplier that has been qualified by your facility or company. |
| New container and closure | A “new container and closure” shipped from a “qualified supplier” is the first time you receive a shipment of a specific drug product container and closure from a supplier that has been qualified by your facility or company. |
| New supplier | A company from whom you have ordered, or are considering ordering, a shipment of drug product components and/or containers and closures for the first time. |
| Ongoing supplier | A company that has previously sent you several shipments of drug product components and/or containers and closures. |
| Pack | By "pack" we mean placing the pharmaceutical product into its primary container/closure system intended to be received or used by the final user, i.e., a healthcare provider or patient. |
| Parent company | The company that controls the management and operations of your facility; the company of which your facility or company is a subsidiary. |
| Potable water | Water supplied to the facility that is safe for humans and animals to drink without risk of harm. |
| Potential hazards [to the quality of facility's potable water] | Chemical, physical and/or microbiological contaminants. |
| Process or processing | When highlighted in this survey, the term *process* or *processing* includes manufacturing, packing or re-packing, labeling or re-labeling, testing, and/or sterilizing any prescription or OTC drug for use by humans or animals. |
| Repeat shipment of a drug product component | A “repeat shipment of a drug product component” from a qualified supplier would be a shipment of a drug product component that you had previously received other shipments of from that supplier. |
| Responsibility and authority | A person(s) who is both accountable and also possesses the power to make a determination. |
| Risk-based procedures | An agenda of activities regarding a process or product the stringency of which are determined by the potential for harm if the process or product fails or goes awry. |
| Serious adverse events | All drugs can have side effects, but by "serious adverse event" we mean an unintended effect that is life-threatening or damages the user's life and health. |
| Specification discrepancies | The difference between your established criteria (i.e., specifications) for a drug product's attributes and properties, and the actual, measured attributes and properties of a batch of that product manufactured at your facility. |
| Supplier qualification program | An effective supplier qualification program includes determining expectations and requirements, identifying potential suppliers, evaluating them, selecting a supplier, and re-evaluating the selected suppliers, and, if issues arise, communicating with the supplier and managing corrective action. The major purposes are: (1) to determine who is good enough to start doing business with; and (2) who the company should continue to do business with. |
| USP monograph for purified water | USP24 - Purified Water is water obtained by a suitable process. It is prepared from water complying with the U. S. Environmental Protection Agency National Primary Drinking Water Regulations or with the drinking water regulations of the European Union or of Japan, or with the World Health Organization's Guidelines for Drinking Water Quality. |
| Validated | Substantiated, confirmed, and retained in a constant state of control |
| Written procedures that address the scope and scheduling | Such written procedures would, at a minimum, indicate how often such joint meetings should be held and what kinds of information and feedback should be exchanged and discussed. |