Cleaning and Disinfection – Regulatory Requirements

Your Objectives:

At the end of this lesson, you should be able to describe requirements of the FDA / EPA as described on labels on medicines?

Regulation requirements for cleaning and disinfection for [ ] and non-sterile production areas are mentioned in several different regulatory [ ]:

- EU GMP
    - Annex 15
    - Chapter 3 and 5
    - EMA Health based
    - Eur. Ph. (5.1.4)
- US GMP
    - CFR 211.167
    - ISPE Risk MaPP
    - PDA TR 29 and 49
    - USP <1111> & USP <1112>
- PICS/S 006

Guidelines for disinfection and sterilization in healthcare facilities (2008)

Before reading the guidance provided in this document, health care

should be familiarised with the federal laws and regulations that govern the sale, distribution and of disinfectants and . Health care* workers need to know what requirements pertain to them when applying such products. Readers should also have a basic understanding of the roles of the EPA (Environmental Protection Agency), the FDA (Food & Drug Administration) as well as CDC (Centers for Disease Control and Prevention) so that the context for the guidance provided here is clear.

EPA and FDA

In the USA, chemical germicides formulated as , disinfectants, or sterilants are regulated in interstate commerce by the EPA's Antimicrobials Division as well as the OPP (Office of Pesticides Program), under the authority of the FIFRA (Federal Insecticide, Fungicide and Rodenticide Act) of 1947, as amended. Under the FIFRA, any or mixture of substances intended to prevent, destroy, , or mitigate, any pest—including microorganisms but excluding those in or on living humans or —must be before sale or distribution. To obtain a registration, a manufacturer must submit specific data about the safety and of each product. So, for instance, the EPA requires that manufacturers of sanitizers, disinfectants or chemical test formulations, by using accepted methods for microbiocidal activity, stability and to animals and humans. Manufacturers submit these data to the EPA along with proposed labelling. If the EPA concludes that the

product may be used without causing “unreasonable [ ] effects” then the product and its [ ] are registered, and the manufacturer can sell and distribute the product within the United States.

The FIFRA expects consumers (patients) and [ ] care specialists to follow the labelling directions on each product [ ] . The following standard statement appears on all labels under the heading Directions For Use: “It is a violation of federal law to use this product in a manner inconsistent with its labelling.” This statement also means that a health care specialist is to follow the safety [ ] and use the directives that come with each registered product. Failure to follow the specified **use-** [ ] **, contact time, method of** [ ] , or any other condition of use, is considered a misuse of the product, and the law may be applicably enforced upon health care workers under the FIFRA.

In general, the EPA regulates [ ] and sterilants used on environmental surfaces, and not those used on critical or semi critical medical devices; the latter are regulated by the FDA. In June 1993, the FDA and EPA issued a “Memorandum of Understanding” that divided responsibility for review and surveillance of [ ] germicides between the two agencies. Under the agreement, the FDA regulates liquid chemical sterilants used on critical and semi critical devices, and the EPA regulates disinfectants used on noncritical surfaces and gaseous sterilants. In 1996, US Congress passed the Food Quality Protection Act (FQPA), which amended the FIFRA with regard to several types of products regulated by both EPA and FDA. One provision the FQPA removed was the regulation of liquid chemical sterilants used on critical and semi-critical medical devices from the EPA’s jurisdiction, and it now rests solely with the FDA. The EPA continues to register nonmedical chemical sterilants. Both FDA and EPA have considered the impact of FQPA and, in January 2000, FDA published its final guidance document on product submissions and labelling. Antiseptics are considered antimicrobial [ ] used on living tissue and are thus regulated by the

FDA under the Food, Drug and Cosmetic Act (FFDCA). The FDA regulates liquid chemical sterilants and high-level disinfectants intended to process critical and semi-critical devices. The FDA published recommendations on the types of test methods manufacturers need submit to the FDA, under Section 510(k) clearance, for such agents.

More useful info here:

https://www.manufacturingchemist.com/news/article_page/EU_GMP_Annex_1_Whats_new_for_cleaning_and_disinfection/147687

* FYI: Health care—written separately—refers to 'the provider actions who care for our health'. Healthcare—written together—is an official system, or body. We have a healthcare system that employs health care workers.

Aufgabe Lückentext:

Folgende Wörter bitte in den Lückentext einfüllen.
Jedes Wort kommt einmal vor.
Bitte Gross- und Kleinbuchstaben beachten.

animals, application, adverse, chemical, drugs, dilution, disinfectants, effectiveness, explicitly, guidelines, health, labelling, precautions, repel, registered, sterile, sterilants, sterilants, sanitizers, substance, toxicity, use, workers