
RAC Exam Study Guide with Complete Solutions

drug - Correct Answer Any article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man.

medical device - Correct Answer An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or similar or relate article, including any component, part or accessory intended for the use in diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease on man or other animals intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body, and which is not dependent upon being metabolized for the achievement of its primary intended purposes (FD&C Act Section 201)

DRLS - Correct Answer Drug Registration and Listing System

FURLS - Correct Answer FDA Unified Registration and Listing System for establishment registration of medical device operators and distributors).

eDRLS - Correct Answer electronic Drug Registration and Listing System

MDUFMA - Correct Answer Medical Device User Fee and Modernization Act 2002. Required electronic medical device event reporting.

MDR - Correct Answer System used for event Reporting for device manufacturers and importers

Importer - Correct Answer Any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package. The initial importer must have a physical address in the United States staffed by individuals responsible for ensuring the compliance of imported devices with all applicable FDA laws and regulations. Importers are required to report to the FDA and the manufacturer when they learn that one of their devices may have caused or contributed to a death or serious injury. The importer must report only to the manufacturer if their imported devices have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

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