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FDA Issues Updates for Device Manufacturers

By **IVT Staff Oct 20, 2021 12:55 pm EDT**

The U.S. Food and Drug Administration, FDA, released new guidance for industry this past week. Both impact Medical Device Manufacturers and offer further direction in identification and reporting requirements. The Updates are as follows:

"Selected Update for Unique Device Identification: Policy Regarding Global Unique Device Identification Database Requirements for Certain Devices" (Draft)

The intent of this draft guidance is to update section III of the "2020 UDI Compliance Policy Guide". The goal is to lend further explanation around certain class I devices for which the FDA does not intend to enforce Global Unique Device Identification Database (GUDID) submissions. It provides additional guidance to labelers of a class I devices regarding implementation of UDI requirements, as well as meeting the UDI direct mark requirements for certain finished device.

The draft can be commented within 60 days after its publication on October 13, 2021 and is available on FDA´s website.

"**Investigator Responsibilities — Safety Reporting for Investigational Drugs and Devices."**

This new guidance outlines the responsibilities regarding safety reporting for investigational drugs and devices. The guidance is intended to assist clinical investigators comply with the safety reporting requirements for:

1. Investigational new drug application (IND) studies
2. Investigational device exemption (IDE) studies

Recommendations are provided to help investigators identify the following:

1. For drugs — Identify safety information that is considered an unanticipated problem 26 involving risk to human subjects or others and that therefore requires prompt reporting to 27 institutional review boards (IRBs) under § 312.66 (21 CFR 312.66) 28
2. For devices — Identify safety information that meets the requirements for reporting 30 unanticipated adverse device effects (UADEs) to sponsors and IRBs under 31 § 812.150(a)(1) (21 CFR 812.150(a)(1))

Per this new guidance UADEs will vary dependent on specific device design and use within a study. Sponsors are, therefore, required to include risk information in their investigational plan to further assist investigators in identifying possible UADEs.

Moreover, investigators are to provide progress reports to sponsors, monitors, and IRBs at regular intervals, and no less than yearly. Such reports should provide information to sponsors about both anticipated and unanticipated adverse device effects.

For more information please see FDA´s draft guidance Investigator Responsibilities — Safety Reporting for Investigational Drugs and Devices.
