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FDA (Food and Drug Administration) Issues Report on 2012 Quality Systems Regulations Enforcement Activities

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FDA recently issued a report entitled “Food and Drug Administration (FDA) Medical Device 2012 Quality System Data, FDA Inspectional Observations (Form 483) and Warning Letter Citations” (the), which highlights the key 2012 inspection and warning letter findings related to compliance with the medical device Quality Systems Regulations (QSRs).

As reflected in the charts below, which are taken from the Report, the number of quality system inspections has been generally increasing in recent years. According to the report, between 2005 and 2012, FDA’s routine QSR inspections increased by a total of 37%, and by 93% with respect to foreign firms.

In 2012, FDA issued 4,243 FDA Form 483 observations citing QSR deficiencies. The frequency with which specific quality subsystems were cited in these 483s, as compared to citations for the same subsystems over the previous ten years, is reflected in the chart below.

The three most frequent 2012 inspectional observations related to corrective and preventative action procedures (CAPAs) (378 observations), complaint files (349 observations), and quality system audits (234 observations). Also of note, the number of observations related to device history records increased significantly in 2012 (190 observations).

Partly as a result of the increased number of inspections, FDA issued significantly more warning letters citing QSR violations in 2012 than it did in 2011. In 2012 alone, FDA issued 164 warning letters that included QSR citations (an increase of 44 letters over 2011).

Violations related to CAPAs and production and process controls were the most common warning letter citations, each appearing in 30% of the letters. Two QSR violations appeared with greater frequency in warning letters than in FDA's inspectional observations: failures in design history documentation (51 letters) and failures in process validation (49 letters).

Device companies should pay close attention to the types of observations and alleged violations cited in FDA Form 483s and warning letters. In the coming months, we will post summaries of recent FDA enforcement activity with respect to QSR compliance.

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