FDA Regulation -- The importance of standards

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Abstract

The Federal Drug Administration (FDA) has been involved in regulation of medical devices, including in vitro diagnostic devices (IVDs) or laboratory tests, since passage of the Medical Device Amendments of 1976. The regulatory oversight program developed is quite comprehensive and includes requirements for premarket review, production of devices over time according to quality system regulations, and postmarket reporting of adverse device-related events. The agency has from its inception had an interest in developing both methods and materials for ensuring test accuracy. The agency was a founding member in the US of the NCCLS and has been active in the ISO TC 212 process, has collaborated with CDC and WHO on standards development, and is in the process of evaluating new mechanisms for use of standards to improve our regulatory processes. Recently, new review formats have been developed allowing premarket work to be streamlined when performed in conformity to recognized standards. The agency is committed to developing regulation that promotes global harmonization as a matter of good public policy, good science, and good health. Development of recognized and traceable international standards makes it easier for the agency to review and approve new tests. These standards can often be used as analytical bridges to allow existing clinical literature and experience to be applied to the development of new products aiding in more rapid transfer of technology from research to clinical applications.