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This guidance document represents the agency's current thinking on various types of PMA submissions (including PDP and HDE submissions) and the corresponding factors that influence the likelihood that an inspection will occur.

Quality System Regulation Information for Various Premarket Submissions . . . . . **Section 7**

This guidance has been prepared by the Center for Devices and Radiological Health (CDRH), in coordination with the Center for Biologics Evaluation and Research (CBER), to assist medical device manufacturers in preparing and maintaining the QS information required in premarket submissions.

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Guidance on what is needed to show that a device subject to premarket notification meets FDA standards for sterility, including information on sterility assurance levels, validation methods, description of packaging and label samples.

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Seven guidances reflecting CDRH's increased scrutiny of clinical trial facilities and practices. Guidances cover FDA's expectations for in vivo bioequivalence; inspections of in vitro diagnostic devices; good laboratory practice in nonclinical laboratories; EPA data audit inspections of nonclinical laboratories; institutional review boards; sponsors, contract research organizations and monitors, and clinical investigators.

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Guidance issued to MQSA auditors to help them implement the general audit requirements specified in Field Management Directive (FMD)-76, Evaluation of Inspectional Performance, Appendix D: Evaluation of MQSA Inspections. This document represents the agency's current thinking on MQSA audits.

Guide to Inspections of Foreign Medical Device Manufacturers . . . . . **Section 11**

This guide was prepared to address concerns about consistency and uniformity of inspection between the domestic and foreign inspection programs. Consistency and uniformity of inspection and enforcement represent high priority goals for the Office of Regulatory Affairs (ORA). This guide provides instructions regarding the approach to the foreign inspection.