



FDA's Utilization of MDSAP Audits

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Date:

- U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health will accept the MDSAP audit reports as a substitute for FDA routine inspections.

Inspections not covered by MDSAP

- For Cause
- Compliance Follow-up
- Pre-approval or post approval inspections
- Compliance with Electronic Product Radiation Control (EPRC) Regulations

Evaluation of Nonconformities

- Audit report packages are mutually accepted and independently reviewed by each RA (listed as a jurisdiction)
- Nonconformities that do not apply to 21 CFR 820, 803, 806, etc., will not factor into the overall audit classification.