

Inspection and audit readiness for medical devices

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Our Role & Responsibilities in the Regulated Industry

- What to expect during a medical device FDA inspection
- General ground rules for inspection management that builds rapport with auditors
- Examples of critical mis-steps made during inspections
- Navigating known risks and other gray areas ethically and with professionalism

Understanding the Myriad of Inspection Methodologies

- Paths routinely used by investigators/auditors during inspections
- Modeling your internal audit program to position your firm for inspection success
- Incorporating learning from mock audits into your firm's readiness toolkit

Establishing a Dynamic Inspection Readiness Model

- Selecting and training an inspection readiness core team
- Tools & resources to operationalize inspection management
- Prepping and presenting "hot stories" effectively
- Points-to-consider for US-based or OUS-based audits
- Operationalizing the requirement that records/data need be "readily available for inspection"
- Skills needed to adequately fulfill front room/war room roles & responsibilities
- Points-to-consider for establishing an effective internal audit program

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