

Are you ready for every regulatory authority inspection?

Benefits

- Sponsor is well prepared with a systematic approach for responding to inspections and audits
- Persistent and/or systemic issues are identified and mitigated by shepherding client from a reactive state to a perpetual state of inspection readiness
- Scalable process implemented to ensure inspection readiness at all times for multiple inspections

With increasing number of inspections worldwide, clinical functions are challenged to come up with scalable approaches that ensure global and local entities are inspection ready at any time

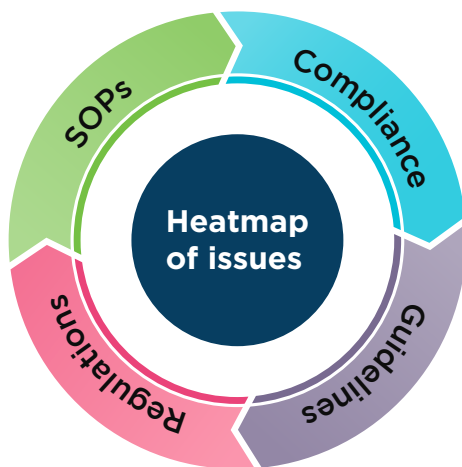
- **1 in 10 FDA inspections require official action**, 1 in 4 require voluntary action
- **1 in 10 EMA inspection findings are critical**, 4 in 10 are major
- **3 in 10 MHRA inspections have critical findings**, half have major findings
- Our data shows that few companies have implemented the ICH E6 GCP R2 Addendum

Navitas Life Sciences provides an integrated approach leading to impactful results

- **Systematic methodology** to implementing and managing a risk based audit and inspection program
- **Governance and process review and re-design** using a robust framework
- Clear communication plan for external stakeholders for successful inspection preparedness

Deliverables

- **Governance and processes that effectively manages inputs and outputs of audits and inspections**
- **Surveys to all stakeholders including sites and sponsors, to identify risks and issues**
- **Inspection (and Audit) SOPs, Tools, Templates, RACI matrices**
- **Risk based methodology for inspection planning**
- **Advice throughout the inspection and audit improvement process**



About Navitas Life Sciences

As a partner for the industry, Navitas Life Sciences leverages industry insights, consulting and technology capabilities to deliver full service clinical, regulatory and safety solutions and desired outcomes to clients. As the dedicated life sciences brand of TAKE Solutions, Navitas harnesses the combined knowledge and experience of three legacy brands—Ecron Acunova, Navitas, and Intelnet—to provide end-to-end services and solutions. Navitas helps clients address their most critical problems by bringing together the capabilities of a full-service CRO, a technology-led life sciences services provider across clinical, regulatory and safety, and a life sciences big data services and analytics provider. Operating from 7 countries across the globe, Navitas works with over 150 customers in Life Sciences.

For more information

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