

## 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**

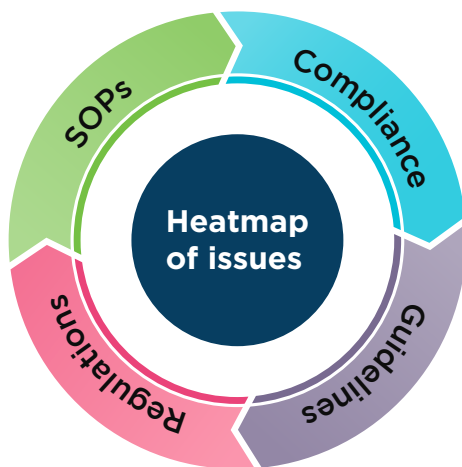
- **1 in 10 FDA inspections require official action**, 1 in 4 require voluntary action
- **1 in 10 EMA inspection findings are critical**, 4 in 10 are major
- **3 in 10 MHRA inspections have critical findings**, half have major findings
- Our data shows that few companies have implemented the ICH E6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

**TAKE Solutions 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 TAKE Solutions

TAKE Solutions delivers domain-intensive services in Life Sciences. In the fast-growing Life Sciences space, TAKE offers clients a unique combination of full-service Clinical, Regulatory and Safety services backed by unique technology expertise. Our range of services span from clinical trials to regulatory submissions to post-marketing safety, all backed by insights derived through proprietary industry networks forums. With a team of leading Life Sciences experts, best-in-class systems and processes, and bespoke, industry-specific technology and analytics, TAKE delivers successful outcomes for clients. Our global roster of clients includes large and small innovator biopharmaceutical companies as well as generics manufacturers. With operations spread across North America, Europe, Asia, and South America, TAKE is a Public Company, listed in India on the Bombay Stock Exchange and the National Stock Exchange. Led by a team of industry stalwarts and domain experts, TAKE has been growing steadily with FY18 revenues touching INR 15,872 Mn, (USD 246 Mn).

### For more information

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