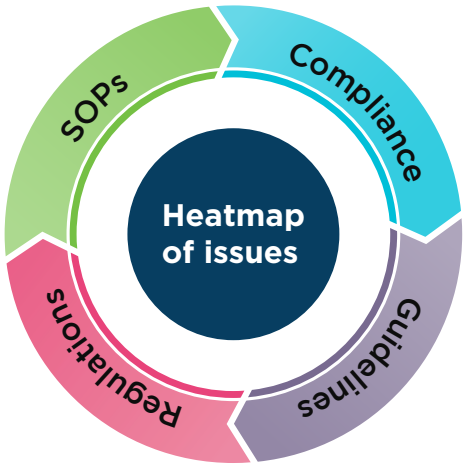
Quality & Compliance

Clinical GCP Rapid Assessment

Are you compliant with the ICH E6 GCP R2 Addendum?

Benefits

- Reduced inspection risk
- Enables effective and efficient compliance with improved visibility and control of risks
- Provides clear and credible roadmap for internal and external communication
- Efficient use of scarce resources to focus on prioritised and systemic risks
- Facilitates continuous improvement



ICH GCP Addendum requires risk based, quality management of clinical trials; quality by design; effective CRO oversight; increased transparency and reduced source data verification

- Our data shows that many companies have not started to implement the ICH GCP Addendum
- Current monitoring services predominantly rely on routinely scheduled site visits to verify source data, resulting in high travel costs, and inefficient processes
- While 100% SDV can cost up to 25% of trial costs, it doesn't contribute to data quality and alternative, risk based, approaches can benefit patient safety

TAKE Solutions provides an integrated approach leading to impactful results

- **Engaging cross-functional stakeholders** through interviews to define impact and develop a tailored compliance roadmap
- **Gap analysis using regulatory expert insight** to compile and review all SOPs, templates, work instructions and associated documents against regulations and best practice
- **Systematic methodology** using risk assessments and maturity matrices to produce visual heatmaps of compliance status
- **Customised model for success** that outlines the vision for GCP compliance

Deliverables

- **Detailed description of gaps** between operational procedures and current legislation
- **Risk Heatmap** and spider diagram of criticality and functions in which the gaps reside
- **A clear roadmap** for implementation of changes that outlines how TAKE Solutions can help you to become compliant
- **Vendor assessment** if required
- **Business case to senior management** on strategy for successful implementation of quality trial management

TAKE®
Enabling Business Efficiencies

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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