

Good Clinical Practice

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human subjects. Compliance with GCP assures that the rights, safety and well-being of trial subjects are protected and that clinical trial data are credible. The International Conference on Harmonisation (ICH) guidance provides a unified standard for the European Union, Japan and the United States to facilitate mutual acceptance of clinical data by the regulatory authorities in those jurisdictions.

How can pharmaceutical and life sciences companies sustain compliance with good clinical practice requirements?

In a period of unprecedented change, regulatory and operational drivers are transforming the clinical trial landscape. Not only are regulators gearing up for more frequent and intensive unannounced compliance audits, but they are changing the focus of their reviews. They seek risk-based compliance approaches versus ‘check-the-box’ procedures, and the application of high compliance standards across a company’s global trials.

Numerous clinical trial operational changes are compounding heightened regulatory attention. New approaches to patient recruitment, data quality issues, privacy law developments, outsourcing of research activities, risk sharing contracts with Contract Research Organisations (CROs), electronic data capture and management, trial acceleration strategies and improved efficiency systems all contribute to these changes. Furthermore, medical journal editors, politicians, the American Medical Association (AMA) and the public are demanding complete and accurate disclosure of clinical trial results in public registries.

Key concerns

Non-compliance exposes corporations to heightened risks such as hefty fines, significant trial delays, endangered patient safety, wasted resources and possible embarrassment and potential litigation resulting from withdrawn products (not to mention reputational damage). Pharmaceutical and life sciences companies must assess their global clinical compliance risk in order to promote and achieve a consistently high level of compliance with good clinical practices, addressing those risks that could prevent the company from meeting its objectives.

To that end, a comprehensive risk-based clinical compliance programme can provide a notable return on investment if well-implemented and well-managed. An effective clinical compliance programme can help achieve timely, efficient and safe clinical trials that conform to GCP regulations.

How can PwC help your organisation?

PwC’ pharmaceutical, quality improvement and regulatory affairs professionals understand the complexity surrounding GCP compliance and performance improvement. We work with our clients to develop optimal compliance and change management plans that address both today’s demands and tomorrow’s expectations.

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Our suite of services in the clinical compliance area combines PwC's strong compliance risk assessment and management skills with a firm understanding and deep practical experience of the application of Good Clinical Practices to the development of pharmaceutical products. Rather than providing a generic approach, we offer customised solutions for the efficient design and implementation of a robust compliance process, tailored to your company's unique needs.

Our GCP compliance and performance improvement professionals can:

Evaluate your current domestic or global clinical compliance risks

Provide a road map to the achievement of an outstanding clinical compliance programme resulting in improved clinical trial processes

Develop key compliance, performance and quality metric tools to monitor both your internal GCP compliance and that of vendors performing outsourced clinical research operations

Perform evaluative GCP compliance inspections of subcontracted vendor sites (e.g., CROs, SMOs, AMCs) to measure their performance against agreed-upon metrics

Integrate a company-wide compliance management platform that includes an overarching Corrective and Preventive Action (CAPA) plan; electronic data management systems (EDMS); and audit management, employee training and change management capabilities to address your global GCP compliance and performance improvement needs

Design more efficient processes to address newer clinical trial regulation developments, including clinical trial registries, adverse event reporting, data privacy and eClinical application needs (i.e., web recruitment of investigators and/or patients, online database tools for clinical outsourcing solutions)

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Global Pharmaceutical and Life Sciences Industry Group

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