CLINMARK
Vital elements merged

CONSULTING
...
GXP & Qualification Audits
Quality Development & Oversight
Training

CLINMARK CONSULTING is a global specialist consultancy, offering a wide range of independent GXP, Quality Assurance and Quality Management services

We work collaboratively with our clients to create a beneficial working relationship that allows us to provide appropriate, customized clinical trial auditing support, and assistance in the development of Clinical Quality Assurance (CQA) programs and infrastructure.

GLOBAL GXP SERVICES

- **Quality oversight:** quality visits, mentoring/supervisory visits, assessments visits - focused on research site, monitoring quality, performance. These activities, implemented from the very beginning of the study, allows early detection of systemic issues and eliminate potential losses by implementing corrective and preventive actions.
- **Pre-inspection evaluation:** This service is designed to support Clients preparation for regulatory inspection. It is focused on trial documentation and key processes review, enabling to identify gaps at the study level. Based on gap analysis and risk assessment Clinmark consultants provide recommendations and, if necessary, support for Corrective And Preventive Action plan development and implementation.
- **Audits:** GCP research site audits, GCP TMF audits, GMP and GDP audits and consulting, GLP audits in laboratories, GVP audits, Mock inspections, Vendor Qualifications, CAPA management.
- **Adaptive risk based audit program**: high level service providing Clients with clear view and quality information on Sponsors clinical program or single project in terms of its quality status, real and potential risks together with risk identification, analysis including - RCA (Root Cause Analysis) and statistical methods, prioritization, assessment, and mitigation strategy with relation to risk impact on the whole program. Step by step adaptive approach enables to adjust the scope of service and its budget to real need of the program.

Clinmark has developed a unique, bespoke audit services to meet client needs. Based on metrics analysis of the most common Regulatory Authority inspection findings and outputs from Clinmark (audit and assessment) consulting activities, we have developed a risk based assessment of the core areas that represent the greatest risk of potential GXP non-compliance.

Our expertise covers over 350 consulting projects performed in 55 countries on 5 continents.

280+ GXP audits

40+ Mock inspections projects

30+ Due diligence projects

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CLINICAL CONSULTING SERVICES

- Identification, qualification and management of vendors
- Optimal vendors allocation referrals based on operational and business criteria
- Support in planning and set-up of project specific QA activities (quality plans, audit plans, risk identification and mitigation plans)
- Auditors QA/QC presentation during Investigators meeting
- Project execution oversight
- Quality assurance and QMS consultancy
- FDA and EMA inspection readiness of Sponsor and investigational site
- System audits aiming to improve the business model and operations
- Due diligence audits to evaluate company value and know-how
- Tailored training solutions

We promote a philosophy of independent, preventative and proactive quality assurance. Our primary focus is to assist our clients in the implementation of GCP quality strategies that support compliance and minimize regulatory risk while being flexible in our consulting approach and service offerings. Foremost, we advise our clients on procedures that protect the safety and welfare of clinical trial subjects. We assist our clients with procedures for regulatory compliance using our knowledge of industry "best practice". We also consider, business efficiencies and apply "common sense" when helping our clients develop quality solutions.

BENEFITS FOR YOU

- Adjustment of clinical development to your needs and business
- Transformation of your organization to the next level competences and maturity
- Increase of operational efficacy
- Assurance that clinical development is consistent and effective operationally and financially
- Smooth execution of clinical development
- Significantly decreased risk of a failure

TESTIMONIALES

"Clinmark team has demonstrated high level of professionalism
CEO of medical device company

''International experiences in auditing are invaluable to any company"
CEO of International consulting company

''Valuable trainings on different clinical research aspects significantly increased our clinical staff competences and awareness of good clinical trial conduct"
Oncology Country Head / European Pharmaceutical company

''Flexible and cooperative, willing to provide service according to client's expectations"
Regional Head of Operations/ American Pharmaceutical company

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The choice of Clinmark's consulting services guarantees fresh and in-depth insight in your organization, professionalism, dedication and personalized solutions.

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