ClinAudits, LLC

The Respected Name in GXP Auditing and Consulting Services Since 1994

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Regulatory Compliance GXP Auditing and Consulting Services Since 1994

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ClinAudits LLC is an independent 3rd party niche provider of Good Clinical Practices (GCP), Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), Good Tissue Practices (GTP), REMS and Tobacco GXP auditing and consulting

By definition, GXP is Good Practice Quality Guidelines and Regulations, and ClinAudits has adapted this doctrine to end-to-end auditing and consulting services for the global life sciences community. Since 1994, ClinAudits has been building on its reputation as the respected name in CRO (contract research organization) services. Whether you are in the business of manufacturing pharmaceutical drugs, bringing biotechnology or tissue engineering products to market, or designing and manufacturing medical devices, ClinAudits offers unmatched services to ensure total U.S. Food and Drug Administration (FDA) regulatory and other government authority compliance.

From Preclinical to Phase IV, and then commercialization, ClinAudits operates strictly within FDA and other governmental authority GXP guidelines. The complete portfolio of services is geared toward complying with FDA guidelines, Drug Enforcement Agency (DEA) laws, EMEA, International Congress on Harmonization (ICH) requirements, client and vendor SOP's and other domestic, international and local governmental requirements. ClinAudits specializes in conducting GCP audits, GLP audits, GMP audits, and GTP audits by providing cost effective, high-quality remediation solutions.

Since the FDA has published its 2009 Smoking Prevention and Tobacco Control Act guidelines, ClinAudits has also gained expertise in mastering GXP auditing and consulting disciplines focusing on targeting quality guidelines and regulation for tobacco industry guidance, compliance and regulatory issues.

ClinAudits mission underscores a dedication to providing a detailed examination and knowledgeable guidance focused on sponsor's clinical trial standards as they directly relate to FDA compliance and GCP standards

ClinAudits' mission is to assess sponsor's clinical trial standards and compliance while helping ensure four critical areas of FDA scrutiny are properly addressed. ClinAudits verifies:

- Clinical trials are conducted in accordance with current world-wide Good Clinical Practice (GCP) standards and the sponsor's and /or CRO /vendor's SOPs and policies.
- Sponsor's clinical trials comply with governmental GCP directives and guidelines. In the event of a GCP inspection, ClinAudits would assist in preparing the sponsor and liaise with FDA inspectors, informing the sponsor of inspector findings and actions.
- Clinical trial data, analysis and reporting is valid, reliable and meets international and national registration and quality requirements (particularly as defined in the sponsor's SOPs, policies and project specific procedures).
- The ICH GCP (E6) Guideline is fulfilled (as applicable) by the sponsor.

Domestic and International GCP Services offered:

- Investigator site audits
- Vendor qualification/capability
- Contract Research Organizations (CROs)
  - -Pre-selection & post capability
  - -Clinical operations
  - -Monitoring
  - -Data entry
  - -Data management
  - -Biostatistics
  - -Medical writing
  - -Drug safety
  - -Regulatory affairs
  - -QA/QC
  - -Central reader
  - -Clinical trial supplies
  - -Project management
- IRB/EC – central, commercial, academic, private, hospitals audits
- Adverse event/Pharmacovigilance audits
- Central & specialty laboratory (GCP) audits
- Final study report audits
- Mock-FDA/EMEA audits
- Electronic submission audits
- IND/IDE Safety report audits
- IVRS Patient randomization audits
  - - (Pre-Qualification and post-capability)
- Clinical trial supply/drug depot audits
- Trial master file archive and records mgt system audits
- Computer systems validation audits
- Case report form design audits
- QA tracking documents audits
- Data mgt/Database audits
- Monitoring department audits
- Clinical trial registry audits
- Phase 1 Unit audits
- GCP customized training
- Risk Evaluation and Mitigation Strategies (REMS) consulting

Domestic and International GLP Services offered:

- Pre-clinical laboratory audits, including 21 CFR Part 58
- Audits of laboratories associated with manufacturing facilities
- Central laboratory audits
- Special laboratory audits
- Laboratories or safety (Phases 1-4)
- Mock FDA/EMEA audits
- Final study report audits
- GLP customized training
- Quality systems assessment, design and implementation
- Process and equipment validation protocols and execution
- Computer and software validation: compliance to 21 CFR Part 11 requirements
- Facility design, environmental monitoring & contamination control
- Utility design and assessment
- Management strategy evaluations for QA/QC systems
- Quality systems integration and harmonization for multiple quality systems requirements and combination products
- Vendor and supplier qualification/capability audits

Domestic and International GMP Services offered:

- Auditing of potential and existing quality systems of manufacturing facilities in order to asses compliance to regulatory and quality systems requirements
- Manufacturing facility audits for:
  - -Drugs – API – Bulk Commercial
  - -Biologics
  - -Medical Devises
  - -Gene Therapy Agents
  - -Gene Therapy – Cell Therapy
  - -Solids, Liquid Dosage
  - -Parentals, IV
  - -Commercial Products
  - -Small/Large Molecules
  - -Tissue Engineering
- Audit of stability programs/data
- Batch record review and QC
- Review facilities design and construction including:
  - -Size – Layout – Security
  - -Warehouse – Production areas – Storage areas
  - -Ante-rooms – Clean rooms
- Review of:
  - -Packaging – Labeling
  - -Storage – Distribution
  - -Destruction of drug product
- Mock FDA/EMEA audits
- GMP customized training
- Regulatory agency response formulation for FDA and other agency audits
- Risk assessment and mitigation for systems, products & equipment
- Audits for compliance to quality systems: FDA & international
- Quality systems assessment, design and implementation
- Process and equipment validation protocols and execution
- Computer and software validation: compliance to 21 CFR Part 11 requirements
- Facility design, environmental monitoring & contamination control
- Utility design and assessment
- Management strategy evaluations for QA/QC systems
- Quality systems integration and harmonization for multiple quality systems requirements and combination products
- Vendor & supplier qualification and audits
- Writing and implementation of SOP's and all types of documents for GMP environments

Regulatory Affairs:

- Create and/or revise FDA IND safety updates
- Create/update FDA NDA/PLA submissions/updates
- FDA 510 (K), NDA, ANDA and annual product reviews
- DEA and other regulatory submissions as necessary

Medical Writing Assignments

SOP Design and Writing (GCP, GLP and GMP):

- Update/revise existing SOPs
- Create new SOPs

Project Management:

- Design and implement clinical project workflow/timelines

Unbundled Services offered:

- CAPA Follow-up
- Hourly QA consulting
- Monitoring (in-house, short-term consulting)
- Question analysis on any QA or regulatory issues
- IDB reviews
- QC audits
- Assessment or audit plans
- Becoming your virtual QA dept.
- Becoming Your Preferred Vendor

Animal Health Services offered:

- Conducting due diligence of nascent or early-phase technologies (drugs, devices, biologicals) perceived as having applications in animals
- Developing programs intended to attract licensing opportunities, sources of capital, or corporate partners
- Designing suitable technical evaluations of early-phase technologies (requiring proof of principle evaluation) through to currently marketed products
- Implement and oversee research conducted by contract laboratories
- Technical writing and document preparation for strategic, scientific, and regulatory purposes (abstracts, technical reports, scientific manuscripts, technical sections intended for regulatory review)
- Advising on matters pertaining to regulatory strategies
- Networking to secure appropriate resources

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Pharmaceutical Product Life Cycle

The Approval Puzzle. Where Do You Fit?

Preclinical (Lab Studies)	Phase I - IIa (Early Clinical)	Phase IIb-3 (Late Clinical)	FDA Approval	Commercialization (Production & Sales)	Phase IV (Post Approval)
Client Issues & Decisions					
• PK and Tox testing (R&M) • Scale up of API production • Start formulation • Narrow down to one API	• First in human • Evaluate absorption • Evaluate dose • Do blood levels meet therapeutic dose?	• Production optimization • Technology transfer to large-scale production • Proof of concept in human	APPROVED	• Full-scale production • Selection of packaging • Marketing information • Second generation process development • Secondary indications	
ClinAudits Services					
• GLP Preclinical Auditing - In life cycle - Final Reports • Labs Associated GMP facilities • GMP - API, bulk, batch, record review - Stability /data - Equipment / Process Validation • Regulatory Affairs Consulting • Medical Writing	• Phase I Units • GCP* • GLP* • GMP* • GTP* • REMS* • Regulatory Affairs* - Mktg Material & Pkg.* - Pre-Sub. Inquiries, Updates & Reviews* • Medical Writing*	• GCP* • GLP* • GMP* • GTP* • REMS* • Regulatory Affairs* - Mktg Material & Pkg.* - Pre-Sub. Inquiries, Updates & Reviews* • Medical Writing*		• GCP* • GLP* • GMP* • GTP* • REMS* • Regulatory Affairs* - Mktg Material & Pkg.* - Pre/Post-Sub. Inquiries Updates & Reviews* • Medical Writing*	• GCP* • GLP* • GMP* • GTP* • REMS* • Regulatory Affairs* - Mktg Material & Pkg.* - Pre-Sub. Inquiries, Updates & Reviews* • Medical Writing*

ClinAudits is a highly specialized world-class consulting and auditing Contract Research Organization (CRO) dedicated to providing end-to-end services for all GXP and regulatory compliance projects. The company has gained domestic and international recognition as a thought leader in Good Clinical Practices (GCP), Good Manufacturing Practices (GMP), Good Tissue Engineering, Cell Therapy and Tissue Bank Practices (GTP), Good Laboratory Practices (GLP), Risk Evaluation and Mitigation (REMS), and Tobacco GXP auditing and consulting.

***GCP:** Investigator Sites Audits (ISA), Central Reader Audits, Institutional Review Board Audits (IRB), Drug Safety / Pharmacovigilance Audits (PV), Interactive Voice Response Systems (IVRS), Final Study Report Audits (FSR), Clinical Trial Supply / Drug Depot (CTS), CROs (Prequalification and Post Capability Audits), Central / Specialty Lab Audits, Computer Systems Validation, Database Audits, Patient Registries Audits, Mock FDA / EMEA Audits, SOP Assessment and Development, GCP Training.

***GLP:** In Life Cycle Audits, Final Report Audits, Central Labs, Specialty (Safety Efficacy) Labs, Methods Validation, Lab Equipment & Process Validation, Microbiological Lab & Analytical Chemistry Consulting, Protocol Development, Computer System Validation, Labs Associated with Mfg Facilities, GLP Training, and Mock FDA / EMEA Audits, SOP Assessment and Development

***GMP:** API, Bulk, Commercial and Batch Review, Stability / Data Audits, Vendor Audits, Vendor Audits of Mfg Facilities, Process Validation, Equipment Qualification / Validation, Computer System Validation, Facility Design, Environmental Design, GLP/GMP Documentation / Batch Record Systems, GMP Training, Mock FDA / EMEA Audits, SOP Assessment and Development,

***GTP:** Tissue Engineering, Cell Therapy and Tissue Bank Audits, Internal Audit System Development, SOP Assessment and Development, GTP Training

***REMS:** Risk Evaluation and Remediation Audits - Patient Package or Med-Guide Insertion, Medication Guide, Implementation System, Communication Plan, Effectiveness Timetable Assessment, Elements to Assure Safe Use (ETASU).

***Regulatory Affairs Consulting:** Serious Adverse Events Reporting / Review, Prepare filings for IND, PLA, NDA, BLA, IDE, PMA, 510(K), Marketing Materials & Packaging, Pre and Post Submission Inquiries, Updates, and Reviews; Domestic and International

***Medical Writing Assignments:** Protocol, Amendments, IDBs, Patient Narratives, and Final Study Reports.

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On average, each senior auditor employed by ClinAudits possesses seventeen years of critical experience relating to complex government regulatory compliance issues. In total, the company offers eight hundred years of collective experience.

As a thought leader with a global network of senior multi-cultural auditors and a think global/act local strategy, ClinAudits enables fast mobilization and deployment of knowledgeable dedicated professionals for our client sponsors anywhere around the world. On average, each member of the auditing team possesses more than seventeen years of field auditing and consulting experience. Taken together, with nearly eight hundred years of collective experience, ClinAudits employs a distinguished roster of professionals that sets it apart from other CROs.

Only senior level professionals with time-tested and field-proven track records working with complex compliance issues relating to government regulatory bodies are on ClinAudit's staff.

ClinAudits helps navigate the 2007 FDAAA in assuring a sponsor's GXP initiatives are fully aligned with the agency's Risk Evaluation and Mitigation Strategy requirements.

Since 2006, ClinAudits has been at the forefront of assisting clients in navigating their Risk Evaluation and Mitigation Strategy (REMS) which was developed by the FDA to manage known risks associated with drug and biologic products. ClinAudits has 5 certified staff auditors specializing in this set of guidelines. The FDA Amendments Act of 2007 (FDAAA) authorizes the FDA to require a REMS as a condition for a new product approval (or retroactively for a product that has been previously approved) if certain available safety information warrants.This strategy is necessary to ensure that the benefits of the product outweigh its associated risks.

With an eye on the REMS elements below listed, ClinAudits applies experience-based guidance to understanding the nature and nuances of a successful REMS approval:

- Patient Package or Med-Guide Insert
- Medication Guide
- Implementation System
- Communication Plan
- Effectiveness Timetable Assessment
- Elements to Assure Safe Use (*ETASU)

(*ETASUs: A REMS may require prescribers and dispensers of the drug or biological to have particular training, experience, or are specially certified)

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ClinAudits delivers best practices in GXP auditing and consulting services targeting quality guidelines and regulation for tobacco industry guidance compliance and regulatory Issues

The 2009 Smoking Prevention and Tobacco Control Act extended FDA's regulatory oversight onto the tobacco industry. ClinAudits delivers best practices in GXP auditing and consulting services, targeting guidelines and regulations for tobacco industry guidance, compliance, and regulatory issues. ClinAudits is assisting clients in tobacco manufacturing and retail by serving as a single point resource on legal, regulatory and policy issues related to tobacco products. Providing GXP services, ClinAudits is helping meet the end-to-end FDA compliance requirements as outlined in the 2009 Smoking Prevention and Tobacco Control Act. Critical compliance and regulatory touch points include:

- Regulation compliance restricting the sale and distribution of product to protect children and adolescents
- The scope of the prohibition against marketing a product in combination with another article or product regulated under the Federal Food, Drug, and Cosmetic Act (FFD&CA)
- Harmful and potentially harmful product ingredients

From retailer product training to upstream manufacturer operations that includes labeling and advertising, proper use of descriptors such as low tar and mild, and the smokeless product rotational warning plan enforcement policy, ClinAudits assists clients in complying with FDA requirements.

BQSI

ClinAudits LLC is proud to have joined the Biomedical Quality Standards Working Group

*****BREAKING NEWS*****

ClinAudits, LLC, an independent, 3rd party provider of GXP compliance, clinical trial auditing, and quality remediation solutions for the pharmaceutical, medical device, biotechnology, and tissue engineering industries, announced in March 2010 that it has joined the Bioanalytical Quality Standard Initiative (BQSI) Expert Working Group, to contribute to the Group's objective of establishing specific regulations and documented, quality management standards for laboratory analytical functions supporting clinical trials.

During the last two years, a pharmaceutical industry consortium has been working to develop an industry acceptable guideline applicable to standardizing acceptable laboratory and quality management practices for bioanalytical studies supporting clinical trials. As a specialized provider of GXP compliance services, with established expertise in Good Clinical Practices (GCP) auditing, ClinAudits has joined representatives from a number of top worldwide pharmaceutical and generic companies in support of this initiative. The BQSI guidance document has been posted to http://www.regulations.gov, and the public has been invited to add comments to the docket file, number FDA-2009-D-0428.

*****BREAKING NEWS*****