



ClinAudits, LLC

GXP Auditing and Consulting Services

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ClinAudits offers auditing, consulting, and training services, specializing in compliance with Good Clinical Practices (GCP), Good Laboratory Practices (GLP), and Good Manufacturing Practices (GMP) to support your business.

ClinAudits has a broad range of technical competencies and a great depth of experience to help you:

- Capitalize on your core competencies
- Improve your Return on Investment
- Minimize or eliminate your compliance exposure/risk
- Increase flexibility
- Complete critical clinical, laboratory or manufacturing activities in a resource effective manner

Industries we serve:

- Pharmaceutical: OTC, Rx (FDA, EMEA, ICH, ISO and DEA)
- Medical Device
- Biotechnology/Gene Therapy
- Tissue Engineering
- Personal care
- Packaging/labeling of drugs/medical devices
- Biologicals
- Combination products
- Active Pharmaceutical Ingredients (API)
- GLP Laboratories

Geographic areas served:

- North America & South America
- European Union & Non EU countries
- Australia/New Zealand
- Asia (India, Russia, China, and Hong Kong)
- South Africa

Domestic and International GCP Services offered:

- Investigator Site Audits
- Vendor qualification/capability
- Contract Research Organization (CRO)
 - Pre-selection and post capability
 - Clinical Operations
 - Monitoring
 - Data Entry
 - Data Management
 - Biostatistics
 - Medical Writing
 - Drug Safety
 - Regulatory Affairs
 - QA/QC
 - Clinical Trial Supplies
 - Project Management
- IRB/EC - central, commercial, academic, private, hospital 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 Management Systems Audits
- Computer Systems Validation Audits
- Case Report Form Design Audits
- QA Tracking Documents Audits
- Informed Consent Process Audits
- Data Management / Database Audits
- Monitoring Department Audits
- Clinical Registry Audits
- Phase 1 Unit Audits
- GCP Customized Training

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
- Specialty laboratory audits
- Laboratories for 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 and 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 assess compliance to regulatory and quality systems requirements
- Audits of manufacturing facilities for:
 - Drugs
 - Medical Devices
 - Gene Therapy Agents
 - Biologicals
 - API
 - Bulk
 - Commercial Products
 - Small/Large Molecules



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• Domestic and International GMP Services offered (Continued):

- Audits of manufacturing facilities for:
 - Solids, Liquid Dosage
 - Parentals, IV
 - Cell Therapy
 - Gene Therapy
 - Tissue Engineering
- Audit of Stability Programs / Data
- Batch Record Review and Quality Control
- 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 and 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 and 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 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, & GMP):

- Update/revise existing SOPs
- Create new SOPs

Project Management:

- Design and implement clinical project workflow/timelines

Unbundled Services offered:

- CAPA Follow-up
- QA Consulting On a Hourly Basis
- 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 Department
- Becoming Your Preferred Vendor

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