
GCP Auditor Resume

Job Objective

Qualified GCP Auditor seeking work with an established firm in which to put my skills and knowledge to good use.

Work Experience:

GCP Auditor, August 2005 – Present
Idexcel, Dallas, TX

- Planned and conducted external audits of clinical studies and third parties.
- Performed internal audits within the affiliate and at Country Offices in the affiliating territories.
- Provided advice and implemented compliance issues and the Quality Management System (QMS).
- Prepared and conducted audits and inspections.
- Ensured the safety, well-being and legal protection of subjects and the validity of study data.
- Ensured escalation of business critical compliance issues.

GCP Auditor, May 2000 – July 2005
Roche, Dallas, TX

- Performed assigned audits on internal GCP systems, external vendors and clinical sites.
 - Utilized available information to provide well-informed audit findings and recommendations.
 - Reviewed and verified GCP reports.
 - Evaluated requirements of the protocol, informed consent form, case report forms, and essential documents.
 - Assisted Inspection Management Team in regulatory authority inspections.
 - Presented observations to appropriate representatives and prepared a written audit report.
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Summary of Qualifications:

- Remarkable experience working in a clinical, regulatory and quality assurance environment
 - Excellent knowledge of GCP auditing
 - Good understanding of GCPs, ICH and procedures and practices in a clinical research setting
 - Skilled in monitoring and auditing of EU and other non-US clinical trials
 - Sound knowledge of FDA regulations, ICH guidelines, and corrective action plans, etc
 - Sound ability to prioritize and understand work impact
 - Ability to work under pressure and independently
 - Excellent communication and intrapersonal skills
 - Excellent report writing capabilities
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Education:

Bachelor's Degree in Physical, National American University, Rapid City, SD

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