Clinical Research Coordinator

AREAS OF EXPERTISE

- **GLP and GCP Audits**
- **Review Protocols**
- **Perform Critical Phase Inspections**
- **Audit Data and Final Reports**
- **SOP Writing**
- **Clinical Supplies Audits**
- **Investigation of New Drug Candidates in Laboratory Animals**
- **On-Site and Off-Site Facility Inspections**
- **GLP Training**

INTRODUCTION

Consultant is an expert quality assurance auditor with experience in FDA/OECD/EPA Good Laboratory Practices, human Good Clinical Practices, animal health GLPs and Good Clinical Practices (VICH GL9), and some aspects of Good Manufacturing Practices. Compares documents and facilities versus protocols, SOPs, and regulations to uncover compliance issues.

WORK EXPERIENCE

1986 – Present
Industry Consultant
Duties:

- Independent quality assurance consultant in all aspects of FDA/OECD/EPA Good Laboratory Practices and VICH GL9 Good Clinical Practices (animal health studies and clinical trials). Human GCP report audits and on-site audits. GMP batch record review, packaging inspections, and analytical and stability data and report audits.
- Proficient at protocol audits, informed consent audits, case report form reviews, master schedule preparation, critical phase inspections, contract laboratory inspections around the US and abroad, data audits, study report audits, facility audits, compliance advice, FDA submission document audits, standard operating procedure generation and audits.
- Review both regulated and non-regulated data in a large array of scientific disciplines.
- Train laboratory staff on Good Laboratory Practices and VICH GL9.
- Review computer validation documentation.
- Documentation control experience.
- Write clear and concise audit reports and follow up on all compliance issues noted.
- Have worked for large, small, and virtual companies. Clients have included sponsor pharma/medical device/chemical firms, contract research organizations, and academic institutions.

10/2010 – 03/2014
AlcheraBio, LLC, Edison, NJ
Clinical Research Coordinator, (part time-as needed)
Duties:

- Reviewed casebooks and databases and generated queries on animal GCP studies. Monitoring visits at veterinary hospitals to review data and close out studies.

1981 – 1986
Ortho Pharmaceutical Corporation/The R.W. Johnson Pharm. Res. Institute, Raritan, New Jersey
Laboratory Quality Assurance Compliance Assistant/Associate/Administrator
Duties:

- Inspected non-clinical laboratory studies (at Ortho and its contract facilities) to assure compliance with GLPs, standard operating procedures, and protocols. Performed facility inspections. Audited non-clinical (and occasionally clinical) study final reports, as well as other research reports from the Basic Sciences divisions. Reviewed non-clinical protocols and SOPs for conformance to GLPs. Wrote audit reports.
- Updated master schedule.
- Assisted Ortho research employees in understanding and implementing the GLPs via GLP orientations for new employees, a GLP Alert newsletter, and frequent employee contact.
- Determined Research QA's computer auditing procedures for non-clinical studies.

1978 – 1981
Ortho Pharmaceutical Corporation, Raritan, NJ
Research Assistant/Associate, Reproductive Pharmacology
Duties:

- Investigated chemical compounds for efficacy as new male and female contraceptives.
- Performed endocrine bioassays.
- Dosing, observations, and necropsy of rats, mice, hamsters, and rabbits.

EDUCATION

1979 - 1982
Rutgers University, Piscataway, NJ
Master of Science: Pharmacology

1974 - 1978
Smith College, Northampton, MA
Bachelor of Arts: Biology

ADDITIONAL SKILLS

- Apply compliance regulations to new situations.
- Apply common sense to regulatory implementation.
- Negotiate compliant solutions to regulatory problems.
- Educate auditees to think from a regulatory perspective.
- Prioritization of work load.
- Familiarity with written and spoken German language.
- Standard computer skills.