LEIGH ANNE MYERS

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WORK HISTORY:

2009 – Present	**Myers Quality Consulting, LLC,** Carmel, IN President, GCP/GLP Consultant
2008 - 2009	**Targanta Therapeutics Corporation,** Indianapolis, IN Director, Quality Assurance – GCP/GLP
2007 - 2008	**Roche Diagnostics,** Indianapolis, IN Quality Systems Audit Principal
2005 - 2007	**Quality Source by Blood Systems,** Scottsdale, AZ Quality Source Consultant
2000 - 2005	**U.S. Food and Drug Administration,** Indianapolis, IN Consumer Safety Officer
1999 – 2000	**Community Tissue Services,** Indianapolis, IN Director, Tissue Bank
1998 – 1999	**Central Indiana Regional Blood Center,** Indianapolis, IN Manager, Audits
1990 – 1998	**U.S. Food and Drug Administration,** Indianapolis, IN Consumer Safety Officer

EDUCATION:

Bachelors from Indiana University Purdue University at Indianapolis
Certified Quality Auditor (CQA) from American Society for Quality

EXPERIENCE:

GCP Compliance and Consulting

- Performs routine and for cause clinical investigator site audits of Phase I-IV (Drug), Premarket Approval and In Vitro Diagnostic Studies (Medical Device).

- Conducts vendor audits of Contract Research Organizations (CROs) that provide the following services; study monitoring, selection of clinical investigators, electronic data capture (EDC and datacenters), investigational drug distribution, central laboratories, pharmacovigilance and safety reporting, data management, independent readers of imaging, Interactive Voice Response Services (IVRS) and Interactive Web Response Services (IWRS), biorepositories and Risk Evaluation and Mitigation Strategies (REMS).

- Performs sponsor audits (Drug and Device) that cover the following; selection of clinical investigators, selection of study monitors, study monitoring, data management, pharmacovigilance and safety reporting, biostatistics, validation of computerized systems, investigational product management, training, Standard Operating Procedures (SOPs) and document control, maintenance of the trial master file, medical writing, oversight of CROs and due diligence audits.

- Identified non-compliances during audits with applicable FDA regulations, ICH Guideline, and internal procedures. Audit observations are documented with regulatory reference and recommended corrective actions provided.

- Hosted sponsor audits, regulatory inspections, wrote responses for audits/inspections and Warning Letters.

- Performed routine and for cause clinical investigator site audits in the United States, Canada, Mexico, Norway, United Kingdom, Spain, Italy, The Netherlands, Hungary, Sweden, Estonia, Poland, Ukraine, Greece, Taiwan and South Africa.

- Provided quality oversight for the conduct of clinical trials and for key projects. Assisted with regulatory responses. Selected, contracted and managed quality consultants used to perform GCP/GLP audits and project work. Enhanced and managed the Quality System. Conducted GCP training and prepared clinical investigators and sponsor staff for regulatory inspections.

- Performed routine and for cause FDA inspections of clinical investigators, sponsors and CROs conducting Phase I-IV drug or device studies. FDA-483 was issued when non-compliances were identified. Significant non-compliance issues were submitted for regulatory consideration.

- Conducted training for new FDA investigators on conducting inspections of clinical investigators, non-clinical laboratories and biologics firms. Identified non-compliance issues and reported findings.

GLP Compliance and Consulting

- Performed assessments and compliance audits of third-party vendors including central laboratories, animal testing facilities, clinical trial material manufacturing and distribution facilities.

- Conducted FDA inspections of non-clinical laboratories that included assessments of personnel and training, quality assurance unit, facilities, SOPs, equipment calibration and maintenance, animal care, histology/pathology, test and control articles, validation of computerized systems, protocol, final study report and archival. FDA-483 was issued when non-compliances were identified and significant non-compliances were submitted for regulatory consideration.

Institutional Review Board

- Conducted FDA inspections of Institutional Review Boards responsible for review and approval of drug and device studies. FDA-483 was issued for non-compliances identified.

Project Management

- Served as a project manager to coordinate global GCP vendor audits, identified auditors, served as primary liaison and ensured adherence to project timelines.

Standard Operating Procedures (SOPs)

- Wrote SOPs, policies, forms and templates for GMP, GCP and biologics environments.
- Performed gap analysis to evaluate procedures for compliance with applicable regulations and industry standards.
- Hosted SOP Committee Meetings. Provided training on writing, revising and archiving SOPs.

Therapeutic Experience

- Cardiology
- Immunology/Infectious Diseases
- Oncology
- Neurology
- Psychology
- Respiratory/Pulmonary
- Gastroenterology
- Dermatology
- Endocrinology
- Autoimmune
- Urology
- Ophthalmology
- Hematology

PROFESSIONAL SOCIETIES:

- American Association of Blood Banks (AABB)
- American Society for Quality (ASQ)
- Association of Clinical Research Professionals (ACRP)
- Society of Clinical Research Associates (SoCRA)