



3704 Duxford Drive  
Raleigh, N C 27614-8110  
(919) 676 - 4801, office  
(919) 845 - 1444, facsimile  
ehkrohl@fdacompliance.com  
www.fdacompliance.com

## Curricula Vitae for Erin Krohl

### Education:

B.S. Biochemistry, Louisiana State University, Baton Rouge, LA, 1984  
M.S. Pharmacology, LSU Medical Center, New Orleans, LA, 1986  
Masters Public Health, University of Alabama-Birmingham, 1990

### Professional Experience:

#### **President, EHKrohl Consulting, Inc., Raleigh, NC January 1996 - present:**

Provide advice, expertise, in-house training, project management to the human and veterinary API and finished pharmaceutical manufacturers, medical device, biologics, biotechnology and affiliated industries worldwide. Audit and assess GXP industries for compliance with: FDA Good Manufacturing Practices (GMPs), Quality System Regulations (QSR), Good Laboratory Practices (GLPs), Good Clinical Practice (GCP) regulations; Part 11 Electronic Records, Electronic Signatures requirements; as well as ICH guidelines.

- Facilitate FDA approval of product applications, including performance of mock FDA pre-approval inspection audits, serve as firm representative to the FDA, and participate in on-site FDA inspections.
- Determine GXP/QSR compliance, including performance of routine and mock FDA audits, GMP, QSR, GCP (sponsor, site, PI, CRO - Phases I-IV), GLP compliance audits, contractor/vendor/CRO audits and assessments.
- Analysis and development of GMP, GLP, GCP, and Quality Assurance systems and processes.
- Audits and analysis of computer systems for compliance with 21 CFR Part 11 requirements.
- Audits of analytical/bioanalytical laboratories, bioequivalence/pharmacokinetic studies.
- Focused audits – data, potential fraud, due diligence, etc.
- Serve as “cGMP expert auditor” for firms that have received a consent decree.
- Serve as official Drug monograph expert.
- Development and management of corrective action plans to bring firms into compliance.
- Review of regulatory applications, process validation, computer system validation documentation, stability programs, CMC, etc.
- Safety/post-marketing adverse event reporting/ complaint system audits.
- Prescription Drug Marketing Act process review.
- Preparation of responses to FDA Warning/Untitled letters and FDA- 483 with CAPA approach.
- Aiding firms with recall situations.
- Analysis and development of Standard Operating Procedure systems and documentation.
- Conducted GXP audits in Asia/Pacific, Eastern Europe, Japan, India, Middle East, North America, South America, Western Europe

#### **QA Senior Compliance Auditor, Quintiles, Inc., Research Triangle Park, NC July 1995 - July 1996:**

Responsibilities included: planning and performance of client and contractor Good Manufacturing



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Practice, and investigator site Good Clinical Practice audits; planning and performance of QA systems audits, including computer system validation review; Assisted in the development of Standard Operating Procedures; Developed training program and conducted training of QA auditors; Provided training to employees on GXP topics; Participated in client business development presentations. Served as a consulting project liaison.

**FDA Investigator: New Orleans, LA; Raleigh, NC  
July 1989 - July 1995:**

Developed extensive knowledge of the FDA regulations, as well as expertise in GCP, GLP, and GMP inspections, foreign and domestic, in the bioresearch, pharmaceutical, medical device, and biotech industries, including routine and “for cause” fraud inspections. On FDA **Foreign travel cadre** for bioresearch, human and veterinary drug, device, and biologics inspections.

**Biologics/Biotech industry:** inspection of plasma fractionator, PLA approval inspections, blood banks and plasma collection facilities, including team inspections with FDA Headquarters scientists and training other FDA Investigators.

**Bioresearch:** conducted inspections of foreign and domestic GLP facilities; bioequivalence/bioanalytical facilities; Clinical Investigators; IRBs; Sponsor/Monitor; CROs; QAU; Contract Clinical Laboratories, including team inspections with FDA Headquarters scientists and training other FDA Investigators. Also proficient at conducting inspections of computer systems - completed FDA Training course “Computer System Validation”. Audited pharmaceutical NDA, ANDA, IND, non-clinical and device 510(K), PMA clinical trials in the following therapeutic areas: audiology, cardiovascular, general surgery, gynecology, immunology, infectious diseases, nephrology, neurology, oncology, psychiatry, pulmonary, and urology. Selected as the Atlanta **District Bioresearch Monitoring Specialist** in November 1992.

**Medical Device industry:** inspections of domestic and foreign Class I, II, III sterile and non-sterile device manufacturers including in vitro diagnostics, and implantable devices; PMA and 510 (K) pre-approval inspections; extensive knowledge of device GMP/QSR, validation, Medical Device Reporting, and ISO 9000 requirements.

**Pharmaceutical industry:** inspections of foreign and domestic innovator and generic manufacturers of all dosage forms, including sterile, irradiated, and lyophilized products; NDA and ANDA pre-approval inspections; Inspections of bulk drug, veterinary drugs, investigational drugs manufacturers. Inspections of ETO, steam, and irradiator sterilizers; Review of IQ, OQ and process validation, pharmaceutical water systems; complaint and DQRS follow-up inspections.

**Other Activities:**

- Instructor for “Preparing for FDA Inspection”, Society Clinical Research Associates (SoCRA), 1997 – current .
- Speaker at numerous industry meetings internationally, as well as domestically, on GXP topics.

**Professional Societies:**

DIA; PDA; PDA Southeast Chapter; SQA



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**Primary Therapeutic Areas of Expertise for GCP studies:**

- Allergy
- Analgesic agents including ICU sedation
- Antibiotic therapies
- Cardiovascular (Angina, Arrhythmias, Coronary Angiography, Hypertension, Imaging agents, Intervention for diabetics at risk, Pulmonary Arterial Hypertension, Thrombolytics)
- Dermatology (Acne, Ichthyosis Vulgaris, Onychomycosis, Skin Infections)
- Diagnostics (Contrast Media, In vitro diagnostic for pharmacogenomic testing, Lab Tests)
- Devices (Audiology, Bone, Diagnostic, Graft Access, Prosthetics, Spine, Stents, Neurological, Vascular)
- Gastroenterology (Crohn's disease, Gastric/Duodenal Ulcers, GERD, Post-op nausea and vomiting)
- Immunology (AIDS, Hepatitis)
- Nephrology (hyperphosphatemia in dialysis patients)
- Neuropharmacology (Bipolar disorder, Diabetic neuropathy, Insomnia, Neuropathic Pain, Parkinson's disease, Seizure disorders, Opioid Dependence)
- Oncology (Breast Cancer, Chemotherapy, Immunotherapy, Lung cancer, Melanoma, Hodgkin's Lymphoma, Non-Hodgkin's Lymphoma, Prostatic Cancer, Human papillomavirus, B-cell chronic lymphocytic leukemia, Renal -cell carcinoma, Thrombocytopenic Purpura, T-cell lymphoma)
- Psychiatry (Abuse Studies, Anxiety, Depression, Smoking Cessation)
- Respiratory/Ear/Nose/Throat (Asthma, Bronchitis, Cystic Fibrosis, Influenza, Meningitis)
- Rheumatology (Osteoarthritis, Rheumatoid arthritis)
- Transplants (Renal Transplant Rejection)
- Urology (Benign Prostatic Hyperplasia, Overactive Bladder)
- Vaccines (Influenza, Pediatric combined - meningitis, diphtheria, tetanus, pertussis, hepatitis B, poliovirus)