EHKrohl Consulting, Inc.

1034 Steinbeck Drive
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Curricula Vitae for Erin E. 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 / Durham, NC
January 1996 - present:

Provide advice, expertise, in-house training, project management to the human/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; Postmarketing Adverse Drug reporting (PADE) and Risk Evaluation and Mitigation Strategies (REMS) reporting, Safety Reporting for INDs and BA/BE, Good Pharmacovigilance practices (GVP); as well as associated ICH and ISO guidelines.

- Facilitate FDA approval of product applications, including performance of mock FDA GXP pre-approval inspection audits, serve as firm representative and participate in on-site FDA and Health Canada inspections.
- Conduct mock-EMA GCP and GVP audits.
- Determine GXP/QSR compliance, including performance of routine and mock audits, GMP, QSR and ISO 13485, GCP (sponsor, site, PI, CRO - Phases I-IV), GLP compliance audits, contractor/vendor/CRO audits and assessments, and pharmacovigilance/post-marketing adverse event reporting/ complaint system audits, as well as call center audits.
- Audits of analytical/bioanalytical laboratories, bioequivalence/pharmacokinetic studies.
- Focused audits – data, potential fraud, due diligence, etc.
- Prescription Drug Marketing Act process review.
- Analysis and development of GMP, GLP, GCP, GVP, and Quality Assurance systems/processes.
- Audits, analysis of GXP computer systems for compliance with 21 CFR Part 11 requirements.
- Serve as “cGMP expert auditor” for firms that have received a consent decree.
- 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.
- Preparation of responses to FDA Warning/Untitled letters and FDA- 483 with CAPA approach.
- Analysis and development of Standard Operating Procedure systems and documentation.
- GXP audits in Asia/Pacific, China, Japan, India, Middle East, North America, South America, and Europe.

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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 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 to clients.

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 of other FDA Investigators.

Bioresearch: conducted inspections of foreign and domestic GLP facilities; bioequivalence/bioanalytical facilities; Clinical Investigators; IRBs; Sponsor/Monitor; CROs; QAUs; 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**.

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 9000/13485 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.

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Laboratory Technician, LSU Eye Center: New Orleans, LA
July 1987 – July 1989:

Responsibilities included support of physician researchers involved in a FDA-regulated ophthalmic laser medical device clinical trial and corneal studies, as well as scientific research animal studies; garnered skills in small animal care and surgery, computerized topography techniques, laboratory research and clinical trial documentation.

Laboratory Technician, Tulane Medical Center, Clinical Pharmacology: New Orleans, LA
July 1986 – July 1987:

Responsibilities included supporting 3 local hospitals by testing patient samples for drugs of abuse and other special clinical pharmacology tests for therapeutic efficacy and dose titration therapy; evaluation of AIDS subjects' CDC research samples; developed an HPLC method for detection of Naprosyn in plasma; performed urine screen analyses for drug of abuse for corporate new hire testing programs and the Tulane University athletic department; served as on call lab tech supporting 3 emergency rooms for toxicologic drugs of abuse determination.

Other Activities:

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

Professional Societies:

DIA; SQA; North Carolina Chapter SQA

Primary Therapeutic Areas of Expertise for GCP studies:

- Allergy.
- Analgesic agents including ICU sedation.
- Antibiotic therapies.
- Cardiovascular (Angina, Arrhythmias, Chronic Heart Disease, Chronic Obstructive Pulmonary Disease with history/risk of CV disease, Coronary Angiography, Coronary Heart Disease, Hypertension, Hypertrophic cardiomyopathy, Imaging agents, Pulmonary Arterial Hypertension, Scleroderma, Subarachnoid Hemorrhage – Stroke, Thrombosis).
- Dermatology (Acne, Acne vulgaris, Atopic Dermatitis, Chronic Eczema, External genital warts due to human papilloma virus (HPV) infection, Ichthyosis Vulgaris, Onychomycosis**,** Plaque Psoriasis, Skin Infections).
- Diagnostics (Contrast Media, In vitro diagnostic for pharmacogenomics testing, Lab Tests), including first de novo artificial software for disease determination approved by FDA (indication diabetic retinopathy).
- Devices (Audiology, Bone, Diagnostic, Graft Access, Post-surgical incision for Reduction Mammoplasty, Prosthetics, Spine, Stents, Neurological, Ultrasound, Vascular).

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Primary Therapeutic Areas of Expertise for GCP studies: (cont.)

- Endocrine (Intervention for diabetics at risk, Type 2 Diabetes, Type 2 Diabetes with inadequate glycemic control; Enzyme-replacement therapy for rare diseases).
- Gastroenterology (Celiac disease, Crohn's disease, Gastric/Duodenal Ulcers, GERD, Post-op nausea and vomiting).
- Gene therapy studies several therapeutic indications, including enzyme deficiencies, gene mutations
- Immunology (AIDS, Autoimmune diseases, Blood coagulation factor deficiencies, Hepatitis, β-Thalassemia, Myelodysplastic syndromes, Paroxysmal nocturnal hemoglobinuria).
- Nephrology (hyperphosphatemia in dialysis patients, lupus nephritis, urea cycle disorders).
- Neuropharmacology (Alzheimer's disease, Bipolar disorder, Complex Regional Pain syndrome, Dementia, Diabetic neuropathy, Insomnia, Migraine, Mild Cognitive Impairment due to Alzheimer's Disease, Multiple Sclerosis, Neuropathic Pain, Opioid Dependence, Parkinson's disease, Seizure disorders, Treatment-resistant Major Depressive Disorder).
- Oncology (Acute Myeloid Leukemia, Breast Cancer, Chemotherapy, Immunotherapy, Lung cancer, B-cell chronic lymphocytic leukemia, Chronic Lymphocytic Leukemia, Hodgkin's Lymphoma, Melanoma, Metastatic melanoma, Multiple myeloma, Neuroblastoma, Non-Hodgkin's Lymphoma, Ovarian, Prostatic Cancer, Relapsed/Refractory Acute Myeloid Leukemia, Relapsed/Refractory Multiple Myeloma, Renal-cell carcinoma, Soft tissue sarcoma, Synovial Sarcoma, T-cell lymphoma, Thrombocytopenic Purpura).
- Otology (bilateral middle ear effusion).
- Psychiatry (Abuse Studies, Acute Depressive Episodes Associated With Bipolar 1 Disorder, Anxiety, Depression, Major Depressive Disorder, Schizophrenia, Smoking Cessation).
- Rare Disease: gene therapy in several therapeutic indications, including enzyme deficiencies, gene mutations
- Respiratory/Ear/Nose/Throat (Asthma, Bronchitis, Cystic Fibrosis, Influenza, Meningitis)
- Rheumatology (Gout, Osteoarthritis, Osteoarthritis associated with bone marrow lesions, Rheumatoid arthritis).
- Transplants (Renal Transplant Rejection).
- Urology (Benign Prostatic Hyperplasia, Overactive Bladder).
- Vaccines (Human Papillomavirus, Influenza, Pediatric combined - meningitis, diphtheria, tetanus, pertussis, hepatitis B, poliovirus).

Signed: Erin E. Krohl

Erin E. Krohl

06 April 2021