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**Steven R. Koepke, PhD**  
SRK Consulting, LLC  
9812 Greenbrier Lane  
Walkersville, MD 21793  
(301)-845-2721  
e-mail: [skoepke@srk-consulting.com](mailto:skoepke@srk-consulting.com)

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## Professional Experience

**SRK Consulting, LLC.** Walkersville, MD  
**President and CEO**

*January 2005- present*

- Provide drug related consulting emphasizing strategic planning for interactions with regulatory bodies
- Provide regulatory consultation for in-house clinical projects or stand-alone regulatory projects regarding chemistry, manufacturing, and controls issues
- Prepare technical chemistry, manufacturing, and controls documents in support of clinical trials (INDs) or marketing applications (NDAs) in compliance with FDA/ICH guidelines/regulations
- Plan, organize, and moderate meetings with the FDA
- Specialty in consulting on combination drug products such as drug eluting stents, ICD leads and various types of implants.
- Specialty in the requirements of novel drug delivery systems (metered dose inhalers, dry powder inhalers, transdermal patches, needleless injectors, etc.)

*2001- January, 2005*

**PharmaNet, Inc.** Princeton, NJ  
**Senior Director, PharmaNet Consulting**

- Provide regulatory consultation for in-house clinical projects or stand-alone regulatory projects regarding chemistry, manufacturing, and controls issues
- Prepare technical chemistry, manufacturing, and controls documents in support of clinical trials (INDs) or marketing applications (NDAs) in compliance with FDA/ICH guidelines/regulations
- Plan, organize, and moderate meetings with the FDA

**Food and Drug Administration,** Rockville, MD  
**Deputy Director, Division of New Drug Chemistry II**  
**Office of New Drug Chemistry, Office of Pharmaceutical Sciences,**  
**Center for Drug Evaluation and Research**

*1992 – 2001*  
*(1997 – 2001)*

- Responsible for ensuring the regulatory and scientific quality of the reviews of chemistry, manufacturing and controls sections of applications from seven chemistry teams associated with the following six clinical divisions:
  - Division of Gastrointestinal and Coagulation Drug Products
  - Division of Anesthesia, Critical Care and Addiction Drug Products
  - Division of Pulmonary Drug Products
  - Division of Metabolism and Endocrine Drug Products
  - Division of Reproductive and Urologic Drug Products
  - Division of Medical Imaging and Radiopharmaceutical Drug Products
- Interacted with other disciplines across the organizational structure within the FDA and the regulated industry in order to facilitate expeditious availability of promising drug therapies
- Originated the concept and was primary person responsible for ensuring that the new electronic CMC section for applications was consistent with CDER's need for life cycle management of NDAs
- Served on the committee that produced the Postapproval Changes Guidance

**Review Chemist, Division of Oncology Drug Products** (1992 – 1997)

- Evaluated the CMC sections of INDs, NDAs, and Supplemental Applications of oncology and pulmonary drug products.
- Assisted in the development of the Biotech Reagents Guideline
- Responsible for the generalized approach to electronic CMC submissions adopted by CDER as the representative to the Office of Pharmaceutical Sciences Information Technology Working Group
- Received multiple awards for productivity and the design and implementation of computer related tools to assist reviewers in their evaluation and tracking of applications

**Environmental Protection Agency, Washington, DC** 1990 – 1992**Review Chemist****Chemistry Branch Tolerance Section I, Health Effects Division  
Office of Pesticide Programs, Office of Pesticides and Toxic Substances**

- Review position to evaluate petitions to register pesticides for food use
- Redesigned and standardized the Chemistry Branch's internal database for monitoring the status of petitions and existing tolerances of pesticides

**National Cancer Institute, NCI-FCRF-BRP, Frederick, MD** 1978 – 1990**Scientist II**

(1980 – 1990)

**Chemical Aspects of Chemical Carcinogenesis Program**

- Investigated the mechanisms of chemical carcinogenesis
- Supervised two postdoctoral fellows
- Responsible for relevant sections of the laboratory's biannual research proposal
- Interfaced laboratory equipment with computers and developed software for analyzing the resultant data

**Scientist I**

(1978 – 1980)

**Chemical Aspects of Chemical Carcinogenesis Program**

- Investigated the mechanisms of chemical carcinogenesis
- Supervised two technicians
- Discovered a new pathway of activation of nitrosamines

**Education****University of Nebraska, Lincoln, NE***PhD – Physical Organic Chemistry***University of Nebraska, Lincoln, NE***MS – Physical Organic Chemistry***Oberlin College, Oberlin, OH***BA – Chemistry*