



Regulatory Compliance Initiatives, Inc.

P.O. Box 95651, Las Vegas, Nevada 89193
Phone: 702-914-0798 Fax: 702-269-9341

inquiries@regulatorycomp.com
www.regulatorycomp.com

Leading the Way

CURRICULUM VITAE

JAMES E. CARTER, Ph.D.
PO Box 95651
Las Vegas, NV 89193-5651

Phone: 702 914 0798
Fax: 702 269 9341
Email: jcarter@regulatorycomp.com

EDUCATION

- 1966 B.S., Chemistry, Brigham Young University, Provo, Utah
- 1969 M.S., Microbiology, Brigham Young University, Provo, Utah
- 1975 Ph.D., Medicinal Chemistry, University of Utah, Salt Lake City, Utah

PROFESSIONAL EXPERIENCE

2002 – Present Principal, Regulatory Compliance Initiatives, Inc.

- Filing of electronic INDs, NDAs, ANDAs and DMFs in eCTD format
- Writing, assembly and review of Chemistry, Manufacturing and Controls documents for INDs, NDAs and ANDAs
- Writing, assembly and review of DMFs
- Audits/Preparation for Preapproval Inspections
- Consent Decrees and CAPA Initiatives
- GMP training
- All aspects of Quality Assurance/Quality Control including instituting Quality Systems and Quality Policies.
- Analytical work/validations including establishing an Analytical/QC function
- Bioanalytical work/validations including auditing and preparing a bioanalytical laboratory for an FDA inspection.
- Due Diligence Audits

- 1994 – Present Principal, Omega Pharmaceutical Consulting, Inc.
 Consultant to the pharmaceutical industry in the areas listed for RCI
- 1991 - 1994 Boehringer Mannheim Pharmaceuticals – Now part of Roche
 Responsible for all aspects of Product Development and Quality Assurance including interaction with international affiliates and contract manufacturers. Built out and staffed analytical laboratories including all aspects of Quality Control. Established the QA function including SOP's and all associated systems. Staff of 14.
- 1989 - 1991 Janssen Research Foundation
 Titusville, NJ 08560
 Director, Product Development
 Responsible for assembly and review of numerous INDs and NDAs. Functional areas included analytical laboratories, bioanalytical laboratories and formulation development. Staff of 20.
- 1985-1989 Janssen Pharmaceutica
 Director, Quality Assurance/Technical Services
 Responsible for all aspects of QA, analytical & bioanalytical Labs.
- 1982-1985 Ortho Pharmaceutical Corporation
 Research Manager, Drug Characterization
 Responsible for analytical methods development, characterization and specifications for new drug substances.
- 1975-1982 American Critical Care
 Group Leader, Analytical Development
- 1973-1975 University of Utah
 Research Assistant, College of Pharmacy

PUBLICATIONS

Over twenty-five publications and numerous meeting presentations available upon request.

PROFESSIONAL ORGANIZATIONS

American Association of Pharmaceutical Scientists (AAPS)

American Chemical Society (ACS)

Drug Information Association (DIA)