

NORMAN LEWIS
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JOB OBJECTIVE

To secure a position in Quality Assurance or Regulatory Affairs with a pharmaceutical organization that will benefit from my initiative, capabilities, and insight. I am especially interested in a position with increased decision making responsibilities as Director of Supplier Audits.

PROFESSIONAL

Perform Quality Assurance audits for pharmaceutical, clinical trial, medical device and dietary supplement corporations to ensure the integrity and regulatory compliance of products or services.

QUALIFICATIONS / EXPERIENCE

Quality Assurance Auditor IRCA ISO 9000 Auditor Certification, ASQ certified Auditor, Statistics, Microsoft Word, Access, Excel, FDA 483, Response Letters, Facilitated FDA/Regulatory Agency inspections, Consent Decree/Compliance Audits, Developed System Audits, Customer Complaint Resolution, Laboratory Record Review, Corrective Action Implementation, Investigation of Deviations, Tracking and Trending, Error and Accident Reports, Review of Non-Conforming Materiel, Supplier Quality Audits, Equipment / Process Validation, ICH Q7A Active Ingredient Audits, Finished Pharmaceutical Audits (21CFR 211), Good Clinical Laboratory Practices, Blood Regulations and Audits of Facilities, Audits of Contract Research Organizations, ICH Regulations, GLP Review, Clinical Trial Audits

EMPLOYMENT HISTORY

Sun Pharmaceutical Industries Inc. and Caraco Pharmaceutical Laboratories (subsidiary of Sun Pharmaceutical) - Detroit, Michigan – 2006 - Present

Sr. Compliance Auditor for North and South America

Responsibilities include identifying areas or departments that are out of compliance with FDA regulations, monitoring compliance activities, tracking and trending observations, and reviewing corrective/ preventive actions. External audits are performed for Caraco and Sun Pharmaceuticals of India, Sun Pharmaceuticals of Cranbury, New Jersey and Bryan, Ohio. External audits are performed domestic and internationally at active pharmaceutical ingredient manufacturers, excipient manufacturers, dietary supplement manufacturers, contract research organizations, clinical and non-clinical research facilities, packaging operations, and pharmaceutical finished product manufacturing sites. Sun Pharmaceutical Industries saved approximately \$75,000 by my reorganization of the domestic supplier auditing program.

Stiefel Laboratories – U.S. Manufacturing Facility • Oak Hill, New York • 2005 to 2007

Manager, Quality Assurance External Auditing for North and South America

Performed audits of Active Pharmaceutical Ingredient suppliers, finished product suppliers, components suppliers, clinical testing facilities and contract testing in North and South America at a rate of 2-4 audits per month. Responsible for organizing and disseminating detailed objective audit reports that are used to make procurement decisions, concerning all classes of pharmaceutical products. Also responsible for auditing clinical, non-clinical research facilities, packaging & components, dietary supplement and medical device manufacturers as needed.

Oak Park School District – Oak Park, Michigan • 2003 to 2004

High School Biology/ Chemistry Teacher and District Summer Substitute Teacher

Responsible for the science education and safety of 9th through 12th grade high school students. Developed detailed lesson plans for the teaching of biology and chemistry, conducted biological and chemical experiments based upon various methods of learning and supervised scientific field trips to emphasize classroom learning.

American Red Cross - National Headquarters • Rosslyn, Virginia • 1998 to 2002

Quality Assurance and Regulatory Assessments, Quality Auditor II-III

Conducted world wide independent quality and regulatory assessment audits of American Red Cross Regional, National Testing Laboratories, Computer Development Centers, National Headquarters, and assorted suppliers to monitor, assess and report the effectiveness of applied standards. Results are used to identify areas needing improvement and also assist management in preventing errors and improving quality of blood products.

American Red Cross - National Testing Laboratory • Detroit, Michigan • 1995 to 1998

Quality Assurance Specialist

Facilitated FDA, ARC-QRA, AABB, CLIA, and other regulatory agency inspections of the laboratory. Analyzed clinical data identified trends associated with, but not limited to laboratory testing, proficiency testing, QC, equipment / supplies /

reagent defects.

Generates System Audit Reports, Error and Accident Reports, Laboratory Record Review Audits, to be forwarded to the Quality Assurance Officer or National Headquarters of Biomedical Services.

American Red Cross - National Testing Laboratory • Detroit, Michigan • 1994 to 1995

Reagent Control Specialist

Inspected 100% of incoming laboratory reagents and supplies for non-conformity. Maintained all records and logs for receipt of reagents and supplies. Also responsible for reviewing package inserts for changes or modifications to testing procedures that could adversely affect blood manufacturing.

EDUCATION

Northwestern California University School of Law
Presently attending law school (2013 graduation date)

Wayne State University, Detroit, MI
Molecular Biology – graduate courses (2002-2004)

Northern Michigan University, Marquette, Michigan
Physiology / Chemistry

PROFESSIONAL MEMBERSHIPS

American Society for Quality (ASQ)
International Register of Certificated Auditors (IRCA - ISO 9000)
Regulatory Affairs Professional Society (RAPS)