EG | ELIZABETH GARCIA

Investigator - Regulatory Compliance

(720) 226 - 5051 eagarcia123@gmail.com linkedin.com/in/elizabethgarcia123

Dedicated professional with experience in conducting regulatory audits requiring well-developed skills in gathering and analyzing large amounts of data information / Strong communication skills developed in both written reporting and oral presentations to key constituencies, including senior managers and board of directors /

Demonstrated ability to cultivate, develop and maintain productive working relationships with corporate personnel at all levels, including regulatory and law enforcement officials.

CORE STRENGTHS

- Risk Management
- Data Analysis
- Collaborative
- SAP
- LEAN & Agile PM
- Salesforce
- MS Office Suite
- Regulatory Audits
- Lexis Nexis
- Previous Top Secret Clearance, U.S. Department of Justice

EDUCATION

Master of Science in Regulatory Affairs for Drugs, Biologics and Medical Devices
Northeastern University, Boston, MA

Master of Science in Organizational Leadership: Leadership and Management
Regis University, Denver, CO

Bachelor of Arts in Biology
University of Colorado, Boulder, CO

RELEVANT EXPERIENCE

Consultant | Denver, CO, 2018-present

- Conducted risk assessments and data analysis to identify possible non-compliance behavior in various healthcare entities.

Corporate Investigator | Amerisourcebergen Drug Corp. | Valley Forge, PA, 2012-2017

- Identified and investigated customers based on various data sets indicating controlled substance and non-controlled substance purchase patterns; provided guidance to cross-functional departments on regulatory policies, federal guidelines and statutes; conducted due diligence investigations on new customers onboarding with Amerisourcebergen (ABC).
- Conducted daily risk assessment of customer base using complex statistical models to identify suspicious activity of controlled substance purchasing and dispensing.
- Utilized report- and query-generating software, SAP to analyze patterns of controlled substance activity on targeted entities who posed highest risk to company.
- Performed in-person visits to various pharmacies all over the U.S. eliciting information to determine legitimate pharmacy activity, including audit functions complying with 21 CFR Part 1300 of Code of Federal Regulations.
- Lead the development of training for the Suspicious Order Monitoring Program; trained all 26 distribution centers nationwide both virtually and in person.

Regulatory Associate | Hospira Boulder, Inc. | Boulder, CO , 2010-2012

- Prepare maintenance reports, original registrations (CMC CTD sections), and other documents to global regulatory agencies and in compliance with FDA regulatory drug filing requirements.
- Ensure accuracy and timeliness of all global drug master file submissions with the goal of decreasing deficiencies from regulatory agencies.
- Coordinate submission peer reviews with other functional areas to achieve accurate and robust CTD documentation for global health authorities in Europe, U.S., Asia, Australia and Canada.
- Selected as team representative in assessing and presenting diagnosis of company relative to attitudes and behaviors in support of LEAN initiatives, while developing tools to improve communication between functional areas.

Diversion Investigator | Drug Enforcement Administration | FBI Academy, Quantico, VA/Los Angeles, CA 2004-2006

- Lead investigator on civil and criminal cases involving pharmaceutical drugs; conducted regulatory audits of importers, exporters, distributors, and manufacturers of controlled substances and List I chemicals; analyzed pharmaceutical records to detect regulatory and criminal law violations.
- Initiated civil case against List I chemical registrant for regulatory violations, resulting in civil penalties; compelled changes in registrant's procedures to comply with DEA requirements based on tenacious investigation to uncover omissions in mandatory reporting going back several months.
- Developed thorough knowledge of Code of Federal Regulations to conduct audits of controlled substances and List I chemicals at place of business of manufacturers, distributors, suppliers and others regulated by DEA.
- Performed due diligence on businesses and individuals to determine regulatory compliance and suitability for controlled substance licensure.
- Chosen to participate on special investigation unit based on proven audit and investigation skills to uncover both overt and subtle regulatory violations.
- Cultivated contacts and collaborated with state and federal law enforcement agencies to conduct surveillance operations that provided key evidence for major drug diversion investigations.

ADDITIONAL EXPERIENCE

Associate Director, Campus Programs & Membership Services | Colorado School of Mines Alumni Association | Golden, CO, 2006-2010

- Analyze, create and implement marketing strategies to retain and increase memberships to the Alumni Association; plan logistics for special on-campus events; develop partnerships with vendors and other departments on-campus; and manage teams of volunteers.
- Played key role in creating marketing appeal messages and strategies to alumni constituents resulting in significantly increased alumni membership.
- Prepared and presented incisive analytical reports for board of directors, including membership trends and campaign statistics resulting in strategic board decisions for future membership campaign direction.
- Reduced marketing and advertising costs by developing strategic partnerships with other departments, student representatives, well-known alumni and key vendors based on proven ability to establish strong working relationships with diverse cross-campus and business groups.