6230 Regency Parkway
Norcross, GA 30071

FERN E. SMITH
SENIOR STAFF CONSULTANT

fesmith@engsys.com

Fern Smith is a Senior Staff Consultant at Engineering Systems Inc. (ESI) in the pharmaceutical and medical device sub-practice group. Ms. Smith specializes in manufacturing compliance, quality assurance, quality control systems, vendor audits, and troubleshooting manufacturing packaging issues. She is a skilled auditor, quality specialist, solid and liquid dose manufacturing investigator, and quality control analyst with extensive experience in the pharmaceutical industry. She has performed numerous audits in the United States and Canada, as well as in countries such as China, Taiwan, Japan, South Korea, Germany, France, and India.

Ms. Smith is committed to continuous improvement and focuses on providing efficient solutions and processes for validation programs, laboratory and manufacturing investigations and audits, as well as data integrity audits and training.

Areas of Specialization

Supplier Management (Vendor Audits, Qualification and Certification)
Customer Complaints (Trending, Investigations)
CAPA (Trending, Effectiveness Checks, Cross Functional Investigation)
Change Control
Deviations (Manufacturing/OOS)

Education

Business, St. Lawrence College
Chemistry, St. Lawrence College
Laboratory Training Program

Professional Affiliations/Honors

American Society of Quality (ASQ)

Positions Held

Engineering Systems Inc., Norcross, Georgia

Senior Staff Consultant, 2017 – Present

Mylan Nashik India, Quality Specialist, October 2015

- Performed third party data integrity review of HPLC chromatograms.

Phone: 678-990-3280 | Fax: 678-990-3285 | Toll Free: 866-596-3994
www.engsys.com

Qualitest Huntsville, Alabama and Charlotte, North Carolina
Quality Specialist; Third Party Oversight Contract, March 2014 – June 2015

- Performed third party review and approval of site OOS Laboratory and Manufacturing investigations to ensure nonconformance was contained, product impact evaluated, appropriate corrective action taken, and product disposition determined based on documented evidence.
- Performed site audits, reported findings, and evaluated corrective action taken. Evaluated OOS, manufacturing, and customer complaint investigation trends and initiated investigations when trends were identified. Lead cross-functional investigation teams utilizing 6 sigma principles.
- Mentored investigation writers to document manufacturing and OOS deviations in an independent chronological manner, based on documented evidence.
- Performed retrospective reviews of OOS Laboratory and Manufacturing Investigations including applicable chromatograms, method validation, SOPs, manufacturing batch records, cleaning documentation, and related materials from determined impact to marketed product.
- Prepared training materials related to investigation writing, good documentation practices, and importance of independence of the quality unit.

Novartis Vaccine and Diagnostics, Holly Springs, North Carolina
Quality Specialist; Supplier Management Contract, November 2012 –December 2013

- Performed QA Supplier Management function for on-boarding and approval of raw materials and components for use in VPP.
- Created phase appropriate strategy and procedure for approval of IMP materials per ICH Q 8,9 & 10 guidance and the Novartis Quality Manual.
- Developed phase appropriate strategy and procedure for approval of third party contractors performing pre-clinical and clinical operations per current guidance and in compliance with the Novartis Quality Manual.
- Performed vendor audits.

Hospira, Rocky Mount, North Carolina
Technical Writer Contract, March 2012 – Oct 2012

- Translated analytical methods into worksheet templates for routine lab use.
- Prepared templates for a variety of analytical tests and equipment including HPLC and GC Chromatography.

Trillium Health Care Products, Brockville, Ontario, Canada
Compliance Specialist-Vendor; Qualification/Audit, 2005 – 2012 (2009 – 2012, Contractor)

- Managed and executed the Vendor Audit Program.
- Performed vendor audits individually and as part of an audit team (lead auditor) worldwide including China, Taiwan, Japan, South Korea, Germany, France, Spain, Italy, Ireland and India, as well as in Canada and the United States.
- Developed audit tools and checklists - evaluated vendor performance history in preparation of the audit through trending of rejection and customer complaint data bases.

- Prepared vendor qualification documentation - wrote audit reports with specific references to the applicable audit standard for each audit finding and rated the findings.
- Followed-up on corrective action plans as required.
- Prepared and submitted vendor qualification packages for laboratory certification evaluation.
- Performed internal audits including review of batch records, validation documentation, deviations, change controls, customer complaints, rejection reports, and laboratory test results.
- Participated in Internal, Customer and Regulatory audits (Health Canada and FDA).
- Generated regulatory (USA and Canada) documentation for label submission.
- Participated in compliance team continuous improvement activities.
- Participated in cross functional investigations.

Trillium Health Care Products, Brockville, Ontario, Canada
QA Document Reviewer / QA Specialist, 2004 – 2005

- Reviewed laboratory test results and manufacturing batch records.
- Finished product document review and approval for distribution.
- Performed deviation and customer complaint investigations.

Warner Lambert/Trillium Health Care Products, Brockville, Ontario, Canada
Laboratory Analyst, 1976 – 2004

- Performed finished product and raw material testing utilizing HPLC/GC, UV, IR, and NIR.
- Performed dissolution testing on solid dose products.
- Implemented robotic/HPLC assays.
- Performed method validation testing.
- Performed stability testing to approved specification stated in the stability protocol on several dosage forms including solid dose, semi-solids, liquids, creams, and suppositories.
- Performed routine peer review of analytical data including chromatography, dissolution, UV, IR, and chemical tests.
- Performed OOS investigations.

Continued Education

Data Integrity Training
FDA Inspection Training
Personality Dimensions Training
Train the Trainer
FDA Pre-Approval Inspections Training
QSIT (Quality System Inspection Technique) Auditor Training

Certifications

Six Sigma Green Belt Certification, Edgecombe Community College, 2012
ASQ-CQA Recertification (certified since 2005), 2012