



Curriculum Vitae

SENIOR CONSULTANT, CHEMISTRY AND QUALITY SYSTEMS

JOHN HUFFMAN

Mobile: 847-445-0049

Summary of Qualifications

John has over 30 years of experience in the pharmaceutical and medical device industry focusing on analytical chemistry, methods development and validation, stability programs, medical device packaging, and regulatory compliance. Regulatory compliance included coordination of failure, complaint, and OOS investigations and implementation of associated CAPA programs as well as preparation of responses to FDA 483 observations. He has organized and directed both chemistry and microbiology laboratory operations.

Professional Experience

SR. CONSULTANT, CHEMISTRY AND QUALITY SYSTEMS, *LexaMed, Ltd.*

- Responsible for coordination and performance of laboratory testing and daily activities, training of personnel in the chemistry department, and development/validation of instruments and techniques.
- Responsible for the coordination of failure investigations, corrective action implementation and closure.
- Consults in the areas of analytical chemistry, laboratory operations, methods development and validation, regulatory compliance including deviations, complaints and OOS investigations, CAPA implementation, stability and accelerated aging programs, and medical device packaging issues.



John Huffman
Senior Consultant, Chemistry and Quality Systems

Selected examples of consulting activities include:

Major U.S. Based Dietary and Nutritional Supplement Manufacturer

John has provided service to the dietary and nutritional supplement industry for a one-year period. During that time he was involved with supporting on-site remediation efforts to establish compliance with 21 CFR Part 111. Specific areas of involvement include, but not limited to:

- Auditing and compliance surveillance activities
- Practice versus Procedure Gap Analyses
- Compliance Plan Development and Execution
- Quality Systems Design and Implementation
- Compliance Training inclusive of GMP, Conducting Investigations, Good Documentation Practices and Responsibilities in a GMP Environment
- CAPA Program Implementation and Effectiveness Evaluation
- Product Non-Conformance investigation and resolution
- Standard Operating Procedure (SOP) generation and amendment for production and laboratory practices

Global Testing, Research & Development Laboratories

- Acted as Interim Manager, Method Development and Validation
- Oversaw the design, development and validation of analytical methods to ICH guidelines. Effort directed toward raw material, in-process, API release and stability indicating method development.
- Oversaw highly sensitive HPLC procedures for cleaning verification and/or validation and Safebridge compliant industrial hygiene sampling and analysis procedures.

Global Manufacturer of vaccines and plasma derivative products

- Organized QC Chemistry Laboratory and performed gap analysis on all instrument and method validations through a successful Pre-Approval Inspection (PAI). Prior to PAI, the company had been under Notice of Intent (NOI) to remove its Biological License Application for approximately three years.

Global Researched-based Pharmaceutical Company

- Authored and executed laboratory instrument and associated software validations, including those associated with rapid microbial identification methods. All work performed under heightened scrutiny of a company under consent decree.



705 Front Street, Toledo, Ohio 43605 1.888.232.5227 / 419.693.5307 www.lexamed.net

John Huffman
Senior Consultant, Chemistry and Quality Systems

Biotechnology Company focused on the development and commercialization of novel therapeutics that address the immune system to fight cancer

- Organized and summarized historical stability data for a variety of medical devices used in the company's dendritic cell treatment process.
- Authored final reports for the stability studies and performed gap analysis of the overall stability program.
- Coordinated accelerated aging and container closure integrity programs for all product configurations.

Medical Device Manufacturer of orthopedic support products

- Developed and coordinated stability programs for determination of product expiration dating include CCI investigations.

Developer and Manufacturer of tissue grafts and blood cell preservation products

- Worked with team to develop novel method of liquid sterilization of tissue products.
- Assisted in development of product packaging configuration.

SR. CONSULTANT, *Pharmaceutical Systems, Inc.*

- Responsible for coordination and performance of laboratory testing and daily activities, training of personnel in the chemistry department, purchasing, and development/validation of instruments and techniques.
- Conducted and/or coordinated failure investigations, corrective action implementation and closure.
- Provided consultation services to pharmaceutical and medical device companies in the areas of analytical chemistry, methods development and validation and investigations.
- Designed and administered stability program for a surgical kit packer for inclusion of drug products (lidocaine, bupivacaine and ropivacaine) in disposable surgical packs subject to sterilization using ethylene oxide.

MANAGER, CHEMISTRY, *BEC Laboratories, Inc.*

- Coordinated all daily activities in the chemistry section including test scheduling, training, SOP authoring, client contact and report generation.
- Responsible for method validation protocol generation; validation execution; primary method validations of nutraceuticals (herbals) and of client-supplied SOP's.
- Participated in the design and execution of special studies; performed HPLC analysis of monomers; participated in audits by clients/regulatory agencies including FDA and USEPA; and served on the internal ISO implementation committee.



705 Front Street, Toledo, Ohio 43605 1.888.232.5227 / 419.693.5307 www.lexamed.net

John Huffman
Senior Consultant, Chemistry and Quality Systems

CHEMIST, *BEC Laboratories, Inc.*

- Responsible for EO sterilization residual analysis; USP/NF monograph testing; metals analysis by AA and ICP; gas chromatography – PCB's pesticides, herbicides and special projects; and conducted a variety of analyses on environment samples.

CHEMIST, *Prestolite Battery Company*

- Responsible for a variety of quality control tests on automobile battery components.

Education

- ◆ B.A., Biology, University of Toledo
 - Minor in Chemistry, University of Toledo

