Bob Haldane

Summary

Bob is an experienced Sr. Quality Assurance Engineer with a demonstrated successful track record of providing cost effective guidance and technical expertise in achieving and maintaining regulatory compliance. 12+ years pharmaceutical cGMP experience and 11+ years cGMP experience in medical device manufacturing. Pharmaceutical dosage forms include tablets, softgel capsules, empty gelatin capsules, sterile injectables and bulk dialysate powder. Medical devices include fixation implants for bone plates and screws, orthoscopic cutting instruments, drill bits and dental implants.

Diverse history of supporting regulatory compliance including on-site and remote auditing of suppliers and internal departments, Material Review Borad team member, production process trouble shooting, validation of process/equipment/utilities and execution of Gage Repeatability & Reproducibility studies. Exceptional understanding of manufacturing statistics and process capability calculations. Technical writing skills include generation of QMS documents, CAPA's, pFMEA's, deviations and investigations, and validation master plans.

Experience

QA Consultant QMS systems and Audit Specialist 2023 -Present

- Audited Development and Commercial CDMOs
- Developed SOPs and QMS in support of virtual companies
- Batch record review and product release for virtual companies.

Medical Device Quality Assurance Engineering Roles 2008 - 2022

Held several Quality Engineering roles in support of the manufacture of fixation implants and cutting instruments

Capsugel, Validation and Audit Specialist 2008 - 2008

- Generated risk-based Validation Master Plan
- Developed SOPs in support of capsule manufacturing.

Alcami. Validation Specialist II 2003 - 2008

- Project Leader for the validation of equipment, processes, steam sterilization cycles, depyrogenation cycles and cleaning procedures in support of the manufacturing of sterile liquid drug products.
- Generated, managed, executed, and reviewed FATs, SAT's, IQs, OQs, PQs, Process Validations, Cleaning Validations, Container Closure Integrity Studies, in support of contract sterile drug manufacturing.

Catalent Pharma Solutions, Validation/Technical Specialist

1997 - 2003

- Generated validation documents for the manufacturing of softgel capsules containing OTC and Rx products.

Teva Pharmaceuticals. Clinical Supply Coordinator 1992 - 1997

- Designed packaging for clinical supply kits.
- Supervised single blind and double-blind packaging and labeling operations of investigational drugs.
- Managed and tracked shipping, receipt and return of clinical supplies.

Philosophy

Never stop learning. Be open minded to new approaches in problems solving.

Personal Traits

Innovation – Creative problem solving.

Mentoring – Enjoy sharing knowledge and training production personnel.

Client-driven – Providing cost effective solutions.

Strengths

- Production problem solving
- Technical writing
- Validation SME
- Expert QA auditor
- Adaptable
- Flexible
- Executes business needs while ensuring quality.

Education

BS Chemistry

1991-1994

Florida International University, Miami, FL

AS Electronic Technology

1977-1979

Miami-Dade Community College, Miami, FL