



Steve Hennigar

VP Validation

Steve Hennigar, P. Eng., brings strong analytical and communications skills to Quality & Compliance Services Inc. His positive outlook and proven problem-solving abilities allow Steve to complete projects and tasks efficiently without compromising quality. Steve's presentation of his research thesis on the chemical modification of polymers was given a Neish award by Queen's University faculty and industry members.

SKILLS AND HIGHLIGHTS



Validation

- Reviewed protocols for compliance to Health Canada and FDA requirements
- Initiated, investigated and determined corrective and preventative actions for deviations and non-conformances
- Drafted HVAC IQ/OQ/PQ protocols
- Drafted and executed equipment IQ/OQ protocols for pharmaceutical and medical device manufacturers and packagers
- Performed Qualification (IQ/OQ) on warehouses, freezers and Refrigerators, including temperature mapping of small size refrigerators and walk-in refrigerators
- Drafted Process Master Validation plans
- Drafted and executed analytical method validation protocols for drug product manufacturer
- Developed protocol and performed process validation for large-scale chemical manufacturer
- Drafted retrospective Process Validation protocols
- Developed computer validation project plan for NHP manufacturing company
- Evaluated computer systems for validation plan requirements
- Performed validation on filling and packaging operations for drug manufacturing company
- Initiated, determined actions and closed actions for change controls related to Validation
- Performed shipping validation studies



Large Compliance Project Management

- Reviewed more than 2,000 batch production records to assist with biologic manufacturer's backlog due to staffing transitions
- Produced medical devices according to FDA requirements in GMP environment



Quality Assurance/Quality Control

- Initiated, determined actions and closed actions for change controls related to all aspects of Quality Assurance
- Initiated, investigated and determined corrective and preventative actions for deviations and non-conformances



Auditing

- Performed internal audits to ensure compliance with corporate quality standards
- Hosted Health Canada inspections
- Performed audits to ensure compliance to Health Canada Drug GMP regulations, NHP GMP regulations and FDA cGMP regulations of manufacturers, packagers/labelers, importers and wholesalers
- Coordinated and executed self-inspection program for pharmaceutical and NHP facilities



Technical Writing

- Drafted and revised cleaning procedures and work instructions to meet GMP standards



Computer Skills

- Microsoft Office – Microsoft Word, Excel, PowerPoint, Visio

EDUCATION

- Bachelor of Science, Engineering Chemistry, Queen's University, Kingston, Ontario

CONTINUING EDUCATION, CAREER DEVELOPMENT

- Shipping Validation, PDA
- Analytical Method Validation, PSG
- Design and Validation of Critical Utility Systems, University of Toronto (U of T)
- Process & Cleaning Validation, U of T
- Validation Master Plan - Roadmap to Compliance, U of T
- Practical Method Development & Validation for HPLC (Waters)
- cGMP Overview, Aventis Pasteur
- Fundamentals of Dissolution, PSG
- Fundamentals of GMP for Packaging Suppliers, Q&C
- GMP for Importers/Distributors, Q&C
- GMP Overview
- GMP Training, Aventis Pasteur
- Industrial Drug Legislation, Seneca College
- Advanced GMP Auditing, Q&C
- Auditing Skills, Q&C
- ISO Internal Auditor, Quality Management Institute (QMI)
- ISO Overview, Q&C
- Manufacturing Control in the Pharmaceutical Related Industries, U of T
- Review of Analytical Data
- SOP Writing
- Technical Writing Course, Q&C
- WHMIS certification
- Worked on project resulting in publication of "Determination of Alkoxyamine Concentrations in Nitroxyl Mediated Polymerization Products." *Macromolecules*, 35, 7628-7633 (2002)
- Worked on project resulting in publication of "Silica Agglomeration and Elastomer Reinforcement: Influence of Surface Modification." *Plastics, Rubber and Composites*, 32, 1-8 (2003)