

Senior Change Analyst

Six years of experience in the biotech industry, both pharmaceutical and medical device. Trained and experienced in Good Manufacturing Practices (GMP). I have extensive experience in the administration of cGMP and controlled documentation; proven strengths in multi-tasking various responsibilities, adhering to written procedures (SOP's) and exceptional attention to detail.

Computer Skills

70 w.p.m., Windows XP, MS Word, WordPerfect, Flaps 2.0, Time Slips, QuickBooks, One-Write Plus, Day-Timer Organizer, Internet Explorer, Dictaphone, Microsoft Outlook, Microsoft Access, UPS World Ship™ 2011, Log Tag Analyzer, Cognos, Oracle and Agile PLM, Bluebeam PDF Revu

Professional Experience

Atrium Medical Corporation Hudson, NH
a Maquet Getinge Group company

Document Control Change Analyst
Promoted to Senior Change Analyst

November 2011 to September 2014
September 2014 - Present

- Ensure BOM structure configuration and document format are compliant to Atrium standards
- Assess and judge proposed product and procedure changes for compliance to the Quality Management System (QMS) and business standards at all product lifecycle phases
- Ensure data accuracy and completeness of documentation including change orders, procedures and drawings
- Responsible for updating and formatting documentation using MS Word and Excel
- Conduct final configuration verification prior to product release or change implantation in Document Management Systems (Agile PLM)
- Monitor change activity, manage workflow timelines, and act to resolve issues among multi-department teams during the change process
- Provide training and guidance to new employees on change orders and item creation
- Guide change initiators in the development of accurate changes
- Maintain database (Agile PLM) and a complete historical record of all engineering documentation.
- Support department in creating and implementing documentation
- Maintains revision control in company training database
- Support IT in revision control for QMS Reports
- Accountable for training newly hired change analysts
- Perform related duties as required

Bio-Concept Laboratories, Inc. Salem, NH
Quality Assurance Documentation Specialist

May 2008 to November 2011

- Process, distribute, and maintain controlled documentation for revision and approval using a document control system
- Monitor the distribution and reconciliation of process or reference documents
- Review documents for completion, accuracy and compliance with policies and procedures
- Ensure all training records are completed as a result of document form changes
- Store and maintain records for record retention purpose
- Retrieval of archived records, notebooks and/or logbooks as requested by departments
- Email daily notification to Bio-Concept personnel of documents made effective or obsolete
- Coordinate with document originators to resolve and document issues and discrepancies

- Maintain a Quality Documentation System
- Maintain documentation master list
- Receive and process any drug products for client specific testing
- Receipt and inspection of raw materials, components and drug products
- Copy all necessary documentation pertaining to a manufactured batch record in order to prepare it for Quality Assurance review
- Perform monthly inventory of expired raw materials to ensure they are removed from inventory upon expiration
- Audit document control files in order to ensure that they are in compliance with cGMP regulations and Bio-Concept's internal procedures
- Accountable for the packaging and shipment of drug products per cGMP requirements
- Accountable for the programming of log tags to monitor temperature during shipment of drug products
- Data entry and filing of all employees training records
- Receipt of incoming ETO cycles
- Maintain Material Safety Data Sheets

Troisi & Sullivan Law Offices

Salem, NH

February 2007 to April 2008

Legal Secretary

- Provided secretarial support including the drafting and editing of complaints, motions, and correspondence relating to criminal, divorce, domestic, personal injury, zoning, business formation, and estate planning law
- Familiarity with the New Hampshire courts and filing system
- Opened daily mail and updated client correspondence and/or pleading files
- Structured and organized open and closed filing systems
- Provided receptionist responsibilities

Schreiber & Associates P.C.

N. Andover, MA

November 2003 to July 2005

Legal Secretary

- Obtained bankruptcy information from potential clients via telephone, and forward information to bankruptcy attorney
- Verified bankruptcy information and scheduled appointments
- Provided litigation secretary support to 2 attorneys, including the drafting and editing of complaints, motions and other pleadings
- Prepared and forward quarterly billing invoices to clients
- Provided receptionist relief as needed

Education

Pinkerton Academy, Derry, NH - Graduated 1985

References

Available Upon Request