

Dorothea Blackwell

QA/Doc Control Assistant - Joule Clinical & Scientific Staffing

Norristown, PA - Email me on Indeed: [indeed.com/r/Dorothea-Blackwell/91b0ae81c6488b2f](https://www.indeed.com/r/Dorothea-Blackwell/91b0ae81c6488b2f)

Authorized to work in the US for any employer

WORK EXPERIENCE

Quality Assurance/Document Control Assistant

Joule Clinical & Scientific Staffing - Horsham, PA - March 2016 to Present

- 21 CFR 11 - QMS File Management via Track Wise
- Track Change Control progress
- Convert Word and Excel documents to PDF's and upload files from Track Wise to QA file shares
- Prepare batch records for achieving and offsite storage
- Create and maintain Excel spreadsheets to track progress of QA/QC projects in order to better manage resources

Data Entry Assistant

CKhobbiegroup Agency/Merck Co - West Point, PA - March 2015 to January 2016

Perform data entry for batch records in XMII and MES databases.

- Clear up batch record data entry backlog.
- Perform quality review of batch records and SOP's to ensure compliance with company policies and procedures.
- Maintain tracking spreadsheet of leading measure summaries on document room activities on monthly bases by batch identifier for analytical purposes.
- Work with operations technicians to ensure that batch records are clearly labeled, filed, and stored properly.
- Enter laboratory results into SAP/LIMS database.
- Prepare weekly LIMS paperwork for Sample Deliveries.
- Create and populate EC schedules associated with processes for environmental monitoring in LIMS and HanDEL.
- Manage Vent Filter Room.
- Write, update, and maintain SOP's and train managers and technicians on the vent filter delivery processes.
- Created and maintained Excel spreadsheets, compiling measureable information on personnel performances throughout the vent filter delivery process. Used pivot tables and charts, to track issues, actions, and resolutions, for analysis of information on weekly, monthly and quarterly bases, to assist managers in counseling and disciplines, and to develop and enact better quality processes.
- Assist in change order process

Administrative Assistant

Randstad Staffing/GSK - King of Prussia, PA - October 2014 to January 2015

Prepare manufacturing documents for change order process

- Research drug submission documents for the preparation of redaction of critical information.
- Redacted appropriate information from drug submission documents.
- Verified document information and entered results in the appropriate spreadsheets.
- Transferred regulatory documents from company database to file share folders.

Regulatory Affairs Specialist

Volt Agency/VWR - Radnor, PA - April 2014 to May 2014

Coordinated efforts that identified company vendors whose products were subject to new GHS regulations requiring vendors to update their Material Safety Data Sheets, and produce and/or update their labeling for hazardous chemicals.

- Liaison with company vendors and assisted in organizing the GHS program ensuring the vendor's compliance with and completion of the required hazard reclassification of GHS styled labels and the new unified structure of Safety Data Sheets.
- Compiled, stored, and maintained accurate regulatory data relevant to the scope of the GHS compliance project, along with other essential information using Excel and Access databases for analyzing and reporting purposes.

Data Entry Consultant

Disys Agency/PNC Bank - Philadelphia, PA - December 2013 to March 2014

Assisted VP of Credit Investigations with formatting and editing of procedures and statistics stored in Word documents and Excel spreadsheets that logged the activity and performance of department personnel.

- Sectioned mail for sorting out clients having or receiving lines of credit from clients whose inquiries for credits would be rejected.
- Entered all information in Excel spreadsheet and AS400 database.

Freelance Graphic Artist

Self Employed - Pottstown, PA - December 2006 to December 2013

Designed graphic artwork for sales to the modern home and business.

- Created innovative designs for textiles and ceramics.
- Administered sound business and project management practices.
- Created portfolios using Adobe Photoshop and MS PowerPoint, for use in meetings with prospective clients.
- Researched markets to identify new trends in art and design to broaden my artistic style and open up new streams of potential clients and revenue.
- Produced and maintained databases in Excel and Access to store detailed information about products and clients.

Document Controller

Tech USA/Synthes - West Chester, PA - September 2010 to December 2010

Performed quality inspections pertaining to product documentation.

- Change Control Management
- Assured accuracy and completion of upgraded documents before their release to the production floor.
- Cleared up backlog of controlled documents.
- Produced medical device product catalog as visual aid for use by Quality Engineers during meetings with vendors in order to discuss nonconformance issues and their corrective/preventive actions.
- Assured of quality and operations documents were completed, signed, and dated by the appropriate engineer.

Quality Assurance Assistant

Inteprod LLC - Eagleville, PA - January 2010 to June 2010

Edited, revised, updated, and maintained the company Quality System Manual to reflect company quality policies in accordance with the CFR Title 21, Section 820.20.

- Maintained and assisted in the control of documentation (820.40) as it pertained to the production of products in conformance to regulatory standards and company quality policy, thus guaranteeing customer satisfaction.
- Managed the Document Control Department.
- Perform Audits.

- Managed and processed all document alterations through the Change Control process.
- Presented and summarized new or revised documents effectively to the management review team.
- Formatted templates for documents and forms.
- Maintained logs relating to document identification, revision, archiving, and distribution.
- Performed and documented internal audits and other quality assurance activities.
- Assisted in the monitoring of corrective and preventive actions.
- Assisted in examination of materials and products for quality performance and quarantine purposes.

Clinical QA Administrative Assistant

Devon Consulting/Sanofi-Aventis - Malvern, PA - July 2004 to December 2005

Provided administrative support to the Pharmacokinetic and Metabolism scientific group.

- Performed quality checks and data entry for batch records and blind clinical trial studies.

Executive Secretary

Option One/Aventis Behring - King of Prussia, PA - June 2001 to December 2002

Supported Regulatory Affairs management team.

- Maintained Directors' calendars, Managed expense reports, Arranged travel and hotel accommodations, Arranged teleconferences, Planned seminar events, Created itineraries for meetings both nationally and internationally, created PowerPoint presentations for meetings and training events.
- Assisted in the preparation of summary documents appropriate for submission to the FDA.
- Participated in revising documents relevant to INDs and NDAs.
- Assisted in the creating of product labeling and their files.
- Assisted in the drafting and revising of drug product packages.
- Proofread and edited drug product inserts for packages.
- Assisted in reviewing and editing of the department SOP's.
- Helped in coordinating efforts for the preparation and implementation of communications with regulatory agencies regarding pre submission approaches.
- Helped to define relevant regulatory channels needed to identify clarifications and any follow up of submissions that were under review.
- Assisted in the coordination of hard copy and electronic documents for FDA submission.
- Created and maintained drug reference library used by the regulatory affairs department.

Administrative Assistant

RCN Telecommunications - Trooper, PA - January 1999 to June 2001

Supported Commercial Sales Office.

- Maintained calendars, Prepared and maintained expense reports, Arranged hotel and travel accommodations, Arranged conference calls and meetings, Planned seminars and other training events for sales team, Provided itineraries and PowerPoint presentations for meetings.

EDUCATION

Associates in Network Administration

Computer Learning Center

2000

Criminal Justice

Philadelphia Community College

1979