Deborah A. Fernandes

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Documentation quality assurance professional with over 20 years experience. Customer service and administrative support skills with training experience including GMP, GLP, GCP, ISO 9001, word processing, construction, Regulatory electronic document management (EDMS and Documentum) payroll, electronic mail, ERP, case management, life insurance, and toxicology data collection software.

**The Premier Group 2010-2011**

**Regulatory Document Coordinator (consultant for Achillion Pharmaceuticals, New Haven**)

* Assist by reviewing final documentation for IND submission for accuracy
* Compile and audit various documents for seamless verification for upload into Documentum (version 5.3) for submission to FDA.

**ADECCO 2009-2010**

**Quality Assurance Specialist (consultant for Mannkind Corporation, Danbury, CT)**

* Perform compliance review of study protocols, validation documents, and controlled documents (SOPs, TMs, Specifications, Change Controls, Batch records) to internal company documents and external regulations.
* Create and/or revise departmental SOP’s.
* Assist in internal audits.
* Coordinate and compile documents for the product specification file for clinical material used in studies complying with European Commission directives.
* Assist with training and acting as a department liaison to help facilitate the resolution of quality issues or questions.
* Work with a variety of Change Control Review authors to prepare and facilitate reviews of major change requests. Ensure that CCRs submitted meet CCR requirements and are suitable for review. Ensure that approved and closed CCRs are accurately updated in the document control system in a timely manner. Facilitate company use of required CCR preparation processes and documentation systems. Manage all aspects of CCRs reporting as needed.
* Ensure that document content, formatting, and organization meets requirements and retains technical accuracy.
* Prepare and/or incorporate changes, release, storage, distribution, and archive of controlled files (including: SOPs, process instructions, protocols, reports, specifications, methods analysis, logbooks, and notebooks).
* Implement improvements in current document control systems, provide written procedures, reviews and comments on related documentation procedures, and ensures their proper implementation.
* Communicate with appropriate departments to ensure changes are well documented and easily understood.
* Ensure the correct and timely implementation of requests and coordinates the resolution of problems. Develop and communicate both drafting standards and change control process standards.

**ADECCO 2008-2009**

**Operations Coordinator (for Obagi Medical Products, Milford, CT)**

**Temporary Contractor**

Coordinate activities to support daily manufacturing including: administrative, purchasing, HR, SOP document coordination, QA/QC, IT, ERT systems, materials management, vendor relations, outsourcing warehouse logistics, licensing and batch record review.

* Review batch records according to GMP regulations
* Identify, communicate and resolve various software and hardware issues with Corporate IT Department (in CA) for MicroSoft Navision rollout
* Perform user acceptance training for Navision before go live
* Utilized MAS 200 for work orders
* Coordinate Returns of chemicals and materials when discrepancies are present
* Identify MSDS sheets for product requests
* Schedule and coordinate GMP training, ERP and MicroSoft training as required
* Audit and maintain all employee training files
* Coordinate time off for employees and record in HRB system
* Work with agencies to identify new candidates and review aptitude tests
* Prepare and coordinate new vendor paper work including W-9’s, POs and CDAs
* Handle discrepancies with vendors and coordinate resolutions
* Schedule preventive maintenance on all equipment
* Process I-9s and all coordinate all employee paperwork to Human Resources
* License coordination for Obagi products throughout the US

**Deborah Fernandes (Page 2 continued)**

**Mannkind Corporation, Danbury, CT**

**Outsourcing Coordinator/Contract Administrator 2007-2008**

* Coordinated and participated in regular project reviews to assess vendor performance.
* Aided in the process of developing requests for proposal by coordinating the input from the Clinical Trial Managers and study teams
* Identified and communicated to Management recurring issues with vendors relating to invoicing practices and contract compliance. As appropriate resolved recurring issues.
* Facilitated and coordinated external vendor contracts, maintained records and databases of vendor profiles and performance.
* Assisted in the negotiation of clinical investigator and institutional study and consulting agreements
* Coordinated various Clinical Documents for Master Trial files (Financial Disclosure, FDA 1572, CVs) and revised Clinical trial agreements for start up trials working with Legal, management and clients directly.

**Quality Assurance Associate 2005-2007**

* Reviewed study protocols, computer and equipment validation documentation.
* Created and revised departmental Standard Operating Procedures which resulted in standardization of processes.
* Performed compliance review of controlled documents (SOPs, TMs, Specifications, Change Controls, and Batch Records).
* Assisted with training and acted as a department liaison to facilitate the resolution of quality issues.
* Assisted in internal audit.

**E & L Fire Protection, LLC, Plantsville, CT 1999-2006**

**Operations Manager**

* Project coordination and management including job closeouts, scheduling, and service issues.
* Managed bookkeeper and staff in their daily responsibilities.
* Provided training to all employees on software and business processes.
* Managed and resolved employee relations issues including performance and benefits.
* Proposed, created and tracked change orders with clients.
* Maintained, managed and built vendor and General Contractor relationships.
* Reviewed AIA Contracts and purchase orders for terms and accuracy to proposals.
* Provided customer service to clients for insurance certificate needs.
* Audited job cost reports.

**Oread Biosafety Center, Farmington, CT 1997-1999**

**Manager, Document Control/Training Coordinator**

*Managed Document Control Staff while assisting various departments with coordination and implementation of training and processes. Recruited, trained and developed staff to build a solid unit within the organization.*

* Recommended departmental support for the Statistical Analysis function for Toxicology using SAS software. This resulted in expediting deadlines for the clients.
* Provided an Information Systems role for Microsoft and Toxicology Data Collection software.
* Coordinated and developed Good Manufacturing Practices training.
* Acted as a liaison for Kansas office with State of Connecticut for training funds.
* Assisted in Project Management role to identify and resolve bottlenecks in report schedules.

**Deborah Fernandes (Page 3 continued)**

**Oread Biosafety Center, Farmington, CT 1997-1999**

**Technical Document Specialist Supervisor**

* Processed and reviewed Study reports and SOPs for format and continuity while serving as a resource person for questions on controlled documents.
* Assisted Validation team in coordination and review of validation documents and protocols.

**Lockheed Martin IMS, West Hartford, CT 1996-1997**

**Trainer/Help Desk Support**

*Acted in a consultant role as a trainer and a liaison to the State of Connecticut Department of Children and Families for a newly designed case management software package*

* Validated training material for acceptance testing and field training.
* Provided help desk support for software users statewide.
* Assisted in components of technical writing for software user manuals.

**Ciba-Geigy Corporation, Farmington, CT 1988-1996**

**Technical Document Specialist**

* Provided PC training and on-the job coaching to Environmental Health Staff.
* Designed and wrote technical manuals for Digital’s All-in-1 Electronic Mail System.
* Conducted WordPerfect training classes including individual and group instruction to all levels of staff.
* Produced technical documents and reports integrated from computer files consisting of text, computer analysis tables, graphics and handwritten material from the laboratory personnel.
* Provided executive level administrative and Human Resource support for various Fortune 500 companies.

**Crown Brokerage Associates, Farmington, CT 1987-1988**

**Marketing/Administrative Assistant**

* Assisted Hartford and Fairfield County Vice Presidents in marketing, administrative, customer service and software support roles.
* Installed Crown Software and conducted training for brokers.
* Coordinated and maintained all licensing agreements.

**COMPUTER SKILLS**

Microsoft Word 2002 (and all previous versions), Excel, Outlook, Powerpoint, TrackWise(Quality Management Software)Word Perfect for Windows, TMS Contractor software, Adobe Acrobat, Cognos, Mas 200 ERP system, Microsoft Navision and Great Plains

**Education**

AS credits towards, Business Administration, Tunxis Community College

Diploma in Project Management