

# ARGENIS GONZALEZ

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## ***SUMMARY OF QUALIFICATIONS***

- ❖ Experienced with using data or electronic document management systems.
- ❖ Experienced in maintaining important documentation in a medical device environment.
- ❖ Skilled in customer service and telephone operations; handle customer inquiries and phone presentations in a professional manner.
- ❖ Skilled at learning new concepts quickly, working well under pressure, and communicating ideas clearly and effectively.
- ❖ Managed multiple tasks in a fast paced and dynamic environment while maintaining focus on quality and compliance with local SOPs, policies and directives, and regulatory requirements
- ❖ Proficient in Microsoft Office System, Microsoft Windows® operating system
- ❖ Proficient in English and Spanish.

## ***COMPUTER SKILLS***

- Microsoft Dynamics Great Plains
- J.D Edwards
- Prolog (Project Management Database)
- Adobe Acrobat XI Standard & In Design
- Microsoft Office (Excel, Word, PowerPoint, Access, Outlook & Visio.)
- E-Infotree (Document Database)
- Lotus Notes, Groupwise
- LogMeIn Rescue, Send this file, Filezilla
- Bartender, Avery and Surething Label software

## **COVARIS - WOBURN, MASSACHUSETTS 2008-PRESENT**

### **QUALITY ADMINISTRATOR**

- Managed the quality systems databases for SOPs, training, change controls, CAPAs, Deviations, and Nonconforming Materials.
- Ensured all Quality System records such as device fabrication files, ECO, Deviation, First article inspection reports, EMC Reports, Calibration Certificates, Test Reports, and ETL Inspection Reports are maintained in a manner in which ensures integrity and accessibility including photocopying/scanning of documents.
- Managed the proper storage and filing of fabrication file & ECOs while keeping an archive log.
- Administered Engineering Change Requests from submission to implementation.
- Created and administer part number systems to ensure smart and concise naming of parts and facilitate part number request process.
- Created, entered, and maintained bill of material (BOM) structure in ERP system.
- Distributed controlled documents supporting the manufacturing and testing of products.
- Creates and maintains new documents with input from Quality Assurance, Manufacturing, Engineering, and Marketing such as technical notes, instrument assembly procedures and customer manuals.
- Coordinated and assisted in developing naming convention guidelines for Finished Goods.
- Supports individual and group training sessions for system users on making document changes.
- Ensured new employees are trained on SOPs per specific job function
- Maintained the Training Matrix to ensure that employee training records are up to date.
- Performed instrument validation and verification of software design.
- Created and validated end user documentation for instrument software installation on various Windows Operating systems.
- Worked directly with staff, customers, sales reps, and distributors over the phone or via remote desktop connection to answer product specific software and driver installation questions.
- Support Manufacturing with software and WHQL driver installation by creating recovery images of laptops.
- Performed on-site internal audits of MFG procedures.

- Operate production equipment to produce labels, manuals, and software CDs.
- Coordinated, purchased and set up Zebra Label Printers.
- Assisted in the software and driver installation of Zebra printers into user desktop.
- Supported the Bartender application. Create new templates as well as edit existing templates.
- Artwork approval for new and existing version as well as worked with vendor to develop new labels.
- Administered equipment calibration system.
- Assigned equipment id numbers and coordinated with external calibration vendors for quarterly calibrations.
- Managed the proper storage and filing of calibration certificates.
- Administered CAPA system by ensuring closure in a timely manner and resolved to clients satisfaction.
- Managed non-conforming material in quarantine while seeking corrective action from vendors.

### **GENZYME - CAMBRIDGE, MASSACHUSETTS 2008-2008**

#### **CLINICAL DOCUMENT PUBLISHER**

- Support studies and submissions globally
- Prepare the clinical section for submission (CSR, CRF, CRT)
- Ensure all final clinical section deliverables are fully compliant with regulatory agency guidance and regulations
- Hands off content in submission-ready format directly to RA Ops
- Provide quality control across clinical sections of submissions to ensure that all sections support each other and no contradictions
- QCs to ensure all published content for clinical sections of submission meet publishing requirements

### **WYETH BIOTECH - ANDOVER, MASSACHUSETTS**

**2006-2008**

#### **DOCUMENT/PROJECT COORDINATOR**

- Maintain GMP-related documentation and software ensuring compliance with established procedures
- Coordination of Records Room and Project Turnover
- Created reports for internal documentation and system audits
- Follow established procedures used to document project submittals and turnover requirements
- Participate in Project Team meetings
- Receive and distribute all project documents and drawings
- Prepare outgoing transmittals
- Maintain document files and drawing sticks
- Maintain Email and project note electronic filing
- Schedule and attended all project meetings while taking meeting minutes.
- Setting up contractors: Provided forms to Contractors for background checks, completed forms for badge requests and send weekly e-mail to Security as needed and followed up with Proudfoot .
- Schedule and coordinate new contractor training
- Transmit resumes and job descriptions to the EVM training group for contractor training files
- Prepare and update project documentation as needed (i.e. organization charts, presentations, agendas, monthly report, contact list)

**BAXTER HEALTHCARE – ANDOVER, MASSACHUSETTS**

**2001-2005**

***Data Entry Clerk/ Documentation Specialist/Receptionist***

- Maintained efficient revision control system and acted as the gatekeeper for all production documents.
- Document work processes. Review and revise standard operating procedures.
- Maintained the integrity of Device History Records in a timely manner.
- Monitor the flow of product into and out of work area of the Complaints Department.
- Ensured that complaint processing was performed in a detail oriented, timely and contentious manner.
- Provided administrative support to two engineers and my supervisor
- Organized meeting, training and luncheons
- Operate a variety of office machines such as copier, fax and scanner.
- Prepare reports, letters, mailing labels, and other text material.
- Prepare electronic/paper copy files (including specs, editing, researching, etc)
- Coordinate with outside and internal sources to accomplish tasks by email.
- Front Desk assistance, Operate main desk multi-line switchboard

***EDUCATION***

2005 Emmanuel College

Boston, MA

- Bachelors, Business Management

2007 Northern Essex Community College

Haverhill, MA

- Project Management Certificate