

DEANNA L. PARE

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SUMMARY

Experienced Document Change Control Specialist with extensive knowledge in Product Development Process requirements. High energy, extremely detailed and highly efficient at prioritizing tasks. Team player with a positive "Can Do" attitude who is willing to go that extra mile for the success of the team. True commitment to excellence and takes pride in producing quality work. Track record for guiding new product teams through the product development process requirements is outstanding. Participated in the development and the implementation of Quality Systems for ISO Certification. Experienced in setting up systems for tracking all types of documentation resulting in numerous awards & recognition.

- FDA Regulations (GMPs/GCPs/OSRs)
FDA 21CFR820; Quality System Regulation;
ISO 13485; ISO 14971; Medical Device Directive
- Quality Management Systems/ISO 9000/9001
- Internal Audit Compliance
- Document/Engineering Change Control
- Proof and Edit Technical Documentation
- Technical Writing
- Design Controls
- Process Improvements
- Project Management
- Data Analysis

PROFESSIONAL EXPERIENCE

BAXTER HEALTHCARE CORPORATION/BAXA CORPORATION, Englewood, Colorado

2006-Present

Regulatory Affairs Coordinator

Assist with coordinating activities with the Internal Audit program. Aid in the preparation and maintenance of regulatory submissions and technical files. Aid with the creation and implementation of company procedures. Update and submit Product/Drug Master Files to the FDA & Health Canada. Assist with international registrations.

Documentation Specialist

Responsible for the preparation, finalization & security of controlled documents. Change control execution. Design control record management. Quality record management. Training record management. Conduct defect training. Perform internal audits. Records management and records retention.

SKYWEST AIRLINES, St. George, Utah

2005-2006

Production Control Assistant

Monitor & schedule all repetitive maintenance due on all fleet types. Monitor & schedule all one-time items for all fleet types. Audit maintenance paperwork for completion of maintenance items. Maintain tracking sheets for all necessary items. Input needed data in maintenance computer.

SPENCER TECHNOLOGIES, Seattle, Washington

2004-2005

Regulatory Affairs/Quality Assurance Specialist

Provide assistance to the Regulatory Affairs/Quality Assurance Manager by performing data trending, coordinating regulatory submissions, logistics, and international documentation.

VOLT TECHNICAL SERVICES/AMGEN, Bothell, Washington

2004

Administrative Coordinator II, Contract Assignment

Provide support to 2 Managers and 3 groups in the Engineering Operations Services Department. Manage multiple and/or complex calendars including group calendars. Coordinate onsite-offsite meetings, prepare agenda, draft minutes, track action items, and communicate details to participants. Prepare and process forms, documents and correspondence, on own initiate and upon request; create, maintain, update and reconcile spreadsheets, edit and format presentations, SOP's, notices, etc. Disseminate information to appropriate parties in a timely manner, monitor and follow-up on requests. Order coordination for office and other supplies including cleaning, and office equipment as needed. Interact with outside vendors as needed. Compile data and information sent to various agencies. Assist in management of department/team budget. Enter and track purchase order requests. Project tracking (i.e., budget, database, and timelines). Process invoices, code and interact with Amgen Corporate AP department to make sure invoices are paid on time.

ACT•1/AMGEN, Bothell, Washington

2003

Documentation Specialist, Contract Assignment

Provide support to clients in the initiation, routing, approval, and distribution of documentation. Documentation includes Standard Operating Procedures (SOP), Manufacturing Procedures (MP), controlled forms/logs, validation documents, and maintenance work orders. Generate document processing requests. Route documents for review and approval. Track the entire documentation process. Edit documents to incorporate redlines from initiators and format documents to conform to guidelines and standards. Coordinate timelines and schedules with clients and Document Management Services (DMS). Receive and distribute controlled documents to Manufacturing and support areas.

PROFESSIONAL EXPERIENCE, continued**OFFICE TEAM**, Bellevue, Washington

2003

Executive Assistant, Contract Assignment

Executive Assistant to the Director of Sales & to the Director of Marketing/New Business at Continental DataGraphics (a Boeing Company). Update & maintain CRM package (ACT), assist with proposals, business plans, and RFPs. Coordinate the distribution of incoming sales leads from telemarketing and trade shows to account executives.

ALSTOM ESCA CORPORATION, Bellevue, Washington

2000-2002

Product Administrator

Perform general administrative tasks to support the Product Management team. Manage assignments with diplomacy and discretion at all levels inside the company and between business areas. Gather information and analyze data for monthly reporting. Initiate and track all invoicing and budget activities for assigned engineering initiatives and projects. Compile raw data from engineering groups relating to various types of documentation and coordinate with internal or external technical writing staff for development of documentation. Work with documentation writers to ensure compliance with all ISO/9001 procedures.

PARKER STAFFING SERVICES & OFFICE TEAM, Bellevue, Washington

2000

Multiple Contract Assignments

Executive Assistant to the President & CEO of Coinstar. Executive Assistant to the Vice President of Corporate Communications and Marketing at Nintendo of America. Administrative Assistant to the Administrative Manager at ALSTOM ESCA Corporation.

BOSTON SCIENTIFIC CORPORATION/HEART TECHNOLOGY, Redmond, Washington

1994-2000

Product Development Process Specialist (1998-2000)

Assist new product teams to comply with product development process requirements. Create and maintain Design History Files. Coordinate meetings and provide meeting minutes for Executive Program Review, Process & Component Improvements, and product team meetings. Create and maintain product schedules and report on milestones. Manage patent research & maintenance of Patent Files.

Senior Documentation Coordinator (1994-1998)

Develop and maintain system for tracking engineering test protocols and reports. Coordinate and chair Testing Approval Board System meetings for obtaining approvals on engineering test protocols and reports. Set up Quality Systems for ISO Certification. Ensure compliance of engineering document change control procedures. Incorporate document revisions. Proofread documents scheduled for release. Work with blueprints, Bill of Materials, Routers, Shop Floor Paperwork & Document Change Orders.

SOFTWARE PROFICIENCY

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|---------------|-------------------------------|----------------------|
| • Word | • LiveLink (EDMS) | • VISIO |
| • Excel | • FileMaker Pro (EDMS) | • SkyTrack |
| • Project | • SharePoint | • Sabre FliteTrac |
| • Access | • MAXIMO | • Exchange & Outlook |
| • Power Point | • ACT Database (CRM) | • Lotus Notes |
| • Publisher | • CostPoint Accounting System | • Baan |
| • SAP | | • JD Edwards |

RAPS CERTIFICATION IN REGULATORY AFFAIRS (MEDICAL DEVICE)

2011

AWARDS RECEIVED

The following awards were presented by Boston Scientific Corporation Northwest Technology Center, Inc.

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| • Outstanding Teamwork for Floppy Gold Guide Wire Team | 1999 |
| • Commitment to Excellence for Product Development Support Team | 1998 |
| • Employee of the Month | 1997 |
| • Recognition for Exceptional Teamwork & Documentation Support | 1997 |
| • Unsung Hero for Contribution to Manufacturing | 1997 |
| • Commitment to Excellence | 1997 |