# LINDA LARSEN

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## OBJECTIVE

**DOCUMENT CONTROL professional** with a passion for the rigors of document control seeking a position in a high tech, pharmaceutical or medical device company.

## SUMMARY – WORK HISTORY

Over 10 years of experience in high tech start-ups, pharmaceutical, non-medical laser, and medical device industries. Familiar with Agile, Documentum and Laboratory Information Management System (LIMS) and SharePoint document management systems.

## EXPERIENCE – ACCOMPLISHMENTS

**MARSEILLE NETWORKS, San Jose, CA** 8/2012 – Present

Silicon Valley start-up that designed the only Technicolor 4K image certified video processing chip. The chip is designed into HDMI video processing cables.

***Document Control Specialist***

- Designed and maintains the document control system using Microsoft SharePoint Lists and Libraries as the records management system.
- Designed document control forms and wrote document control procedures.
- Review and release Engineering Change Requests (ECR) for accuracy and completeness.
- Route and track ECR's through the process.
- Scan and process ECR records for addition to SharePoint records management storage.
- Designed and maintain multiple SharePoint Lists and Libraries such as Customer Orders (used to track customer purchase orders), Sales Order Acknowledgements (track sales order acknowledgments), Purchase Orders (track purchase orders placed by Marseille), Returned Material Authorization (track returned materials through process), etc.
- Other duties:
    - Create UPC bar codes using GS1 US system
    - Write procedures for product test, purchasing, returned material authorization (RMA), etc.
    - Edit documents; datasheets, release notes, marketing documents, procedures
    - Test silicon chip and cable products
    - Create and maintain sample cable records
    - Maintain accounts payable information
    - Arrange shipping of chips and cables using UPS, FedEx and DHL

**AEROTEK reporting to CIRTEC, Los Gatos, CA** 5/2012 – 7/2012

Part-time temporary position reporting to a small medical device company

***Document Control Specialist***

- Scan and process quality records for off-site record storage.
- Review and release Engineering Change Notices including updating master files.
- Update employee training records in StartOps program.

**LOS GATOS RESEARCH, Mountain View, CA** 9/2009 – 1/2011

Manufacturer of high performance analyzers

***Operations Manager (individual contributor)***

Responsible for the creation and planning of manufacturing and test schedules for scientific instruments, created sales orders, arranged domestic and international shipments, planned blanket purchase orders and purchased components, and entered data, including creation of bills of materials, in the Parts & Vendors (P&V) database.

**NEWPORT CORPORATON, San Jose, CA** 10/2007 – 10/2009

Legacy of Bookham and Oclaro.

Global supplier of innovative optical and laser components and advanced technology products and solutions

***Document Control Specialist III***

Responsible for document control activities including system conversion from a manual document control process to the product lifecycle management (PLM) system, Agile ver. 9.2.2, performed group and one-on-one training of Agile users, and created new ISO 9001 compliant procedures. Wrote multiple FDA product and annual reports for non-medical lasers. Member of data transition team for conversion of document control data from Agile ver. 9.2.2 system to SAP (post sale of division to Newport Corp).

- Key member of Agile conversion team for the migration of data from the manual process to Agile PLM. Determined the Agile system requirements and the appropriate business process.
- Created multiple Agile advanced searches and reports; allowing for faster change order review and increased accuracy of reviews. Advanced searches and reports were available to all users.
- Wrote Agile user guidelines, performed Agile group and individual training sessions for system users in both the U.S. and China. Established accounts for new Agile users based on training and permissions required.
- Reviewed Engineering Change Orders (ECO) for completeness and accuracy in both the old manual system and the new Agile system. Noted issues and returned the ECOs to their originators for correction.
- Routed ECOs for approval in both the manual and Agile systems. Chaired the change control board meetings used for the manual change order process.
- Wrote multiple ISO 9001 compliant Document Control procedures. Passed ISO 9001 audit without a single finding.
- Updated Fourth Shift Materials Requirements Planning (MRP) database post ECO approval.
- Requested to complete document control activities for the Agile to SAP conversion project after resignation.
- Worked with Newport IT department personnel to properly map the data fields in Agile to the appropriate fields in SAP.
- Reviewed Engineering Change Orders (ECO) for completeness and accuracy in the Agile system prior to the data move to SAP. Documented issues and returned the ECOs to their originators for correction prior to conversion. Completed 99% of ECOs prior to system conversion.
- Wrote multiple FDA product reports (21 CFR 1040.10) for Class IIIb and Class IV lasers and wrote FDA annual reports.

**JOHNSON & JOHNSON** 1/2004 – 10/2007

**Scios, Inc. and ALZA Corporation, Fremont and Mountain View, CA**

***Document Control Associate III*** 10/2006 – 10/2007

Responsible for document control activities including system conversions and procedure updates. Wrote validation report to current Good Manufacturing Practices (cGMPs) requirements.

- Exempt position (Document Control Associate III).
- In response to mergers and facility closures, participated in two consecutive data migrations moving controlled document legacy system to current system.
- Witnessed validation testing and wrote system conversion validation report, cGMP compliant, for document management system conversion.
- Modified document control procedures to comply with electronic document management system.
- Identified, organized and coordinated records for off-site record storage. Created an Excel spreadsheet of files and updated the off-site record management system in accordance with policies.

**Kelly Services at ALZA Corporation and ALZA Corp, Mountain View, CA**

***Document Control Assistant III – Temporary to Regular Position*** 1/2004 – 8/2006

Responsible for processing analytical records in compliance with ALZA policies, Standard Operating Procedures (SOPs) and current Good Manufacturing Practices (cGMPs).

- Logged analytical requests into an Access database and/or Laboratory Information Management System (LIMS) database. Identified limitations in LIMS database and provided input to possible database changes.

- Processed analytical data files by recording receipt, labeling, scanning, binding, filing and entering information in Access and/or LIMS databases.
- Identified, organized and coordinated records for off-site record storage. Created Excel spreadsheets of files and updated the off-site record management system in accordance with ALZA policies.
- Located, retrieved, organized and labeled analytical records for FDA, European Preapproval Inspections (PAI) and partner audits. Created Excel spreadsheets of records for the inspection or audit. Collated and organized staff training records for the inspection or audit.

**CANESTA, INC., San Jose, CA**

***Manager of Configuration Management*** 7/2002 – 11/2003

Responsible for document control activities at a new startup company which included establishing the new process, creating an electronic archive of files, authoring and reviewing Engineering Change Request (ECR) and Engineering Change Order (ECO) packages, identifying and resolving problems with documentation, and chairing the Change Control Board (CCB) meetings.

- Established document control processes that included development of new forms and the creation of an ECR/ECO tracking system using Excel spreadsheets. Released documentation was available in PDF format to all personnel with a connection to the server thus increasing efficiency.
- Issued new part numbers, controlled drawings, procedures, specifications, datasheets, test reports, release notes and electronic files for mechanical, electronic, and optical components, chip design files, software, schematic and Gerber files.
- Trained personnel on the new Document Control process so the process would operate smoothly.
- Processed ECRs and ECOs by holding CCB meetings, routing packages for approval and subsequently updating the part number database (including hyperlinks to the released documents). Printed copies of documents were placed in product binders and electronic files were archived. This allowed immediate access to released documents both electronically and physically through the use of the product binders. Also maintained a master paper file of printed documents.
- Served as the chairman of Change Control Board. This required scheduling meetings, preparing an agenda and moderating the meeting discussions.
- Performed comparisons of Bills of Materials, Gerber file printouts, schematics, assembly procedures, and assembly drawings for accuracy and completeness. Wrote ECRs and ECOs to correct errors found as a result of the reviews.
- Created Specification Control Documents (SCD) for off-the-shelf components. This required searching the Web for datasheets from the manufacturers of the off-the-shelf items and converting the manufacturer datasheets into PDF format using Adobe Acrobat.
- Wrote FDA initial product reports for non-medical laser products.
- Conducted in-process testing of the product.
- As the relief receptionist, answered phone calls, took messages, signed for incoming packages, and arranged for lunches.

**INTEGRATED TELECOM EXPRESS, San Jose, CA**

***Document Control Manager*** 10/2001 – 5/2002

Company liquidated.

Responsible for document control activities which include establishing an electronic archive of software drivers and manufacturing documents, and authoring and reviewing Engineering Change Notice (ECN) packages.

- Wrote Quality Assurance and Document Control processes with the intent to comply with ISO 9001 requirements.
- Performed comparison of Bills of Materials (BOM) and schematics for circuit boards to ensure components designed in the schematic appear on the BOM. Wrote ECNs to correct the errors identified.
- Processed ECNs by routing for approval and subsequently updating the part number database, history files and electronic archive.
- Established product history binders, created document history folders and organized software driver master CDs.

- Created complete product binders including schematics, user guides, and software for the marketing department. These binders were one of the products.

**NEW FOCUS, INC., San Jose, CA**

***Document Control Manager*** 7/1996 – 8/2001

Responsible for document control activities that included updating Material Requirements Planning (MRP) database, processing related documents, and reviewing Engineering Change Order (ECO) packaged for completeness and accuracy. Wrote document control processes that allowed ISO 9001 certification.

- Wrote ECO and other document control processes to comply with ISO 9001 requirements. These processes helped obtain ISO 9001 certification.
- Served as chairman of the Change Review Board that required scheduling and moderating meetings.
- Processed ECOs by updating MRP database and controlling various documents including drawings, procedures, software, fabrication files, and part specifications.
- Served as a Certified ISO 9001 – 2000 internal auditor. Wrote ISO 9001 audit checklists and performed audits of various departments within the company.
- Filed numerous annual reports and laser product reports with the FDA for non-medical laser products.

## EDUCATION

**Bachelor of Science**, Animal Science, California State Polytechnic University, San Luis Obispo, CA
Graduated with honors (cum laude)

**Applications:** Microsoft Office, Adobe Acrobat, Microsoft Access, Agile ver. 9.2.2, LIMS database, Microsoft SharePoint and MRP systems

**Additional Training:** Agile ver. 9.2.2, Documentum ver. 5.2.5, and PharmDoc document management systems

## VOLUNTEER ACTIVITIES

**Associated Obedience Clubs of Northern California (AOCNC) –** past president, vice president, board member and volunteer at various club events

**Santa Clara Dog Training Club (SCDTC) –** past board member, current club representative to AOCNC club, organized and staffed many Rally Obedience trial events and continue to volunteer at various club events