Carol Locus

Los Angeles, CA Cell: 818-427-3620

os Angeles, CA <u>Carol@carollocus.com</u>

EDUCATION / CERTIFICATIONS

Masters Degree, University of Connecticut, Storrs, Connecticut
Bachelor of Arts, American College, Paris, France
French Language Certifications, Sorbonne, Paris, France
Web Design & Development Certificates, with Distinction, CSUN
Paralegal Certificate, LA Mission College
Six Sigma Yellow Belt
Scrum Master Certification –in progress

SENIOR TECHNICAL WRITER:

MEDICAL INSURANCE & BIOTECH QA COMPLIANCE - 2014-Present

In the last 7 years Carol has worked with compliance and environmental engineers providing support for regulatory-related reports for FDA, OSHA, EPA and others. She began in manufacturing and aerospace and transitioned to the medical industry with a short project for Medtronic. Carol then spent 4 years at L.A. Care documenting medical insurance industry workflows and legacy apps for conversions to more recent and more robust industry-standard enterprise systems. Most recently Carol worked at Gilead in AmBisome(R) manufacturing to sync up manufacturing WIs, P&Ps and SOPs to CAPA requirements. Then worked at Amgen helping Engineering update some of their key Standards. She continued in Amgen R&D QA Compliance in the Process Documentation Management (PDM) Dept as a TW/Editor; and was later trained in their document process as a lead. Leads orchestrate Compliance documentation creation or revisions with directors, managers and other business unit leads and SMEs in R&D QA Compliance Dept.

AMGEN, Thousand Oaks, CA

Summer 2019 - Fall 2020

- Process Documentation Management (PDM) Lead, orchestrate Compliance documentation creation or revisions with directors, managers and other business unit leads and SMEs in R&D QA Compliance Dept.
- Editor-writer, P&Ps, SOP's, manuals in R&D QA Compliance, 3/2020-9/2020. (per 21CFRPart 11, GDP, GxP)
- Editor-writer, P&Ps, SOP's, manuals in Engineering Department 9/2019-1/2020

GILEAD, San Dimas, & La Verne, CA

Spring-Summer 2019

- Member of Manufacturing Compliance team; trained in 21CFRPart 11, GDP, GMP, GxP
- Tasked with auditing manufacturing production reports, forms and processes for GMP, GxP and GDP
- ISO 8 Gown and Material Transfer trained; spotted floor processes to note SOP gaps or needed clarifications

LA CARE, (FTE) Los Angeles, CA

Spring 2015 - Jan 2019

- Member of IT Application Development and Support, and later in Solution Delivery facilitating fixes
- Tasked with fully documenting complex legacy systems to facilitate updates, upgrades and redesign
- Documented planning for conversions to new enterprise medical insurance architecture systems, including:
 - Business user and system workflows
 - Functional and technical specifications; system technical details for developers
 - o Run books; compliance responses
 - Executive summaries for senior directors and corporate officers
 - User guides and user references and training materials
 - Trained in Change Management (ITIL)
- Member of four conversion project teams; documenting conversion strategies and technical specifications
- Based on experience with documentation for regulatory agencies have indicated areas of risk
- Edit project and budget proposals; prepare internal communications about technology implementation options
- Provided legal references, and full technical descriptions for web scraping as implemented by LAC

- Fully documented all plant manufacturing processes from delivery of raw materials to shipping product
- Wrote (OSHA) Health and Safety operating procedures and regulatory related guidelines used in training
- Researched and wrote guidelines based on Exide regulatory permits to operate, Air Quality Monitoring District, Air Resource Board, (EPA) Department of Toxic Substances Control, Cal OSHA regulations

MEDTRONIC/MINIMED, Northridge, CA

Winter-Spring 2014

- Member of Quality Control Department, Design Assurance and Reliability Engineers
- Organized test data sets into the report topic structures and templates
- Per FDA reporting regulatory requirements in order to get FDA product approvals
- Conceived of workflow document progress tracking in Excel, also used by other writers

ENGINEERING TECHNICAL WRITER: IT, SATELITE TV, AUDIO-2008-2013

FIRST AMERICAN FINANCIAL SERVICES CORP., Santa Ana, CA

2012-2013

- Documented many complex IT data base driven applications for offshore administrators, developers
- Coordinated with key SMEs, Directors, and VPs to meet documentation needs
- Interfaced with developers and designers working in the Agile Software Development
- Diagrammed many complex systems in Visio
- Remote work for 6 months: Wrote about 700 pages about title search applications of customized
 instructional materials and quick references for in-house and customer facing personnel of various First
 American subsidiaries (DataTree, DataTrace) and a few other database products that were being
 consolidated or expanded or enhanced

DIRECTV, El Segundo, CA

2011

 Wrote technical documentation with engineering subject matter experts used for in-house training purposes of customer-facing personnel

DTS Digital Entertainment, (FTE) Calabasas, CA

2008-2009

- Formulated new manual design to clarify and facilitate product planner implementation
- Established a new standard of product illustrations
- Converted DTS-HD Decoding Licensee Manual from MS Word into FrameMaker
- Collaborated to put in place new product documentation; worked with marketing
- Designed writing work flow process to streamline subject matter expert time spent on documentation.

BUSINESS ANALYST 2005-2008

TECHNICOLOR, Burbank, CA

2007-2008

Diagrammed dozens of use cases based on my analysis and new system architecture designs

NASA-JPL, CALTECH, Altadena, CA

2007

Researched, and collaborated to update Lab-wide P&Ps and SOPs for JPL management

S.CAL EDISON, COUNTRYWIDE, INDYMAC

2006-2007

- Finalized about a dozen research reports with engineering support
- Developed, wrote, coordinated and edited a variety of properties to include newsletters, technical information, reports and presentations utilizing multiple communications vehicles and authoring tools.
- Worked with corporate IT and departmental senior VP's and Managers to put in place policies and procedures for ITIL style to meet Sarbanes-Oxley audit requirement deadlines
- Documented existing database marketing applications and front end interfaces, to determine and establish new enhancements to marketing systems
- Ensured business continuity with documentation of redundant systems and their interfaces and handoffs

INTRANET DEVELOPER-WEB CONTENT 2004-2005

NASA-JPL, CALTECH, Altadena, CA

2004-2005

- Interviewed and interfaced with many material specialists and senior business analysts for information gathering and updates for Oracle workflow customizations
- Worked off business analysis documentation, use case scripts and diagrams
- Interviewed subject matter experts for authoring and documentation reviews
- Attended, supported and provided training sessions for Manufacturing and Design Engineers,
 Administrative Staff and Managers
- Authored extensive interactive online help was the largest reference system in the history of JPL
- Materials authored fulfilled ISO Work Instruction requirements

ENGINEERING/MANUFACTURING TECHNICAL WRITING WORK 2000-2004

CAPSTONE TURBINE, INC., Chatsworth, CA HONEYWELL/CHADWICH HELMUTH, EI Monte, CA

- Very efficiently updated product data sheets, system operation and installation manuals
- Caught up significant backlog of work instructions needed prior to new product release
- Updated torque specifications reference which resolved inter-department inconsistencies
- Analyzed, debugged and made recommendations regarding custom products and their documentation

APPLICATIONS & PLATFORMS EXPERIENCE

Platforms: MS Windows 10.

Authoring Tools: MS Office, MS Publisher, FrameMaker 5.5, 6, 7, 8, 9; 10. RoboHelp X5, X4, On-Line Help, RoboInfo, DreamWeaver, Qarbon, Captivate.

Graphics Tools: PhotoShop, PaintShopPro, Photo Paint, Mosaic, Spicer Imagenation 7, MicroGraphx; SnagIt; Vellum.

Enterprise Tools: VevaVault, MS Visual Development Studio; MS InterDev; Merant PVCS Tracker, v7.5. MS Visual Source Safe, (MS Visual Development Studio), DOORS Version Control, Avante, Axalante, Maximo, some Passport (industrial enterprise-wide computerized maintenance management, somewhat like SAP or PeopleSoft), Oracle (manufacturing and some financials), Oracle Discrete Manufacturing Module, SmartSheets, Microsoft Project, Visio, SharePoint, MS Project and Server (basics), TFS, Confluence/JIRA, Footprints, CCA, QNXT, TPM, ACCIO...

SKILL SETS SUMMARY

- Over 15 years' experience documenting systems development as technical writer/analyst (
- System specifications, analysis; scope definition; project documentation
 - Visio use case and activity work flow diagrams for product and system functional specifications based on new systems architecture or enterprise resource planning (ERP)
- ISO 8000 and 9000 (manufacturing) work instructions, manuals, end user guides and references
- Project management experience per SDLC, Waterfall, Cascade, Agile
 - o Project management coordination; managed assigned team leads
 - o Review business analysis and design to meet client needs
 - o Experience with Matrix, Waterfall, Agile, and traditional SDLC methodologies
- Strong interpersonal skills: ease coordinating and interfacing with personnel at all corporate levels
 - o Facilitate and coordinate meetings with subject matter experts (SME) for content
 - o Executive presentations, work descriptions and proposals, statements of work, project scope
- Understanding of ERP and basic management and accounting principles
- Disaster recovery, business continuity, Sarbanes-Oxley workflows, documentation, P&Ps, SOPs
- Policies, procedures or standard operating procedures (P&Ps and SOPs) for existing or new systems
- Copy writing; marketing copy, editor for newsletters from engineering SMEs and technical materials
- Compose or update technical user guides and manuals in RoboHelp (expert), FrameMaker (expert)
- Web content; Instructional design of training materials; train-the-trainer
- Conceptualization and presentation of training materials needed for any audience