Objective

Experienced labeling professional seeking a remote position related to medical device labeling, Instructions for Use (IFUs), and documentation.

Summary of Skills

- Detail oriented
- · Able to manage mutliple projects and overlapping deadlines
- Self-motivated; able to work independently and in a team
- Technical Writing, Editing, and Proofreading, Content Management
- Business Software Highlights: Windows OS, Mac OS, Microsoft Office, Adobe Acrobat Pro, Adobe Illustrator, Adobe InDesign, Bartender.

Qualifications Profile

Innovative Leader with advanced expertise in Technical Writing, Editing, Proofreading, Labeling, and Medical Devices.

- 16 years in regulatory labeling for medical devices & bioprocessing
- 12 years experience with technical writing (creating & maintaining Instructions for Use for medical devices)
- 2 years as global regulatory labeling manager
- Positive "can-do" attitude
- Able to learn new skills and software quickly
- Effective team player & collaborator
- Excellent communicator (written, verbal, and visual)
- Proven track record at problem solving & process improvement

RELEVENT EXPERIENCE

Hologic Corporation (Contractor for <u>TEKSystems</u>)

100% Remote

Technical Writer I / Labeling Specilist

July 2023 - Current

Updated medical device manuals, instructions for use, and labels.

Organized and tracked projects for surgical division.

Repligen Corporation

Waltham, Massachusetts

Regulatory Labeling Manager

January 2020 - March 2022

Managed labeling development and production process for a growing number of global sites.

• Designed, created, and edited label templates using BarTender label management software.

...continued...

Ramona Denton

- Established global standards for label design and development.
- Provided technical writing to create and improve procedures and work instructions.

HYCOR Biomedical

Garden Grove, California

Operations Labeling Lead

April 2018 - January 2020

Coordinated labeling projects for IVD medical devices.

- Designed, created, and edited label templates using EasyLabel and BarTender label management software, and database- and scripting-based content management systems.
- Provided technical writing to create and improve procedures and work instructions.
- Created FDA-compliant UDI (Unique Device Identifier) information for labels, including human- and machine-readable (barcode) elements, and FDA GUDID (Global UDI Database) registration.
- Supported Operations teams by automating workflow with VBA Macros, e.g. creating time-saving "one-click" procedures for document change control tasks and email notifications.

Diagnostic Products Corporation

Los Angeles, California

DPC is now Siemens

Programmer/Analyst III

March 2006 - December 2009

Senior Labeling Specialist

September 1996 - September 2005

Print Shop Supervisor

July 1981 - December 1986

In various roles over 17 years:

- Wrote, edited, proofread, printed, and documented labeling and Instructions for Use (IFUs) in English.
- Coordinated with European affiliates to assemble multi-language IFUs in up to 15 languages.
- Provided technical writing to create and improve procedures, work instructions, and training manuals.
- Trained and supported labeling personnel.
- Developed proprietary content management system to manage IFUs in mutliple languages.

Complete Work History (online resume)

EDUCATION

Associate of Arts Degree Candidate

Pasadena City College

Major: English and German

Pasadena, California 32 Semester Units completed

Bachelor of Science Degree Candidate

<u>California Polytechnic State University</u> Major: Graphic Communications San Luis Obispo, California 47 Quarter Units completed

ONLINE RESOURECES

Online Resume (including complete work history)

https://www.ramonaspages.com/resume/

Writing Samples

https://www.ramonaspages.com/samples/

