## Mary Walker

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### Summary

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| Previous |  |
| Preferred | Regulatory Affairs Global Labeling |
| Location | St. Peters, MO, US |
| Desired Work Settings | Remote or On-Site or Hybrid |
| Willing to Relocate | No |
| Work Authorization(s): | Authorized to work in the United States on a full-time basis. |
| Security Clearance Info: | US Citizen (for security purposes) |
| Employment Type | Full-time Contract to Hire - W2 |
| Total Experience | Unspecified |
| Education | Associates @ St. Charles County Community College |
| Profile Source | Dice |
| Profile Downloaded | Monday, December 9, 2024 |

Proactive and conscientious **Regulatory Affairs - Global Labeling Coordinator/Labeling Associate and Document Management** professional with 10+ years in the pharmaceutical/contrast imaging, and medical device industries. Capability to multi-task in fast-paced, highly regulated environments (e.g., FDA, EMEA) with constantly shifting business priorities. Collaborative and resourceful problem solver with an unwavering commitment to quality. Reliable independent or team performer with a positive attitude, a strong work ethic, and a passion for exceeding expectations.

**SKILLS**

Regulatory Compliance

Prioritization

Records Management

cGMP/cGLP

Technical Documentation

Project Management

Communication

Proofreading

Collaboration

**EXPERIENCE**

THERMO FISHER SCIENTIFIC, Berkeley, MO

**Quality Assurance Lead Technician** 2022 - 2023

* Scanned daily product batch documentation into electronic files and archived hard copy documentation in secured Archive Rooms for regulatory inspections or for review by Manufacturing and Quality personnel.
* Limited storage space in Archive Rooms demanded constant movement of older hard copy documentation through indexing, packing, and prepping boxes for Iron Mountain storage.

GUERBET, Richmond Heights, MO

**Global Labeling Coordinator** 2020 - 2021

* Coordinated assigned multiple complex detailed projects to develop domestic and international dosage labeling for (package inserts, patient information leaflets, instructions for use, bottle/syringe product, boxes, and cartons) for new and established contrast media imaging products tracked through their entire life cycle.
* Prepared labeling artwork redline markups using Adobe Acrobat DC supplied to Graphic Designers for artwork and vendor proof creation.
* Reviewed artwork/vendor proofs (e.g., 2D, 3D, and GTIN barcodes) completed by Graphic Designers using exceptional attention to detail and proofreading skills visually and with Global Vision inspection software; provided signature approvals.
* Communicated completed artwork and vendor proof e-files to regulatory health authorities, and production sites for review, and signature approvals.
* Updated Label Code Lists for individual projects/products and posted e-file updates to SharePoint for production sites and distribution centers; mentored team member to learn this task.
* Proactively found and addressed problems preventing potential labeling errors; aided with developing solutions.

**Regulatory Affairs Labeling Associate** 2015 - 2020

* Participated in third round of Global Labeling rebranding of over 4,000 pieces of domestic and international dosage labeling for new and established contrast media imaging products to “Guerbet”.
* Filed over 230 boxes of hard copy documentation in team effort; received “Guerbet Award” for completion of task ahead of critical deadline.
* Reviewed processes to determine where efficiencies could be achieved reducing hard copy sent to IM for storage; Guerbet determined to retrieve all hard copy from IM to be scanned as e-files and hard copy destroyed for cost savings.
* Organized team meetings to review use of Labeling Database History; determined to discontinue duplication of information already contained within the individual project files.

MALLINCKRODT PHARMACEUTICALS, Hazelwood, MO

**Regulatory Affairs Labeling Associate** 2011 - 2015

* Participated in second round of Global Labeling rebranding of all labeling changing to “Mallinckrodt Pharmaceuticals”.
* Utilized knowledge of international and U.S. Federal guidance’s, regulations (e.g., FDA, EMA,) and regulatory references (e.g., ICH, ISO) to resolve questions and apply to relevant work tasks/situations.
* Identified, classified, stored, secured, archived, retrieved, tracked, and destroyed labeling and labeling documents; ensured record integrity throughout the life cycle of projects.
* Reviewed promotional and advertising materials; prepared CTD’s, with associated materials and Form 2253 sent to OPDP for Ad Transmittal submissions; provided Document Control with all copies for in-house storage.

COVIDIEN, Hazelwood, MO

**Regulatory Affairs Labeling Coordinator** 2007 – 2011

* Participated in first round of Global Labeling rebranding of all labeling changing to “Covidien”.
* Researched and provided labeling and labeling documentation for Annual Reports, PSUR’s, etc.
* Completed hard copy and e-file labeling requests sent to Global Labeling Department Outlook mailbox.

BIOMERIEUX, INC., Hazelwood, MO 2003–2007

**Senior Process Technician**

* Updated/enhanced and managed critical control documents including Master Formularies, SOPs, Work Instructions and Batch Records; issued timely, accurate Master Formulary documentation to facilitate daily media production.
* Played a key technical/logistical role in supporting process improvement initiatives for an increase in production efficiency, production scheduling, quality control, product development and business decision-making; attended frequent multidisciplinary meetings to share insights, progress, and concerns.
* Actively participated in Product Change Notice (PCN) committee meetings directly accountable for approving changes to control documents.

**EDUCATION**

Associate of Arts

St. Charles County Community College, Cottleville, MO

Medical Laboratory Technology

Gradwohl School of Laboratory Technique, St. Louis, MO

**CERTIFICATION**

Document Management Certified Professional

The Center for Professional Innovation & Education (CfPIE), Malvern, PA