Marifrances A Cataldi

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Technical Writer/Illustrator

Distills complex technical information into easy-to-understand text and illustration.

- Writes and illustrates user manuals, manufacturing procedures, process and data flow maps, equipment qualification protocols, and regulated quality management system documentation.
- Reviews and copy-edits documents for clarity, completeness, usability, and easy translation to device and software test plans.
- Develops true single-source technical writing with illustration using structured Adobe FrameMaker.
- Designs and develops quality management systems based on externally recognized standards, e.g. ISO 13485.
- Copy-edits technical documentation and academic theses.
- Enthusiastically teaches technical writing skills.

COMPUTER APPLICATION PROFICIENCY

- Microsoft Office, Visio, PowerPoint
- Adobe Photoshop, Acrobat, Illustrator, FrameMaker (Unstructured and Structured)
- Corel Painter

EDUCATION

BS Pre-Med, Mount Mary College, Milwaukee: Majors in Biology and Art; minor in Chemistry
AAS Electronics Engineering, Wisconsin School of Electronics, Madison: Outstanding Student Award, A+ average
Miscellaneous: MATC, Madison 150 credits including CAD, graphic design, and web programming; 3.925GPA

WORK HISTORY

May 2023 –Current

Technical Writer/Illustrator

Elephas Bio, Madison, WI – Development of a cancer treatment diagnostic platform that delivers actionable information for clinical decision making, and accelerated drug development.

- Designed and developed a User Manual for a proprietary microtome that delivers live tumor sections in a live microenvironment
- Developed a system for single source authoring using structured FrameMaker; developed a FrameMaker EDD (Element Definition Document) customized for Elephas
- Photographed user performance with the device; edited the photos to concisely illustrate proper operation of the hardware and consumable accessories, using Photoshop

Sept 2022 – Nov 2022

Technical Writer/Illustrator

Sub-Zero Group, Madison, WI (short term contract through Oxford Global Resources) – Manufactures and sells luxury kitchen appliances.

- Researched and illustrated the intersecting software applications used to manufacture their line of luxury ovens
- Generated linked Visio maps to document the software application data flow

March 2012 – March 2019

Senior QA Engineer/Technical Writer

Lucigen, Madison – Researches and manufactures RUO (Research Use Only) reagents for the cloning and sequencing of DNA and RNA.

- Performed business gap analysis against regulatory standards requirements
- Designed and implemented a quality management system (QMS) in compliance with ISO 13485 Medical Devices – Quality Management Systems; certification audit – zero findings
- Maintained the QMS
- Hosted ISO 13485 notified body (BSI) audits and customer audits
- Evaluated product and process changes based on risk to product quality and other business objectives, in accordance with ISO 13485:2016
- Wrote and illustrated procedures for optimum clarity and usability
- Reviewed customer complaints and any resulting nonconformance management, corrective action and preventive action records to ensure all feedback was fully documented and all investigation loops closed
- Designed test protocols for Installation Qualification (IQ) and Operational Qualification (OQ) of production equipment
- Reviewed and approved documents and quality management records for clarity, completeness, and usability
- Taught technical writing skill improvement

April 2011 – March 2012

Technical Communicator

GE Healthcare, Madison (contracted through Adecco) – Designs and manufactures critical care ventilators and operating room anesthesia delivery systems.

- Reviewed critical care ventilator product specifications to verify specifications are measurable and testable
- Designed user interface (UI) elements in accordance with established design look and feel specifications
- Edited user facing ventilator system message text to improve clarity and facilitate translation, using Simplified English

October 2010 – April 2011

Manufacturing Documentation Specialist

Cummins Emissions Systems, Stoughton (contracted through Aerotek) – Designer and manufacturer of on-highway and off-highway diesel engine particulate filtration systems and diesel engine catalytic converters.

- Developed product manufacturing documentation from the output of a customer-accessible, on-line product customization and purchase order system
- Designed and established a system for delivering customized manufacturing specifications to the production floor in printed or plant-wide accessible digital format

May 2009 – August 2010

Regulatory Specialist

CareFusion, Middleton (contracted through Click on Me, LLC) – Designer, manufacturer, and distributor of neurocare capital equipment and supplies.

- Rebranded product labeling as required by the FDA and global medical device regulatory bodies, to address Nicolet-Viasys-Cardinal Health name change to CareFusion and the company's address change from Verona to Middleton
- Audited product labeling for compliance with the MDD (Medical Device Directive) of 2010; nonconformances found and corrected
- Met aggressive revenue-critical deadlines

January 2008 – March 2009

Regulatory Engineer, Technical Writer/Illustrator

Fairbanks Morse Engine, Beloit (contracted through Van Marter) - Manufacturer of diesel engines used to propel and support the other electrical requirements of nuclear submarines and US Naval and Coast Guard ships.

- Updated the existing ISO-9001 quality management system to include compliance with the US federal requirements for suppliers to nuclear power plants (10 CFR 50 Appendix B and ASME NQA-1 1994). Customer audit passed with no findings.
- Revised, wrote, and illustrated maintenance instructions for large diesel engines used to power naval ships, electrical power stations, nuclear submarines, and nuclear reactor back-up electrical systems

December 2000 - March 2004

Regulatory Engineer, Technical Writer/Illustrator

UltraVisual Medical Systems, Madison - Developer of a software-based 3D viewer of radiology records.

- Developed fully indexed and highly illustrated user guides, quick start pamphlets, and on-line help for use by radiologists and radiology technicians
- Managed change control of product specifications
- Designed and documented an FDA 20 CFR Part 820 compliant quality management system. FDA passed the system during the first audit.

January 1997 - July 2000

Regulatory Engineer, Technical Writer/Illustrator

Locus Inc., Madison - Provided OEM electronics engineering services, specializing in radio frequency embedded systems.

- Designed and implemented an ISO 9001 compliant quality management system, uniquely formatted for clarity and user acceptance. System was accepted by users, but there was no management support for certification.
- Researched, wrote, and illustrated a user guide and tutorial for the US Coast Guard's land-based positioning system, Loran. The users were defined as US Coast Guard engineers.
- Developed assembly drawings in support of manufacturing

October 1988 - October 1996

Verification and Validation Manager

Burdick Inc., Milton – Designed and manufactured electro-mechanical and embedded systems cardiac diagnostic devices such as stress systems (programmable treadmills and monitor-controllers), interpretive electrocardiographs, and defibrillators.

- Created and implemented the processes and controls of a software/hardware verification and validation test department
- Designed test suites based on product specifications, hazard analyses, federal requirements, and industry-wide recognized standards (AAMI and IEC)
- Developed traceability matrices from design specification to test protocol, to ensure and document full test coverage
- Mastered the reading of 12-lead EKGs to evaluate, and then report, the diagnostic impact of product defects
- Recommended to executive management product release from R&D to the production floor
- No product defects were reported from the field that were not documented and approved for release prior to commercial distribution
- No successful product liability suits or product recalls of devices released between 1988 to 1996