Marifrances A Cataldi

Stoughton, Wisconsin 53589
608-354-9206
marifrances_cataldi@yahoo.com
ms-cataldi.com

Technical Writer, Regulatory Engineer, Illustrator

Writer – I distill complex technical concepts into clear description and imagery. Wrote instructional manuals for radiologists using a proprietary 3D image viewer, Navy land-positioning Loran system engineers, maintenance crews of Navy diesel-powered ships and submarines, and laboratory personnel working with precision microtomes. Developed two user manuals using structured single source XML-based documentation technology for paper-based and digital documentation.

Regulatory Engineer – Established three quality management systems compliant with ISO standards, the FDA regulations for the management of medical device development, and the needs of the internal work force. I specialize in engineering design controls, design transfer to production, and document control management. Experienced in gap analysis, root cause analysis, and hazard analysis. I have a creative approach to product specifications and their translation to verification and validation test plans.

Illustrator – Develops fully illustrated and/or photograph-rich user instructions – a thousand words is a waste of space when a single image is adequate.

EDUCATION

AAS Electronics Engineering, Wisconsin School of Electronics, Madison: Outstanding Student Award, A+ average
BS Pre-Med, Mount Mary College, Milwaukee: Majors in Biology and Art; minor in Chemistry
Graphics: MATC Madison Area Technical College, Digital Illustration – raster and vector

SKILL SET

Technical Writer, Regulatory Engineer, Quality Management Systems Designer, Photo Editor, Technical Illustrator, Structured Single-Source Author, Engineering Design Controls, Hazard Analysis, CAPA Corrective/Preventive Action, Document Control, Subject Matter Expert (SME) Collaborator, Business Gap Analysis, Start-up Environments, Photoshop, FrameMaker, Illustrator, and Corel Painter

WORK HISTORY

May 2023 –July 2026
Technical Writer/Illustrator
Elephas Bio, Madison, WI – Start-up developer of a cancer treatment diagnostic platform.

- User Manuals – Wrote and illustrated user manuals for laboratory personnel use of precision microtomes. Single-source structured author, photographer.

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.

- Data Flow Maps – Documented data flow between legacy manufacturing software applications to plan establishment of a modern inventory tracking system.

March 2012 – March 2019
Senior QA Engineer/Technical Writer
Lucigen, Madison – Develops and manufactures RUO (Research Use Only) reagents for the cloning and sequencing of DNA and RNA.

- Quality Management System - Designed and maintained a quality management system (QMS) in compliance with ISO 13485 Medical Devices. QMS scope based on gap analysis, and risk assessment.
- CAPA - Evaluated product and process changes based on risk to product quality. Evaluated customer feedback for complaints and nonconformances. Verified corrective actions for effectiveness.

April 2011 – March 2012

Technical Communicator

GE Healthcare, Madison (contracted through Adecco) – Division for design and manufacture of critical care ventilators.

- Product Specification Review – Evaluated product specifications for translation to test plans.
- Simplified English - Edited embedded user-facing messages for clarity and accurate language translation.

October 2010 – April 2011

Manufacturing Documentation Specialist

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

- Product Specifications - Developed a semi-automated system to format customer specifications into manufacturing specification documentation.

May 2009 – August 2010

Regulatory Rebranding Specialist

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

- Product Rebrand Project - Rebranded regulated labeling. corporate name and location change.

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 electrical requirements of nuclear submarines, and US Naval and Coast Guard ships.

- QMS Maintenance - Updated an existing ISO-9001 quality management system to include compliance with the requirements for suppliers to nuclear power plants (10 CFR 50 Appendix B and ASME NQA-1).
- Edited Technical Manuals – Revised Navy-contracted maintenance instructions (text and illustrations) for ship, submarine, and nuclear back-up diesel engines.

December 2000 - March 2004

Regulatory Engineer, Technical Writer/Illustrator

UltraVisual Medical Systems, Madison - Developer of a software-based 3D viewer of radiological scans.

- Medical Device User Manuals - Developed fully indexed and illustrated user guides, IFUs, and embedded Help systems.
- Change Control Management- Managed change control of product specifications.
- QMS Design - Designed and established an FDA 20 CFR Part 820 compliant quality management system.

January 1997 - July 2000

Regulatory Engineer, Technical Writer/Illustrator

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

- QMS Design - Designed and implemented an ISO 9001 compliant quality management system.
- US Coast Guard Manuals - Researched, wrote, and illustrated a user guide and tutorial for the US Coast Guard's land-based positioning system, Loran.

October 1988 - October 1996

Verification and Validation Manager

Burdick Inc., Milton – Designed and manufactured electro-mechanical and embedded cardiac diagnostic devices.

- Product Acceptance Department – Established the 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 to document and ensure full-test coverage.
- Product Release to Production –Recommendedproduct release from R&D to the production floor.