Marifrances A Cataldi

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Technical Writer/Illustrator

I am experienced in the distillation of complex technical information to simplified text and illustration. I am a practiced and enthusiastic teacher of my expertise.

- **Writer and illustrator**; user manuals, manufacturing procedures, process and data flow maps, equipment qualification protocols, and regulated quality management system (QMS) documentation.
- **Copy-editor**; reviews technical documentation and academic theses for clarity, consistency of terminology, completeness, and usability. Ensures product requirements can be seamlessly translated to device and software test plans. Uses Simplified English to ensure effective language translation.
- **Single-source technical writing**; Structured Adobe FrameMaker.
- **Photo-editor**; develops user instruction manuals based on photos edited for clarity of purpose.

Design Controls and Regulatory Engineer

I am a specialist in the development and management of design control systems and quality management systems (QMS). My focus is the medical device industry and other regulated environments.

- **Risk assessment specialist**; performs risk assessment and tracks risk mitigation plans and outcomes.
- **Verification and validation**; develops equipment and product verification and validation protocols.
- **Requirements matrices**; tracks design requirements to test protocols, and requirements to protocol test results. Provides documented proof of successful verification and validation.
- **UI design evaluator**; tests and assesses user interfaces for consistent function, terminology, and intuitive usability.
- **Quality Management Systems (QMS)**; designs and develops QMS based on externally recognized standards, e.g. ISO 13485 Medical Devices – Quality Management Systems.
- **CAPA management**; evaluates records for completeness, based on risk assessments.
- **Gap analyst**; performs business gap analysis against internal and external requirements and regulations.

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.

- **User Manual** designed and developed for a proprietary microtome.
- **Single source authoring** using structured Adobe FrameMaker, authoring system evaluated and implemented.
- **Photographed and photo-edited** operation of device, Adobe Photoshop.

Sept 2022 – Nov 2022

Technical Writer/Illustrator

Sub-Zero Group, Madison, WI (contract Oxford Global Resources) – Manufactures luxury kitchen appliances.

- **Linked Visio maps** of the intersecting data flow between diverse legacy software applications used in the manufacturing process, in preparation for the establishment of a single overarching ERP.

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.

- **Business gap analysis** performed against regulatory standards requirements.
- **Quality Management System** designed, implemented, and maintained, ISO 13485 Medical Devices – Quality Management Systems; certification audit – zero findings.
- **Audit host**, ISO 13485 notified bodies and customer audits.
- **Technical procedures and tutorials** written for clarity and usability. Documentation usability standards established.
- **CAPA and customer complaint review**, CAPA response assessed for completeness and effectiveness.
- **Equipment qualification** protocols designed, Installation (IQ) and Operational Qualification (OQ).

April 2011 – March 2012

Technical Communicator

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

- **Product specifications** reviewed to verify specifications are measurable and testable.
- **User interface (UI), Simplified English,** designed in accordance with corporate look and feel specifications. User system message text reviewed for clarity and translation, using Simplified English.

October 2010 – April 2011

Manufacturing Documentation Specialist

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

- **Product manufacturing documentation system** designed and established for delivery to the production floor of customer-defined product specifications, 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.

- **Product labeling** rebranding due to corporate name and address change, required by FDA and global medical device regulatory bodies. Labeling reviewed for compliance with MDD (Medical Device Directive), 2010.

January 2008 – March 2009

Regulatory Engineer, Technical Writer/Illustrator

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

- **Updated ISO-9001 QMS** to include compliance with the US requirements for suppliers to nuclear power plants (10 CFR 50 Appendix B and ASME NQA-1 1994). Customer audit passed with no findings.
- **Edited and illustrated** maintenance instructions for diesel engines used to power naval ships, power stations, nuclear submarines, and nuclear reactor back-up electrical control systems. The users were defined as sailors at a 6th grade reading level.

December 2000 - March 2004

Regulatory Engineer, Technical Writer/Illustrator

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

- **On-line help**, user manuals, and quick start pamphlets developed and illustrated.
- **Change control** management of product specifications.
- **QMS designed** and established, compliant with FDA 20 CFR Part 820 for medical devices. Passed first FDA audit.

January 1997 - July 2000

Regulatory Engineer, Technical Writer/Illustrator

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

- **QMS designed** and implemented compliant with ISO 9001, uniquely formatted for clarity and user acceptance.
- **User Manual and Tutorial** researched, written, and illustrated for operators of the US Coast Guard's land-based positioning system, Loran. The users were defined as US Coast Guard engineers.

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.

- **Verification and validation** test department established for qualification of medical equipment; last qualification gate before release to the production floor.
- **Test protocols designed** based on product specifications, hazard analyses, federal requirements, and industry-wide recognized standards for medical device hardware (AAMI and IEC).
- **Traceability matrices** developed from design specifications to test protocol results, to ensure and document full test coverage.
- **Mastered 12-lead EKGs analysis** to evaluate the impact of product defects on diagnostic quality of device output.
- **Recommended product release** to executive management, release from R&D to the production floor.
- **No product defects reported** from the field (customer complaints) that were not approved by executive management before the device's release to commercial distribution.
- **No successful product liability suits or product recalls** of devices released between 1988 to 1996.