

CURRICULUM VITAE
Robert J. Mazzaferro

EDUCATION:

Bachelor of Electrical Engineering (aka BSEE) from Rensselaer Polytechnic Institute (Troy, NY) in 1967.
Master of Engineering in Electrical Engineering (aka MSEE) from Rensselaer Polytechnic Institute (Troy, NY) in 1968.
Certificate in Computer Programming from Montgomery College (Rockville, MD) in 1999.

LICENSURE & CERTIFICATION:

Licensed Professional Engineer (aka PE by the Commonwealth of Massachusetts) since 1976.
Regulatory Affairs Certification (aka RAC by the Regulatory Affairs Professional Society) since 1994.
Certified Software Quality Engineer (aka CSQE by the American Society for Quality) since 1998.

PUBLIC HEALTH SERVICE ACCOMPLISHMENTS:

Commissioned as an officer in the United States Public Health Service (USPHS) in March, 1970 and retired in 2000 after 30-years of service at the Permanent Rank of Captain (Navy-equivalent) in the Regular Corps. During this time I was awarded the following USPHS medals and ribbons: Outstanding Service Medal (1), Commendation Medal (1), Citations with Plaque (2) and Unit Citations (5).

PROFESSIONAL EXPERIENCE:

April 2000 to Present: As the Owner and Manager of RegTech Solutions, LLC located in Montgomery Village, MD. I have worked for a large number of clients on a variety project types and devices as indicated in the Experience section of the Brochure for RegTech at the beginning of this file.

May 1992 to March 2000: As a Medical Device Reviewer of 510k, IDE and PMA submissions for cardiac, respiratory and neurological devices at FDA's Center for Devices and Radiological Health (CDRH) located in Rockville, MD. A few examples of the devices for which I performed reviews are: cardiac pacemakers, leads, cardiac ablation catheters, recorders, thermolulution measurement system monitor, oxygen monitors, transcutaneous nerve stimulators (TENS) and rechargeable batteries that are used in a wide variety of medical devices. I also did some bioresearch monitoring of a range of device and diagnostic product clinical studies that are regulated by CDRH.

June 1975 to May 1992: As a Supervisory Medical Device Test Engineer at WEAC during this time period I supervised and reviewed the work of engineers and scientists who tested a large number of different types of (mostly) medical devices. A small sampling includes: atropine injectors & pneumatic dental drills (1990's); condoms, hearing aids, defibrillators and dog training collars (1980's); medical and dental x-ray machines, contraceptive diaphragms, and Teflon coated cardiac catheters and kidney dialysis filters (1970's). I planned and organized the expansion of my section from four to about fifteen engineers and scientists; worked with a team to expand the physical size and space efficiency of our laboratory; worked with the FDA field and headquarter offices to develop more projects for our laboratory; to specify and either design or purchase the mechanical, electrical and radiation related equipment necessary to support these programs; and to design and validate a Quality Assurance program to assure that our work was accurate, reliable and could withstand cross-examination in possible future litigation.

March 1974 through May 1975: As a Medical Device Test Engineer at FDA's Winchester Engineering and Analytical Center (WEAC), located in Winchester, MA. I designed and built test equipment and calibration facilities and tested a number of medical devices. WEAC is the only FDA medical device test laboratory outside of headquarters.

March 1970 through February 1974: As an Engineer in various job titles at the USPHS Northeast Radiological Health Laboratory (NERHL) located in Winchester, MA. I designed and built animal testing equipment; performed field medical radiation surveys; worked at an area hospital's radiology department for 1 ½ years (part-time) to learn about radiation physics and radiography; designed, carried out and presented (orally and as published papers) a radiography retake study, designed (as part of a team) a thermoluminescent device (TLD) mail-out card for dentists and subsequent on-site follow-up (working

with State Radiation Control personnel in five states). The latter program allowed the states to save a lot of travel money by focusing on dentists who were using too much radiation to produce their films, especially in large states with low population densities.

June 1968 through February 1970: As an Engineer at two divisions of Hamilton Standard of United Aircraft located in the Windsor Locks, CT area. The first assignment was in a division that analyzed data from electronic gyroscopes for the US space program. The second assignment was in a division with a pilot production plant that manufactured a high strength composite material (boron coated tungsten wire, a predecessor of the graphite composite material in use today). This latter assignment gave me experience with preparing and validating equipment calibration procedures (electronic timers and gas flow meters) and a better understanding of the importance of recognizing safety (i.e., high voltage and explosive and corrosive chemicals) as well as the technical engineering problems in a production facility.

September 1967 through January 1968: As a graduate assistant in the Analog Computer Laboratory at Rensselaer Polytechnic Institute.

June 1967 through September 1967: As an engineer with the Torrington Company located in Torrington, CT which manufactured sewing machine needles. My primary accomplishments were to write an electric machine control handbook for mechanical engineers and design staff and to present a course to a group of Torrington Company employees using this handbook.

June through September (1965 & 1966): Worked during the summers of 1965 and 1966 at Aerotherm Corporation located in Bantam, CT, which manufactured commercial airline seats. In 1965 I was a draftsman and in 1966 a design trainee. My primary accomplishment for 1966 was to design and oversee the manufacture and testing of a plug-in tray (made from vacuum-formed plastic and machined aluminum) and to prepare and present the table to the firm's marketing department.

PROFESSIONAL AFFILIATIONS: Active member of the Regulatory Affairs Professional Society and the FDA Alumni Association.

GOAL: To help medical device manufacturers to make good medical devices available to patients, to assist attorneys with medical device litigation and to continue to learn about new developments in computers and engineering.

COMPUTER SKILLS: Microsoft Office and programming, building and maintaining personal computers.