I have been watching **Risk Management** taking the stage in the ***Regulatory Open Forum*** for months, and taken the opportunity to reply to questions and comments when I had the opportunity. Some of the comments have been well done based on experience and knowledge. Others, well…

I want to establish where I am coming from by listing some of my background, training, education, and experience, to use FDA’s QSR requirements. From 1962-1969 I served in the US Navy’s Submarine Service as an Electronics Technician, serving in both diesel submarines, and nuclear-powered missile subs, for two years in a shipyard in new construction. During my time in the boats, we lost the Thresher due to design failure, and the Scorpion due to unknown causes. I met Admiral Rickover during a sea trial, and had loads of experiences that helped prepare me for my quality and regulatory future careers.

My education led me to obtain a BS in Science Education, followed by a Masters degree in Education Administration. Not too closely to regulatory affairs or medical devices, but it is what it is. And I have found over my years (1988-present) in medical devices that a number of people have taken a similar route. In 1982, I was trained in the quality sciences by Dr. Joseph Juran, himself, and later in application of quality engineering by Dorian Shainin. My industrial statistics training came from Dr. Charles Holland, a former scientist at Oak Ridge, and a student of Dr. Donald Wheeler at University of Tennessee.

In 1988, I joined the medical device industry, following 6 years in the machine tool controls industry. The ASQ granted me a CQE in 1988, a CQA in 1991, and a CQM/OE in 1995. The Regulatory Affairs Professionals Society granted me an RAC in 1994. I became an ASQ Fellow in 2012, based mostly on my standards work. I joined the team (IEC SC 62) revising IEC 60601-1 in 1994 , and presently serve as liaison to ISO TC 198 sterilization standards from IEC SC 62A) and worked for ten years leading to IEC 60601-1 Third Edition. I joined the ISO technical committee for medical device risk management, TC 210 JWG1, in 2000, right after the release of the first edition of ISO 14971. Since 2003, I have been on the US national standards committee for quality management standards, AAMI QM01.

For experience, I began in medical devices as a Supplier Quality Engineer, and after 6 years moved to Manager of Quality and Regulatory at a merged company in 1994. We immediately began work to develop a quality system, with certification to ISO 9000 (at that time this was the only quality system standard for devices). As soon as we got our certificate (the first location in the company) we moved on to get certified to the new ISO 13485 standard. As the company expanded, the quality/regulatory group worked to establish a single quality system for all locations, at the time, in the US and Europe.

Later I worked as part of a team to integrate numerous new locations and products into the company, working our way through numerous regulatory issues from the newly integrated companies and products. I was appointed to serve as corporate risk manager in parallel with my position as Director of Quality and Regulatory, responsible for multiple US locations, until a full-time Risk Manager could be appointed.

Since 2003, I have been a consultant in the industry for large and small companies with products from toothbrushes to left ventricular assist devices, and everything in between. The companies have had thousands of employees with multiple locations, down to companies with less than 30 employees at one location, and even one virtual company, that had 5 people who outsourced nearly everything. During this time, I have provided training in quality systems and risk management. I have worked for AAMI since 2003 in their training courses on quality, design, and risk management in many locations in Europe and the US.

At Purdue University Southeast, University of Southern California and University of Washington I have given lectures on quality and risk management as part of quality and regulatory science degree programs. At Virginia Tech’s Healthcare Risk Management graduate degree program

I have written a number of articles and book chapters and even co-edited one book, *Lifecycle Risk Management for Healthcare Products From Research Through Disposal.* I hope I have contributed to the improvement of medical device quality and safety. That is my intent here to write about risk management and ISO 14971.