My Quality Career

Margaret Rooney, formerly a Regional Assessor with NQA, retired

I started my career in quality in 1982, when I took a position as a research assistant in the Welding Group at the then Cranfield Institute of Technology (now Cranfield University). I was studying the economics of defects and in 1988, I went on to do a PhD in quality related costs in the process plant industry. Achieving this PhD was my proudest career moment.

QUALITY *professionals who have been in their* PROFESSION *for* more *than* 20 YEARS share their experiences *on* how QUALITY *has* changed *in their* INDUSTRY

It may seem obvious now, but my PhD work demonstrated that the cost of monitoring and auditing were significantly less than the cost of repair and re-work. At the beginning of my career, there was a culture that repair and re-work was a normal part of the production process. Attitudes to the need for assurance, good record keeping, evidence of competence, customer involvement and feedback, a culture of improvement and striving to do better, are among the many changes I have witnessed over the last 30 years.

Quality, quality control and quality assurance were very much the domain of heavy engineering and manufacturing. That has very much changed, with professionals and consumers in all sectors (public and private), demanding exacting standards and excellent service.

The biggest challenge of my career came in the 1980s. I had completed my PhD, and the National Quality Campaign was at its height. I'd just started working with the NHS – looking at whether the principles of management systems, in particular ISO 9001, could be applied to services. I had no credibility or track record in health, and although some health professionals were enthusiastic about what I was attempting to do, many were initially highly sceptical and sometimes hostile. I quickly learned to up my game, sharpen my act, speak health service language, grasp the generic principles of ISO 9001, and interpret these for health care.

The IQA (now the CQI) published my paper on this work, and to my relief and amazement, it was very well received. To this day I am very grateful for the support the Institute gave me. This work stood me in good stead for the rest of my career, helping me to persuade people in many sectors of the value of quality.

I am now retired, after a very varied career in quality, environment and management systems. Persuading people of the value of quality and management systems, whether as an advisor, an auditor, or a teacher – seeing that light bulb moment – is wonderful. I have been retired for a few months, and I have recently very much enjoyed updating the CQI's history for our centenary year.

My advice for other professionals beginning their career in quality is to keep an open mind and constantly ask yourself what is really important. Stay focused on that and do not get sucked into irrelevant, non-value adding detail.

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Take advantage of every relevant training course available to you, especially quality tools, use of statistical techniques, management systems, the EFQM model and customer care. Apply what you learn intelligently to your situation. Read Quality World and the CQI guidance documents – they are excellent. Become a member of the CQI and encourage other quality professionals to do the same.

Image: Marcus Harvey
Words: Dina Patel

Greg Hutchins, Founder and Director at Certified Enterprise Risk Manager® (CERM) Academy

In 1985, I was project managing one of the last liquefied natural gas (LNG) facilities built in North America. We were having supplier quality problems. This was the start of my quality journey as I created the first quality organisation for a gas utility.

We used Military Specification MIL-I-45208 and MIL-Q-9858A as our quality guidelines. MIL-Q-9858A is the origin of ISO 9001 standard and all other global quality management system standards and regulations. We inspected products using AQL (Acceptance Quality Limit) 10%. AQL is the quality level that is the worst tolerable.

I became a member of the US TAG 176, in 1987, thinking we may want to use ISO 9001:1987 instead of MIL-Q. That same year, we taught ISO auditing and quality at one of the first US registrars – AGA Labs.

In many ways, 1987 was the banner year for quality. In 1987, three quality gurus were anointed: Phil Crosby, W. Edwards Deming, and Joseph Juran. In 1987, Motorola initiated Six Sigma, ISO 9001 was developed, and the Malcolm Baldrige National Quality Award was promulgated.

In the year 2000, quality was maturing throughout Europe and North America. ISO 9001:2000 registrations decreased in the West and grew exponentially in Asia. The demand was such that I wrote four books on quality and ISO, and over the years I wrote more books on quality. Six Sigma became a commonly used Operational Excellence (OpEx) tool.

However, quality now faces challenges. ISO registrations are flat or falling worldwide. Certification bodies' revenues are flat, and many are rebranding to 'risk shops'. There are also no quality gurus pointing to the future of the profession.

Quality has become integrated in most companies and quality has become everyone's job. As a result, the quality professional has become endangered, along with many quality standards.

What's the future of the quality profession? Since 2000, we've evangelised that the future of quality is risk management. We encourage companies to align their quality processes, taxonomies, and controls to governance, risk and compliance.

Why have we done this? In the US, Enterprise Risk Management (ERM) is legally required of publicly held companies and is mandated in every federal department. In the UK, ERM is mandated in the corporate governance code. Also, many UK cities, councils, and towns now have risk management programmes.

We so fervently believe this that we trademarked the expression: Future of Quality: Risk®.

Lindsay Mather, Company Food Safety and Quality Manager at British Sugar

I joined British Sugar in 1983 in a central laboratory function. It was a temporary role, but I then had the opportunity to join the business as a science trainee. As part of that role, I tested the physical, chemical microbiology parameters from the various stages of our process and finished products – even beet seed analysis. During the mid to late 1980s, our business decided to implement certification to the quality standard BS 5750 (BS 5750 was replaced by ISO 9000 – Quality management in 1994) leading to a greater focus on quality. Being a part of our science team meant we played a major part in implementing the various procedures and protocols required and British Sugar was one of the first food businesses to gain this accreditation.

One of the biggest milestones for British Sugar was when we moved to BRC certification in 2001 (the British Retail Consortium was founded in 1996 by retailers who wanted to standardise food safety standards across the supply chain). That was really a turning point for us and our approach to quality has changed in line with any changes to BRC in subsequent years. For example, as a business we're more aware of changing customer requirements and being on a fully unannounced programme is driving the behaviours to always be audit ready. We also started to focus more on the importance of culture and behaviours and the role they play in food safety, which is covered in the training that all our employees undertake.

One of my proudest achievements was when we first achieved our BRC certification and gained the highest grade across the seven sites we had at the time. All of our sites have continued to maintain this high level of achievement. I also felt a great deal of satisfaction when I managed our business management graduate scheme (which covers procurement, product quality and the supply chain). It was very rewarding to be able to recruit these intelligent and passionate graduates and help them mould their early careers. In the future, I'd like to look at quality apprenticeships, as this is another great way to introduce individuals to quality early in their career.

The biggest challenge in my career must be prioritising my responsibilities. I like to be proactive and drive the business forward, but often the world of quality can be reactive – for instance, managing a customer complaint or supporting an internal issue. I am sure that this will be something that a lot of my quality colleagues will recognise too.

What I enjoy the most about my job is the variety – I work in a very diverse business. We work with teams across our group from agriculture, procurement, manufacturing through to logistics and commercial. Sometimes I'm working with suppliers, sometimes with our customers. We make a wide range of sugars – not just granulated, but speciality sugars, such as liquid sugars, syrups and brown sugars. We manufacture sugar for a wide range of companies, such as confectionery, bakery, soft drinks and also pharmaceutical companies. We also supply to the retail market though our sister company Silver Spoon.

My advice to young quality professionals would be to spend time building relationships and focusing on culture so you don't feel like a lone voice trying to convince others of the importance of quality. It should be like health and safety – quality should be a part of everyone's role. Also, take the time to network outside of your business to learn from others, as we often share the same challenges.

Amarjit Kaur Gill, CQP MCQI, Vice President, Quality Assurance at Elekta

My career started in quality when I graduated from University back in 1995 after completing an Engineering and Management degree. I enjoyed the TQM and process improvement modules within my degree, which allowed me to focus on this area when completing my final year dissertation. This led me into my first quality assurance role with a small distributor organisation.

I have always worked in heavily regulated industries, starting with defence and then moving into medical devices. Having undertaken further education specialising in software engineering, I focused on this aspect early in my career. Within these industries, quality assurance and the need for compliance went seamlessly hand in hand. In the early days, quality assurance was closer to inspection rather than assurance. It was mostly people auditing with their clipboards.

During the past twenty years, quality professionals have become partners to their organisation; they're facilitating process improvement and thinking about the quality culture.

Working in the medical device industry has been particularly rewarding, especially in the area of quality assurance where you have the opportunity to support product development and commercialisation of a product.

Being a part of great innovation that makes a difference to patients will always be a proud moment for me.

One of the biggest challenges I have faced in my job is ensuring that the quality assurance team is integrated within the business and is not solely a support function with compliance as its purpose.

When asked what I enjoy the most about my job, there are several things that come to mind, so I think the answer has to be variability. Within quality assurance, no project is the same therefore each year I'm creating strategies and building tactical plans that ensure the quality assurance team is engaged and supporting the business to move forward. I also gain a lot of personal satisfaction in motivating and developing the team – being able to give them opportunities to stretch them and put them forward to lead interesting change projects.

The advice I would give to an individual starting in quality assurance is to keep an open mind, focus more on developing the skills required to influence change. These skills take longer to develop but once established, the impact is far greater.

"Being a part of great innovation that makes a difference to patients will always be a proud moment for me"

Image: Chris Renton

Mark Braham. CQP MCQI. Head of Business Assurance at the AA. Chair of MSEG QS1 (BSI). Head of UK delegation to ISO TC176 and member of the CQI Standards Panel

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When I started in quality, I remember how almost everything was based on manufacturing, enormous paper files containing documented procedures and quality control by inspection. In addition to this, it was the responsibility of the quality team to ensure quality was completed and monitored. This has caused many issues. The standards written for production lines in factories were very time consuming to produce, as was circulating this paperwork and the excessive re-works when things went wrong. The quality team retained the responsibility and were accountable for poor quality.

Today, quality has moved on to include all industries, including service and information technology. More procedures have started to move onto electronic platforms and utilise the cloud and mobile solutions so employees can access procedures quickly and efficiently.

This has also made it much easier and quicker to push out and communicate amendments and identify improvements. The reliance on quality control at the end of the production line was replaced with improved planning during the design stage and checks during product or service delivery to eliminate any errors or defects. All employees engaged in the product or service chain are now responsible and accountable for their part. Everyone needs to work together and support each other, including suppliers and contractors in a supply chain.

There have been many challenges over the past 20 years of my career – the use of technology and automation for quality control, for example. Engagement across the entire organisation and rolling out training on quality tools and techniques to all was another challenge. This was accomplished by implementing a project to regularly communicate the changes and, more importantly, by proactively engaging with end users.

Holding regular workshops with users, designing workflow process maps to consider the current to future state and identifying improvement and efficiencies also helped to overcome the challenges. When working with suppliers and contractors we had to build mutually beneficial relationships that ensured we worked together to build partnerships. When changes or risks occurred, we collaborated to act together, to share best practice and support each other to find solutions.

In the future, artificial intelligence will become multidimensional. AI will be managing, monitoring and evaluating other AI systems. The influence of disruptive technologies and internet of things will also grow and provide links into data streams creating powerful analytics and evaluations. This will feed into product and service development and create more innovation and possibly predict customer needs and expectations.

Julian Jones. CQP MCQI. Chief Compliance Officer at Isansys Lifecare

My current role is Chief Compliance Officer and head of Quality and Regulatory Affairs at Isansys Lifecare. I started working in the medical device industry shortly after leaving university back in the early 1990s. The medical device industry has always been heavily regulated with a very strong emphasis on patient safety and quality improvement, both in regard to devices and the quality management system itself.

In my professional career, over the last 25 years, I have been involved in performance monitoring, process control, risk management, failure investigations, process and product improvement, design and development, new product introduction, process validation, statistical process control, Lean Six Sigma and Right First Time initiatives.

I have been fortunate to work in a variety of functional roles and have held various positions including Scientist, Project Manager, Technologist and Senior Management. The range and diversity of roles available within the realm of quality and compliance is truly astounding.

One of the big challenges for any aspiring quality professional, now and few decades ago, is often the vast opportunity and diversity of roles available. Where do you start and what area of expertise do you develop? My advice is to keep challenging yourself, take on new roles and responsibilities and never stop learning.

The early part of my career dealt mainly with the rewards and challenges of process and product improvement. The likes of Deming, Juran and Shewhart made a significant impact on me during this time. Having roles that have enabled me to directly contribute to the improvement of patient care has and continues to be hugely rewarding for me. As my career developed and I became more experienced, I transitioned into quality system implementation, system and product certification, regulatory compliance, leadership and governance.

For many years the quality and regulatory requirements applicable to both small and large medical device manufacturers remained largely unchanged. While medical devices have remained crucial to the diagnosis, treatment and prevention of disease the current Medical Device Directives have struggled to keep up with technological developments over the past 25 years.

The medical device industry now has until 26 May 2020 to adopt the latest European Medical Device Regulation (Regulation (EU) 2017/745), bringing improvements to public confidence and patient safety.

The future of quality and the need for quality professionals within the medical device industry has never been stronger. There has never been a better time to expand your professional knowledge, support colleagues and grow. The future of quality is bright.

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