

Senior Quality Professional

Technically astute and detail-oriented professional with extensive experience in leading all aspects of quality assurance, quality engineering and control within business. Stellar track record of excellence in monitoring project quality performance by reporting metrics, assessment, and auditing regimes in line with business needs. Well-versed in developing and devising quality strategies across business for quality improvement. Known for customer services, risk management, lean manufacturing, Prince2 project management, and business systems implementation. Proficient in QMS, investigation of issues, and successful CAPA deployments. Instrumental at effective utilization of Minitab statistical software, Six Sigma, CMM, CMMI and EFQM. Proven success in fostering congenial and professional relationships with broad cross section of customers, suppliers, leaders, and managers.

Areas of Expertise

- ◆ Quality Management
- ◆ Six Sigma Techniques
- ◆ Statistical Process Control
- ◆ Project Management
- ◆ Technology Integration
- ◆ ISO9001
- ◆ TS16949
- ◆ ISO14971
- ◆ DFMEA
- ◆ ISO17025
- ◆ Root-Cause Analysis
- ◆ Quality Tools & Techniques
- ◆ Process Improvement
- ◆ Business Transformations
- ◆ IT Service Transition
- ◆ ISO27001
- ◆ PFMEA
- ◆ ISO14001
- ◆ Critical To Quality (CTQ)
- ◆ Classification of Characteristics
- ◆ Continuous Improvement
- ◆ Relationship Management
- ◆ Statistical Studies
- ◆ Troubleshooting & Problem Solving
- ◆ Team Mentoring & Leadership
- ◆ ISO13485 & 21 CFR Part 820
- ◆ APQP
- ◆ NPI
- ◆ Six Sigma
- ◆ Quality Training

Professional Experience

Qualiconnect Ltd, Doncaster UK Principle Quality Consultant & Trainer

2017 – Present

Contribute to implantation of Medical Device Single Audit Program (MDSAP) to conduct regulatory audit of medical devices for ensuring quality. Support creation of a detailed PFMEA at their Supplier plant in South Korea. Serve as Interim Quality Manager to offer support for developing upcoming FDA Medical Device Inspection focusing on CAPA and MDD/MDR processes amongst others. Coordinate with Microbiologists and Validation Teams to evaluate wash plant and environmental controls. Employ various statistical process control techniques for environmental controls in compliance to ISO13485, ISO14971, and FDA standard. Streamline characteristics processes from critical to quality CTQ. Coach quality department in statistical concepts and techniques

- Introduced statistical Quality Engineering leading to a better understanding of the manufacturing process of a key component
- Developed and deployed database for indispensable data storage.
- Established supplier quality function for monitoring Major suppliers, including NPI, PPAP, ISIR, PSW, PFMEA, APQP, Statistical Analysis CPK, and PPK while serving as supplier quality engineer.

HCL Technologies, Leeds UK Senior Technical Lead

2016 – 2017

Assured quality, verified designs, and contributed to new product development utilising DFMEA, SPC, DMAIC, PFMEA, RCCA, 8D, and CAPA. Ensured control plans and PFMEA's, by evaluating. Cpk, Ppk, and MSA processes.

- Guided and trained cross-functional teams of graduate engineers regarding emerging quality techniques.
- Initiated medical Implants, IQ, OQ, and PQ into medical market by Integrating planning tools and techniques.

Conducted quality training sessions for management and production team leaders. Administered reporting on NCR's. Led meetings with production team leaders and formulated performance reports. Introduced process failure mode and effects analysis. Performed internal audits for product, system, and processes.

- Managed customer returns and analysis.
- Trained senior managers, Production foremen and Quality staff in Quality concepts
- Conduct PFMEA's on all production lines
- Calculated and Introduced a Cost of Quality Program
- Created a database for NCR's and customer returns
- Assisted in the Maintenance of the QMS ISO13485 & iso 9001

Additional Experience

Principle Quality Consultant, Qualiconnect (Prior to registration), Doncaster UK
Group Quality Director, Pearson Assessments & Testing, Maltby UK
Quality Manager Promoted TO Operations Manager, Plastic Insulated Cables (PIC) Ltd, Andover UK
IT Quality & Risk Manager, BT CELLNET (O2) (IT Services, Software, various others), Slough
Director – Powerway Institute Europe, Powerway UK (Automotive, Software, various others), Maidenhead UK
Managing Director & Principal Consultant, Quality Techniques & Systems, Johannesburg SA
Quality engineering & Supplier Quality Assurance Manager, FHE Automotive Technologies (Automotive), Pinetown SA
Quality Facilitator, Mossgas (PTY) LTD (Petrochemical), Mossel Bay SA
Quality Engineering Manager & Supplier Quality Assurance Manager, Smiths Manufacturing (SA) (PTY) Ltd Pinetown South Africa. (Automotive),
Senior Quality Engineer, Kostal (Automotive)
Supplier Quality Representative Lyttleton Engineering Works (Armcor) Pretoria South Africa

Professional Development

Armament Technologies
PRINCE2 for Practitioners, PARADAM Training
Management Development, PETA Portsmouth
Advanced Reliability Engineering, QTC Bob Bruneau
Advanced Quality Engineering, QTC Bob Bruneau
Certified Quality Engineer Preparation Course, QTC Bob Bruneau
Basic Injection Moulding and Raw Materials, Natal Training Centre
Certified Reliability Engineer Preparation Course, QTC Bob Bruneau
Advanced Quality Engineering, QTC Bob Bruneau & H. Hacquebord
Basic Inspection & Quality Control, Ed Reynolds (American Consultant)
Certified Software Quality Engineer Preparation Course, ASQ Norm Moreau
How to create and measure Customer Satisfaction, Foundation for Quality, Jeff Dewar
Quality Auditor: Quality Systems Audits and Evaluation, South African Bureau of Standards

Certifications

National Craft Certificate: Bulawayo Technikon
Certified Prince2 Practitioner: APM Group (Project Management)
Certified Quality Manager: American Society for Quality (ASQ)
Certified Quality Auditor: American Society for Quality (ASQ)
Certified Quality Engineer: American Society for Quality (ASQ)
Certified Quality Technician: American Society for Quality (ASQ)
Fitter Including Machining: Rhodesian Apprenticeship Board
Armourer/Gunsmith: Services Trade Training Centre



Daniel Clark PCQI

Research And Development Manager at Inotec AMD

April 22, 2021, Elwyn worked with Daniel in the same group

Elwyn's appreciation and passion for quality is evident in all his work. His skills with statistics, explaining and interpreting data are fantastic. Not only does Elwyn understand statistical analysis on another level he also takes the time to teach his colleagues and bring them on the journey too. On a personal level Elwyn is the consummate gentleman, a respectful and well-liked member of the team



Ivan Perez Chamorro

CEO at MedBoard - Medical Devices Intelligence Platform & More

May 17, 2020, Ivan worked with Elwyn but at different companies

Elwyn has a great passion for quality and statistical processes, that combined with his many years of experience makes him a very top level quality professional, with very solid quality principles and practical approach. In addition, his level of detail and methodical approach with tools allows teams to obtain very good data and insights for development and improvements



Clare Holt

Quality Manager at Inotec AMD Ltd

July 1, 2020, Clare managed Elwyn directly

Elwyn is an excellent person to work with, he is logical and relentless in the search for a logical data driven answer. I would recommend Elwyn in an instant to anyone who wanted a clear thinking, data driven, individual who is capable of analysing a problem and reaching a statically valid conclusion. I would also recommend any of his training courses, they have been beyond benefit to myself and my team.



Kelly Reah

1st degree connection1st

Senior Quality Assurance Associate at Inotec AMD

Leicester, Leicestershire, United Kingdom

I have had the pleasure of working with Elwyn within the medical devices sector. He has a wealth of knowledge on statistical analysis, PFMEA, Process Mapping, Quality Management Systems and Engineering. As such it has been an eye opening and invaluable experience for the whole team. I believe he is a valuable asset and contributor to any quality team



Philip Gravelle

Consultant at Gwalia Life Science Consulting Ltd

October 16, 2018, Elwyn worked with Philip in the same group

In my time collaborating with Elwyn, he showed a remarkable knowledge of the correct application of Statistical Process Control. His eye for detail enabled us to garner significantly greater information from process data and this facilitated improvements in control and yield. His background as a Chartered Quality Engineer was very evident. Furthermore, he was also humble enough to help out with more mundane tasks when the urgency on the project demanded. This was greatly appreciated.



John Boon

Directeur, dga

April 17, 2018, John managed Elwyn directly

Elwyn impresses, with his direct, practical approach to QA he is capable of communication with and earning respect from both management and shop floor. Constantly he surprised me with practical instructions for the machine operators. Thorough analysis towards suppliers and a true professional in discussions with customers. He singlehanded found ways to significantly reduce scrap and optimize production runs. With a clear understanding between motivating and activating.



Ian Potter

Contract Quality Engineer at HP Chemie Pelzer (Retired)

November 9, 2017, Ian reported directly to Elwyn

Elwyn was my Manager for some months during 2013.

I can say with honesty that he was one of the most respected and approachable Managers I have had the good fortune to meet.

He was certainly the most academically qualified of any having attained all four of the Qualifications in the American Society for Quality and one of only a few to accomplish this.

Elwyn leads by example and was supportive to me throughout our working relationship. Listening was a strength reinforced by tolerance.

He exudes a professional demeanour, is assertive but not aggressive and appears to command respect with little effort. His depth of knowledge on multiple Quality Tools and techniques is admirable. We have worked well together to resolve technical issues establishing Root Causes and implementing Containment and Corrective actions. Elwyn is a Quality Professional and extremely competent and capable at the highest levels.

I firmly believe that he would be an asset to any company and would in my opinion be part of the "intellectual capital ". He is also quite a modest man which is an endearing aspect of his character



Prem Murgiah

Howe Leather

March 6, 2013, Prem worked with Elwyn in different groups

An incredibly intellectual individual, he has trained me in various Quality Systems and Techniques, just to name a few

Quality Management System

Basic to Advanced Quality Statistical Techniques

QS900, APQP and PPAP

Core Tools

I have been trained and mentored by Elwyn approximately 16 Year ago and I am still inspired by his passion for the subject matter and his determination to get businesses to realise the untapped potential that exist within an organization through the use of effective Quality Management System and Techniques.



Graeme Winton

Programme Manager

November 20, 2012, Elwyn worked with Graeme in the same group

I worked with Elwyn at BT Cellnet at the start of its transformation into O2 UK and in most need of innovative problem-solving and a structured quality approach. Elwyn is a thought-leader in his field who is an impressive advocate of quality techniques. In my experience he has a unique ability to convey the full life cycle quality approach in a way that inspires middle and senior management and speaks to them in terms of compelling cost-benefits. At a personal level he is an open, supportive professional that I found a real pleasure to work with. Inspiring subject-matter expert on quality management and a supportive colleague through the difficult times. A real pleasure to work with.



David Wilkinson

Business Process Architect

November 20, 2012, David reported directly to Elwyn

Elwyn is a highly experienced quality professional with extensive experience in multiple industries. His wealth of knowledge, warm character and boundless enthusiasm for process, quality improvements and metrics is extremely engaging and infectious for those around him. A very approachable and supportive manager who leads by example.

Imraan Rashid

QA Manager at Behr

June 29, 2012, Elwyn worked with Imraan in the same group

Elwyn Lewis is a meticulous person who has thorough, in depth, knowledge of Quality management, both from an operational and system perspective. Enjoyed working with Elwyn.

Mike Bosse

Regional Sales Manager at Smiths Manufacturing (Pty) Ltd

October 24, 2011, Mike worked with Elwyn in different groups

I worked with Elwyn when he was both Quality Engineering Manager and Project Timing Manager. I found him to be innovative and effective, in particular the project management system which he established for the launch of new products proved to be successful. I would recommend Elwyn as a key member in any effective team.



Tony Hargraves FAPM, FCMI, CMgr, CITP, MBCS

Chairman at Age UK Berkshire

February 26, 2010, Tony managed Elwyn directly

Elwyn worked for me at BT Cellnet and proved to have an excellent grasp of quality management and its impacts and benefits on the business. His diligence, knowledge, expertise and professionalism enables me to have no hesitation in recommending him for roles in this domain.

Martyn Leese

Business Owner at Various small businesses
February 11, 2010, Martyn managed Elwyn directly

Elwyn reported to me in my role as Chief Operating Officer for Pearson Assessments and Testing International. The group consisted of a number of large business units all of which had their own/varied quality systems. Elwyn worked to unify those systems, make them more robust, filling gaps where they existed working with co-workers and customers at the highest levels.



Rick Suverkrop

Director at Active Leadership
January 27, 2010, Elwyn worked with Rick in the same group

Elwyn's involvement during his period at T&N was in the main, within the High-tech Heat Exchanger/Radiator division. As a Tier 1 supplier to OEMs both locally, in South Africa, and internationally. Elwyn's responsibility, through the team reporting to him, was to install and maintain systems to satisfy the appropriate audits and accreditations as specified by the range of customers. Further Elwyn used his practical experience, in particular with regard to Statistical Techniques, Problem-Solving techniques and Reliability Engineering, to achieve significant improvements, which contributed very clearly to overall company performance.

During Elwyn's time at T&N, I was responsible for turn-around projects within the T&N group and had the occasion to have Elwyn's input on some of the projects, that I was running in other divisions of the T&N group. I found his approach to be professional at all times. His approach achieved solid buy-in from the management and operators that he was advising, and as such produced effective and robust solutions.



Timothy Maber

Program director improvement / development at UNIQ evercreech
February 19, 2010, Timothy managed Elwyn directly

Elwyn worked directly for me at Smiths Manufacturing South Africa as my Engineering Manager, Elwyn led a successful team of quality engineers ensuring product reliability / cost effective optimization. A strong leader, advanced Quality management qualifications who would be an asset to any organisation. Tim Maber