**CURRICULUM VITAE**

**PERSONAL DETAILS**

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## Citizenship: British Driving License: Yes

**Memberships:** American Society for Quality (ASQ).

**Languages:** English (Primary) Email: elwynlewis1@gmail.com

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**Key Skills & Personal Profile**

* A result orientated, seasoned and experienced Quality Professional
* A widely experienced Change Manager with experience managing both cultural changes and complete business transformations - covering various industries such as Armaments, (Automotive more than 20 years’ experience), Electronic, Petrochemical, Textile, Chemical, Software Development, IT, Telecommunications, Leather Tannery and Foam Moulding industries. Petrochemical Laboratories (plus more).
* Experienced in Customer Services, Risk Management, Lean Manufacturing, Prince2 Project Management and implementation of business systems to QS 9000, VDA 6, ISO9001/2000, ISO 9001-3, ISO TickIt, TS 16949, ISO14001, ISO27001, ISO 13485, ISO 14971, RUP, Six Sigma, CMM, EFQM and other standards.
* Effective “hands on” management skills with analytical trouble-shooting and problem-solving, utilising tools such as: Lean, JIT, Kanban, Project Management (Prince2), Software Quality Engineering, Advanced Statistical Techniques (such as DOE, Taguchi, SPC, Reliability Engineering, process validations IQ, OQ, PQ) and many other skills / techniques 8D, RCA. Practical experience applying these tools in a multitude of industries.
* Diplomatic management style with the ability to listen to others in a sensitive manner, but strong enough to guide and support. Hard working, determined and results-oriented, seeing tasks through to completion.
* An Experienced Supplier Quality Assurance Engineer/Manager
* Trained more than 1000 quality managers and engineers, in quality techniques and quality certifications
* Experienced in using **Minitab** statistical software
* Speaker at International Quality Convention

**Some Background:**

I have started my career as an apprentice and qualified as a dual tradesman in 1980 (Armourer and Fitter Machinist) and since became a certified Quality Professional in 1983 (34 years ago) via the (ASQ) American society for Quality and have held a Quality Management Position since 1986 (31 years’ experience which includes 12 years in Supplier Quality Engineering). As a Quality consultant for more than 2 decades mainly working with the automotive suppliers implementing TS16949. I was a successful trainer in South Africa, in total I’ve trained many thousands of delegates from basic quality tools to advanced quality engineering & training other Quality professionals preparing them for certification through the (ASQ) American society for Quality furthermore My experience covers a vast variety of industries such as Petrochemical, Automotive, Software Development and precision machining, heavy machining, fabrication, laboratories plus many more.

I was injured in 2004 due in a serious motor vehicle accident, resulting in a slight disability; I unfortunately have had my arm amputated at the elbow. I feel that my wealth of quality knowledge and experience together with my supporting project management knowledge can be utilised by a company whose management are committed to, and seriously seeking Quality and continuous improvement.

***Qualifications***

Certified Prince2 Practitioner: APM Group - February 2003 (Project Management)

Certified Quality Manager: American Society for Quality (ASQ) - 1996.

 Certified Quality Auditor: American Society for Quality (ASQ) - 1995

 Certified Quality Engineer: American Society for Quality (ASQ) - 1983

 Certified Quality Technician: American Society for Quality (ASQ) - 1983

 Fitter Including Machining: Rhodesian Apprenticeship Board - 1980

 Armourer (Class 2 Grade A): Services Trade Training Centre - 1978

 National Craft Certificate: Bulawayo Technikon - 1976

 Rhodesian Certificate of Education - Higher’: Milton High School - 1974.

***Courses Attended***

PRINCE2 for Practitioners – PARADAM Training 2002

Management Development – 2001 – PETA Portsmouth

Certified Software Quality Engineer Preparation Course – 1999 – ASQ Norm Moreau 5 days

How to create and measure Customer Satisfaction – Foundation for Quality – Jeff Dewar 1992

Quality Auditor: Quality Systems Audits and Evaluation: 1991 - South African Bureau of Standards (3 weeks)

Certified Reliability Engineer Preparation Course*: 1984 – QTC Bob Bruneau, 5 days*

Certified Quality Engineer Preparation Course*: 1983 - QTC Bob Bruneau 5 days*

Advanced Reliability Engineering*: 1983 – QTC Bob Bruneau 45hrs*

Advanced Quality Engineering*: 1983 – QTC Bob Bruneau & H. Hacquebord 400hrs*

Basic Inspection & Quality Control*: 1982 - Ed Reynolds (American Consultant) 45hrs.*

Armament Technologies: 1976 - 1978 (3000hrs)

Basic Injection Moulding and Raw Materials 1992, Natal Training Centre, *5 days*

Medical Device Regulations MDR 2017/745- Udemy- 53 Lectures **EMPLOYMENT UNITED KINGDOM: - PRESENT Back to 2000**

**Qualiconnect Ltd https://www.elwynlewis.com)**

**Position: Owner & Principal Quality Consultant (Contracting) May 2017 to Present (see below)**

**July 2021 to Present:** A Sabbatical to review my Quality Engineering Courses and to visit my son in Canada

**September *2019 to July2021* Inotec AMD Ltd: (*Medical Devices*)** *.*

Initially a 3 Month Contract based in Cambridge Supplier Quality Engineer, to establish and Implement a Supplier Quality function monitoring and developing the Major Suppliers, (*NPI,PPAP, ISIR, PFMEA, APQP) (Statistical Analysis CPK,PPK) P*rocess validations *IQ,OQ,PQ)* and assisting the implementation of MDSAP (which was achieved in February 2020)

 **November 2018 to January 2019 Handicare: Based in the West Midlands -** *Medical Devices*a 6-month contract as Interim Quality Manager focusing on assisting to prepare for an upcoming FDA Medical Device Inspection focusing on CAPA and MDR processes amongst others.

**March 2019 to June 2019: Vicentra (Netherlands)-** *Medical Devices*3 Month Contract |Supplier Quality Engineer focused on Supplier Quality Management Process to satisfy ISO -13485:2016

**FRP** **July 2019: A Short consultation**: To assist in the creation of a detailed process Map and PFMEA at their Supplier plant in South Korea.

**February 2018 to May2018 Genedrive: -** *Medical Devices*an IVD Companybased in Manchester: a 3-month contract February 2018 to May 2018 focusing on the Supplier Quality Management Process.

**May 2017 to November 2017** **Zimmerbiomet: -** *Medical Devices*based in Bridgend: a 6-month Contract May 2017 to November 2017, working as a Senior Quality Engineer I have been working with the Microbiologists and Validation Teams Analyzing the wash plant and environmental controls and ‘End of Line data’ setting up Statistical sampling sizes and analyzing and verifying processes. i.e., Cpk, Ppk and investigated various statistical process control techniques for environmental controls, in preparation for compliance to ISO 13485, ISO 14971, FDA and other standards. I also introduced a process of identifying critical to quality characteristics which help fed into Design verification and allow the focus to be on the 20% of the characteristics responsible for 80% of function.

**HCL April 2016 to** **April 2017**

**Position: Senior Technical Lead**

HCL contracted me out to DePuy Synthes in Leeds for Implementing Quality, Verifying Designs, Processes and contributing to New Product development, utilising DFMEA, SPC, DMAIC, PFMEA, RCCA, 8D and CAPA. Applying Quality Planning tools & techniques for the introduction of medical Implants, IQ, OQ, PQ into the medical market, verifying control plans and PFMEA’s, analysing and verifying processes. i.e., Cpk, Ppk, MSA. I developed and implemented a process to Analyse and Product characteristics against design requirements and functional factors to identify Critical to Quality Characteristics. CQT’s this process also highlights risks; this approach strengthens compliance to ISO 13485, ISO 14971 & ISO 9000 – 2015. Compilation of PMS reports

**RSL Steeper (Orthotics Division) May 2014 to May 2016**

**Position: Senior Quality Engineer (Deputy Quality Manager)**

Implementing SPC, DMAIC, PFMEA, CAPA, RCCA, 8D and maintaining, ISO14001, ISO 9001:2008 & ISO13485. Driving continuous Improvement by providing quality training to Management and the production team leaders. Analysing and reporting on the NCR’s. Conducting meetings with the production team leaders and providing reports on their performance as well as introducing Process Failure Mode and Effects analysis. Conducting internal audits for Product, system & process.

**Qualiconnect (*Prior to registration*) April 2005 to January 2008**

**Position: Principal Quality Consultant**

Due to the injuries sustained in a serious motor vehicle accident and the lengthy rehabilitation required, whilst I was at Pearson Assessments and Testing, I was granted an early pension in June 2005. After a lengthy rehabilitation period 2005 to 2007. I started operating as a sole trader for Quality contracting/consulting under the name of Qualiconnect. During this time, I began by revising and updating my numerous Quality courses, which I previously presented in South Africa, I have also taken the Time to develop and refine my Quality Training Course material for Professional certification, I specifically focused on the American Society for Quality (ASQ) Body of Knowledge required for the (ASQ) certification exams. I have successfully presented a Quality Course for a client here in Doncaster (Chief Assessments) who enjoyed the course so much that they invited me back to present a second which I presented.

**January 2008 to June 2013: Doncaster Motor Spares**: I commenced working as part of my own “back to work programme”. I began by conducting a feasibility study for the implementation and integration of OHSAS 18001, ISO 14001 & ISO 9001 as one management system. They had no real appetite to implement these systems, so I then worked in the IT Department processing DVLA certificates of destructions amongst other duties. During this time, I recovered enough to pursue a Quality related contract.

**June 2013 to September 2013: Krane**: I Successfully completed a 3-month Contract as Interim Quality Manager for Krane in St. Helens responsible for three Quality Engineers. Covering all areas of the business, including SQA, measuring and working to reduce the cost of poor quality (COPQ); utilising statistical tools, 8D APQP principles & Pareto analysis etc.

**October 2013 to March 2014 Kostal:** Successfully completed a six-month contract) at as Senior Quality Engineer implementing 8D, APQP, SPC, Quality Engineering using Minitab, reducing the production line reject and waste, Improving OEE and Continuous Improvement.

**Pearson Assessments & Testing 2002 to 2005**

**Position: Group Quality Director**

As Group Quality Director, I was an integral part of the executive team, which has successfully grown the business revenue 10-fold in less than two years. I was responsible for managing the Software testing Team, Furthermore I was responsible for the Pearson A&T Group’s (EMEA, APAC & USA) compliance with all business standards such as **QS9000**, **ISO9001:2000**, **BS7799:2002**, **CMM**, **RUP** **Prince2** and Risk Management. This includes coaching and facilitating the development and execution of quality strategy ensuring that problem detection and prevention strategies are effective across all areas of the business – thereby reducing cost, streamlining processes. and providing the clients with confidence. Applied statistical analysis using Minitab software. We have successfully implemented and maintained ISO 9001:2000, Implemented BS7799 (ISO27001) and have facilitated the launch and implementation of CMM & RUP- we are currently to a CMM level 3 (our internal rating).

**Plastic Insulated Cables (PIC) LIMITED**  **2001 to 2002**

**Position: Quality Manager Promoted TO Operations Manager**

*Company closed as Dutch holding company TKH under financial strain*.

Manufacturers of Cat 5 & 5e, Cat 6 and Cat 7 data cables direct to OEM’s and other distributors.

I was responsible for managing the factory including Production, Maintenance, Purchasing, IT, Stores, Development and Process Engineering, Quality Assurance, Quality Control and Production planning to maximize profits by achieving increased productivity and quality levels. Managing and aligning all the divisions to focus on common areas – bringing the processes under control thereby optimising productivity and quality. This resulted in dramatically increased efficiencies and higher levels of quality – best productivity & quality levels in five years – utilized PFMEA, SPC, IIP, 6 sigma, 5S & Lean.

It was also in my remit to develop and implement the ISO 9000/QS 9000, APQP (Advanced Product Quality Planning) and project managing all projects through the company. Managing the Production, & Panning department.

**BT CELLNET (O2) (IT Services, Software, various others)** - February 2001 – September 2001 (Contract - Qualiconnect)

**Position: IT Quality & Risk Manager**

Developing and managing the IT Risk and Quality Forums, facilitating the identification, prioritisation and mitigation of risks and quality improvements. Installing and implementing a new electronic QMS, measuring and analysing customer satisfaction and introducing- Balanced Scorecards. Quality Consulting to the Software Development ‘Factories’ (CMM, ISO TickIt, ISO 9001-3) and Procurement, identifying best practice and implementing meaningful *statistica*l measures to manage and improve software design and development processes. Developing and implementing continuous improvement throughout the whole lifecycle.

**POWERWAY UK (Automotive, Software, various others)** **2001 Back to 1999 (Made Redundant)**

**Position: Director – Powerway Institute Europe:** Powerway was a software development company specialising in Quality Management, Electronic Document Control and Advanced Product Quality Planning training. I was responsible for the division of Powerway dealing with after sales Customer Service, including Training, Installation, Consulting and Application Support – largely Automotive:

**EMPLOYMENT SOUTHERN AFRICA: 1999 Back to 1975**

**QUALITY TECHNIQUES & SYSTEMS** **(Automotive, Petrochemical, Defence, Software, various others)**

**Position: Managing Director &** **Principal Consultant 1994 to 1999**

A quality consulting company specialising in Quality Training and System Development (QS9000, ISO 9000, ISO TS 16949, ISO TickIt, ISO 9001-3, VDA 6, and Six Sigma) – later diversifying into the supply of Quality Management Software for the Automotive and other industries – included Customer Service, Training, Installation, Consulting, Project Management and Technical/Application Support. Presented ASQ Preparation courses for all Certifications – Certified Quality Manager, Engineer, Technician, Auditor and Mechanical Inspector,: Clients include but not limited to; Toyota SA,; ADS (Altech defence systems), (FHE Automotive Technologies), Conlog Electronics, Smiths Manufacturing, NF Die Casting, Aunde Textiles Automotive Products, Feltex Automotive, Hullet Aluminium, Alusaf SA, Bell Equipment, Mondi, Richards Bay Minerals, Eagle Ottawa S.A. achieved ISO 9001-2000 QS9000 and VDA 6 simultaneously.

References can be read at:

**FHE AUTOMOTIVE TECHNOLOGIES (Automotive) 1992 to 1994 (continued as consultant till 1994)**

**Position: Quality engineering & Supplier Quality Assurance Manager:** Responsible for all areas of quality including Advanced Quality Planning, Quality Engineering and Supplier Quality Assurance, implementing and maintaining VDA-6, QS 9000, TS16949 and ISO9000. I also carried out training and Auditing as per the Internal and Supplier Audit Program.

**MOSSGAS (PTY) LTD (Petrochemical) 1990 Back to 1992 (Contract)**

**Position: Quality Facilitator:** A petrochemical company built from scratch to produce petrochemical products from gas supplied from offshore well. I was involved in the commissioning and implementation of the new plant, implementing and training thereof in Statistical Process control in all four laboratories, Identifying Customer metrics and measuring Customer satisfaction.

**SMITHS MANUFACTURING (SA) (PTY) LTD (Automotive) 1986 to 1990**

**Position: Quality Engineering Manager & Supplier Quality Assurance Manager**

I developed and maintained a project management system for the effective planning and management of all new projects. Also Responsible for implementing and maintaining **VDA-6**, Q**1,** **QS 9000** and **ISO9001** - **APQP, PPAP, SPC**, Reliability Engineering, Quality Engineering and **Supplier Quality Assurance**.

 **JOY MANUFACTURING CO. AFRICA (PTY) LTD (Mining Equip) - 1988 to 1986**

**Position: Quality Control Manager:** Manufacturers of complex underground mining equipment, low volume process high cost. I managed a team of 30 staff and led the company through the change process from reliance on Final Inspection to Input/Control/, covering all aspects of quality. *Introduced statistical quality techniques* into various areas of the business, namely production and Supplier Quality Assurance. Actively involved in changing the company culture towards quality a productivity where we collectively authored the article

**LYTTLETON ENGINEERING WORKS (Defence/Aerospace) 1980 Back to 1986**

**Position: Senior Supplier Quality Engineer**

A company that manufactures advanced weaponry of various types and calibres. I was responsible for establishing auditing, training, and ensuring maintenance of a Supplier Quality System and product release mechanism with-in the company’s **Major Suppliers** who were involved in the manufacturing of components for various projects. Utilised statistical & Quality techniques (MTBF, MTTF, MTTR, MSA, SPC, APQP, DFMEA, PFMEA, PFMECA & 6 Sigma) leading to better decision-making and increased reliability and productivity. I was responsible for the 88mm & 60mm mortars, 90mm Armoured Cars, the G5 & G6 Field Guns recoil system (safety critical)

Rhodesian Railways / Army: Dual Apprenticeship 1975 to 1980

**Position:** Apprentice initially, later Qualified Fitter Machinist Also Qualified as an Armourer (Gunsmith)

Apprentice training on lathes milling machines, shaping machines, broaching machines, and grinding machines etc.

**LinkedIn recommendations can be found at:** <https://www.elwynlewis.com/references>