CURRICULUM VITAE

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Mr Graham Whitehead. 9 Rochefort Drive, Rochford, Essex. SS4 1HT. UK.
Contact Details: Mobile 07748325884: Home 01702 542193: E-mail grahamw@zestcity.com :

Experience Profile

24 years as Consultant/Contract Quality Engineer and Manager. Locations: UK, the EU, Turkey & China. QMS, Management and Assessment; Product Inspection/Approval/Validation; CAPA, Risk Assessment & Mitigation; pre FDA audit mitigation/corrective actions etc.
Over 7 years in medical device design/development; manufacture; NPI, process & product validation:
Some 14 years automotive OEM and suppliers. Design/development phases. NPI. Risk Assessment. Prototype & final product, APQP activities & GPDS program review/control.

I have also been employed in the telecomm and cable industries.

Qualifications and Memberships:

Member of the Chartered Quality Institute	-	MCQI (formally known as MIQA) [1981]
Chartered Quality Professional	-	CQP (2007)
Incorporated Engineer (CEI)	-	I Eng [1981]
Institute of Quality Assurance Certificate	-	(1979-81)

Software Experience:

MS Office 2000/XP/Windows 7 [Excel, Word, PowerPoint, Outlook Exchange; etc]; MS Project; Byteworx**:**

Company Details:

During the last 17 years I have run my own Limited Company, with my son running the internet based activities. C. K. Developments Limited was incorporated 20th July 1995. Registration number 3082237. CKD is VAT registered. Prior to becoming a contract Quality Engineer I was employed, as Quality Manager at a telephone cable manufacturer, after a career with British Telecoms.

Contract Quality Engineer/Manager placements.

Nov 2014- Feb 2015.
Contracted to Bedfont Scientific as a Quality Consultant at their facility near Maidstone in Kent, UK.
Bedfont Scientific manufacture of exhaled breath and gas monitoring instruments for medical, scientific and industrial uses. I was engaged to review the company systems and identify improvements. I was given the role of Interim Project Manager while a permanent candidate was engaged. The company needed help in managing a period of growth, which is continuing. A successful contract which is expected to complete by the end of February.

May 2014- October 2014.
Contracted to Pfizer as Quality Engineer at one of their facilities in Cambridge, UK. Pfizer, a major international drug manufacturer, are required to complete a program of remediation to comply with revised FDA regulations on a number of combination medical devices. I was part of a team of engineers tasked with producing the (Design History Files (DHF) and associated documentation, for a number of different drug and medical device programs.

February 2014- March 2014.
Contracted to Ortho Solutions as Quality Engineer at their facility in Maldon, UK. Ortho Solutions have a range of Sterile Consumables, for elective Foot & Ankle surgery**.** A short term contract to assist the Quality/RA Manager in preparations for their next FDA audit. Specifically I was tasked with reducing the number of open Non Conformance Reports (NCR) & Change Requests (CR).

May 2013- December 2013.

Contracted to Handicare at their plant in Shanghai, China. Function: Quality Leader:

Handicare are a multinational company who design, manufacture& install mechanical aids for the infirm.

Quality Leader for the introduction of a new chairlift produced in the Shanghai factory. To act as the prime interface between R&D, in the UK & the manufacturing facility in China. This included, from a quality viewpoint, overseeing the introduction of new and changed parts, new suppliers and new processes. Dealing with day to day issues in production. setting the Fit and finish standards, along with the R&D section in the UK. Managing & auditing key suppliers as we moved from pre-production to full production.

Jan 2013- Apr 2013.

Contracted To: Smiths Medical, manufacturing plant in UK. Function: Quality Systems Engineer:

Multinational medical device manufacturer at their manufacturing plant, in the North West of England. A short
A short term contract to assist the Quality Manager in reducing the number of outstanding customer complaints and suppliers response issues (CAPA).

Jul 2012- Aug 2012.

Contracted To: Integra Life Science, manufacturing plant in Ireland. Function: Quality Consultant:

The manufacturing plant is part of a multi-national life science company. This manufacturing arm produce very complex high value devices used in operating theatres during the removal of tumours in the brain and other vital organs. A short contract to assist the Quality Manager & other on-site senior management to prepare for the FDA directed audit. Part of a team of experienced consultants blitzing the QMS & other systems to remove or mitigate as many of the likely issues that the audit would raise. This blitzing action was undertaken to mitigate the under resourcing and recruitment issues during the preceding year(s) & to comply with all the RA requirements.

Mar 2012- June 2012.

Contracted To: Scion Sprays UK (SSL). Function: Interim Quality Manager:

A 6 month rolling contract as the Quality Manager for the UK parent company who also have a daughter company in China to handle the bulk manufacturing operation. SSL are ISO 9001 & 14001 registered company who developed a low cost fuel injection system for small gasoline engines. They manufactured the unique micro injectors used in this novel Pulse Count Injection system. The system will enable small engine machines to meet the increasingly challenging emission regulations worldwide.

I was responsible for the quality system and all quality related matters throughout the company.

The QMS was produced from a model from a much larger company; I was refining the QMS to be more nimble and suited to a smaller development and manufacturing company.

Scion Sprays went into liquidation in June 2012, after the venture capital backing was withdrawn.

Aug 2010- Feb 2012.

Contracted To: Lotus Cars UK. Function: Quality Engineer:

A 6-month contract, extended to 18 months, at this iconic British sports car manufacturer. I was the Quality Engineer (QE) for 3 vehicle programs. The first was for a complete vehicle, the new Exige S, until 90 days after launch. The other two were totally new vehicles, for which I had responsibility for the NPI (New Product Introduction) function for the electrical & electronic systems. This includes FMA, FMEAs (both P & D), Grey Book, warranty statistics, Program Risk Assessment & Mitigation etc.

I represented the Quality Department at Quality Gateways and company specific program management meetings. All the normal QE functions were also part of my remit. The running the Concern system and resolution of the issues formed a major part of the required record keeping. I was heavily involved in the formulating processes for the compliance to ISO 26262, this being a new to Lotus specification.

Nov 2008- May 2009

Contracted To: Cardinal Health UK, Function: Quality Engineer:

A six-month contract assisting with the relocation of the medical device manufacturing base to Ireland. Working to ISO 9001; ISO 13485 and FDA 21 CFR 820 Standards. This was part of the Technology Transfer process between factories. The task involved the updating and integration of manufacturing procedures and software, as well as the re-engineering of brand name changes as the research and development along with design authority, was to be retained at the Chatham (UK) branch.

An important task that was part of this relocation exercise was to retain all the regulated accreditations. The up dating & maintenance of the Design & Technical files were also part of my remit. To this end I was responsible, under the direction of the Regulatory & QA Manager, for the preparation of any required submissions & changes.

July 2007- Nov 2008

Contracted To: Ford Motor Company plc Function: Quality Engineer:

A sixteen month contract within product development for Ford new models e.g. Transit and Transit Connect programs at the GPDS level and to ISO 9001 / TS 16949 Standards, ensuring new programs continue to address customer complaints and negative perceptions. Key Performance Indicators were used to monitor and resolve engineering reliability issues. The contract covered manufacturing facilities in the UK, Turkey and examined implications for the market in the United States.

May 2007- June 2007

Contracted To: Whatman International Banbury UK Function: Quality Consultant/Manager:

A 6 week consultancy contract with Whatman who manufacture high quality filter paper and mediums for medical and other industries. This contract was to cover for absentee managers; completing a pre audit inspection (ISO 9001; ISO 13485 and FDA 21 CFR 820), reporting back to the Vice President QA/RA on the shortfalls & the suitability of the management structure and personnel within these posts.

March 2007- May 2007

Contracted To: SMART Holograms, Cambridge UK Function: Quality Engineer:

A start up company, manufacturing holograms for novel applications for various industries. I was engaged to produce manufacturing procedures conforming to ISO 9001 for the production of a hologram which indicated excess moisture in jet fuel, as delivered to aircraft during refuelling.

June 2006 - Dec 2006

Contracted To: Boston Scientifics Eire: Function: Quality Engineer:

The Galway site as part of Boston's global companywide procedures to retain their FDA compliance, they ran a 6 month validation program on vascular and non-vascular catheter products. The program was run by an independent team and covered all products and manufacturing systems, including the final sterile packaging processes.

2005 - 2005

Contracted To: Varian Medical System's UK: Function: Quality Engineer:

A 3 month contract to provide cover during a recruitment drive and employee annual leave. The Company manufactures oncology system medical devices at their site near Crawly. The contract was as cover during recruitment, primarily on final product release and discrepancy reports of the large/complex 3D x-ray machines. Varian used a SAP based system for tracking components and systems used for each X-ray machine.

2004 – 2005

Contracted To: SMITHS Medical UK: Function: Quality Engineer:

Conducted an analysis of verbatim data and engineering solutions. Produced Key Performance Indicators and compiled Management Reports. Undertook customer complaint resolution and was a major part of the CAPA systems involving design, manufacturing and packaging issues (ISO 9001 & FDA specifications). Completed investigation and resolution of individual complaints and focused effort on areas of concern.

2003 - 2004

Contracted To: **Thermopol UK:** **Function:** **Quality Engineer**

Provided cover during re-organisation of the quality department including the recruitment of Quality Manager(s) and Engineers. Thermopol, are manufacturers of silicon hose supplied to the automotive industry. Duties included PPAP compilation and production methods documentation including visual aids for non-English speaking operators.

2003 - 2003

Contracted To: **Ford Motor Company plc:** **Function:** **Quality Engineer:**

Supported vehicle programs for manufacturing plants in China, India, Mexico and South Africa. Provided interface and representation for electrical electronics systems. Chaired Electrical PMT Meetings.

2002 – 2003

Contracted To: **Bentley Motors:** **Function:** **Zone Leader:**

A 6-month contract involving pre-production interiors of the new Continental GT Coupe.
Involved the validation and feasibility of proposed engineering designs to achieve the quality and production targets of the vehicle. Organised the procurement and build of the cockpit components of a MISTER Build car. Identify and drive the resolution of key feasibility issues within the vehicle Zone.

2002 - 2002

Contracted To: **Visteon Interiors:** **Function:** **Quality Integration / Validation Engineer:**

Responsible for the Advanced Product Quality Planning (**APQP**) activities, validation and testing. This included **FDVS, VPDS, FMEAs**, **DVP**s, project timing and other systems e.g. documentation control & warranty data collation. The program includes the instrument panel, passenger air bag, consoles and wheel arch liners

1995 - 2002

Contracted To: **Ford Motor Company plc:** **Function:** **Technical and Administrative Support:**

Within the Quality and Process Department provided ISO co-ordination and assisted in the enhancement of the ISO 9001/TS16949 Quality System. A prime responsibility was to design & produce web based systems and migrated the QMS onto these new systems, thus enabling intra-net site access to QMS and other data systems. This provided a platform to share the secure program data and result group-wide.
I established the company electronic record retention system. I carried out the training, maintenance and administration functions associated with this electronic procedure system.

Other relevant information

Prior to become a contract/agency Quality Engineer, I had 3 permanent positions. The first was with BT for 26 years, I than took up an offer to become the Quality Manager with Telephone Cables Limited (TCL), a GEC company, a major telephone cable manufacture and installation company. Along with the Quality Director, we produced a QMS system to ISO 9001 & achieved registration under the BASEC program. After this, with a staff of inspectors & auditors, we ran, maintained and refined the QMS until I was made redundant. My last full time position was with Hawtal Whiting, who also suffered economic cut backs; I was made redundant under the last in, 1st out principle. It was then I went onto the contracting/agency working.

Conducted business in China, Germany, Ireland and Turkey: for Handicare, Bentley Motors, Boston Scientific, Ford Motor Company plc, TCL and Visteon: Multi national conference call/net meetings with India, China, USA, Turkey and Germany. Current UK Passport: Full Driving Licence:

11 years service in the Territorial Army: Royal Corps of Transport, attained rank of Lance Corporal. Qualified and instruction in HGV 2 driving; Trade Training B1; and Vehicle Recovery:

Currently I am the elected chairman of a residents protest group that opposes the night flights from a local airport.