



## Grahame Somerville

*Senior Regulatory and Quality Consultant*

During his career, Grahame Somerville has had significant experience in regulatory approvals in Europe, the United States and the Far East. He is also a “Qualified Person” for pharmaceutical products. He has worked on a number of projects with manufacturers of wound care and orthopaedic products. Grahame is an elected member of the Professionals in Regulatory Affairs (TOPRA). He is also a member of the Chartered Quality Institute (MCQI) and is a chartered chemist.

### **EXPERIENCE:**

#### **Sr. Regulatory and Quality Consultant, Emergo UK (formerly Mediqol Ltd.) – 2005 to Present**

Provision of Consultancy Services for European CE Marking of Medical Devices including preparation and assessment of Design Dossiers, Technical files and Risk Management. Provision of advice about obtaining CE Marking and producing Design Dossiers and Technical Files.

Assist in Regulatory strategic pathways and choice of Notified Body. Assist clients in the preparation of FDA Premarket Notifications 510(k) Investigational Device Exemptions, PMA submissions and Device Master File submissions. Oversee the preparation of submission for Regulatory Inspection and liaise with clients during Regulatory audits. Assist in Regulatory strategic pathways for International registration of Medical Devices and assist with the preparation of submissions and Regulatory Authority audits.

GMP Consultancy and Advisory services for ISO: 9000:2000, ISO13485:2003 and FDA cGMP – 21CFR part 820 Quality Systems Regulations. Validation and qualification services for equipment, facilities, processes and computer systems. Contract Qualified Person certification and release of medicinal products under the provision of EU Council Directive 2001/83/EC (the Pharmaceutical Directive). Preparation for Government Regulatory inspection. External/Internal auditor training. Provide training courses on Regulatory and Quality Assurance on Medical Devices. Assistance with the design, development and review of Quality System and GMP documentation including Quality Manuals, Standard Operating Procedures (SOP's), Site Master Files, Technical Agreements, Device Master Records and Technical Agreements.

Provision of Consultancy Services for Device/Pharmaceutical sterilisation including guidance on standards and validation. Assist and advise clients on validation compliance issues for design, process, test method, sterilisation and software. Assist clients with Interim Project Management solutions for key Regulatory or Quality Assurance projects. Provide clients sector specialisms in Medical Device aspects of Surgical Sutures and Ophthalmic Devices. Prepare strategic advice and client documentation for Medical Device European reimbursement. Act as Mediqol, Limited representative on ABHI committees and any relevant device standard committees. Due diligence audits, with financial assistance for mergers and acquisitions. Perform interim Management roles in either Quality or Regulatory functions for clients.



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### **Quality Assurance Manager, Ethicon Limited (Johnson & Johnson) – 2000 to 2004**

Managing and directing the work of the Quality Assurance Department (17 staff Members). Responsible for all in-process quality assurance (IPQA) activities, inclusive of product, premises and raw materials at Ethicon Limited, Sighthill Plant. Ensuring product/Plant is compliant with the requirements of cGMP and BS EN ISO 9001/EN46001 (now ISO 13485:2003) for medical devices and managing and developing Quality Systems standards.

Responsible for managing the evaluation of existing suppliers performance and the quality of delivered materials and services against specification and regulatory requirements and application of technical, business and compliance knowledge to improve results. Leading and directing Incoming Goods QA Staff and defining documenting and controlling quality standards for raw materials and raw material suppliers. Managing and directing Quality Engineer in all aspects of quality system requirements, (QSR's), for in-process validations. Education and training of key QA personnel in all quality activities, including Supplier Quality Management. Conducting and leading supplier quality audits to Johnson & Johnson and ISO standards, within Europe and the US.

### **Quality Systems Manager, Bausch & Lomb Award – 1998 to 2000**

Managing and directing the work of the Quality Assurance Department (88 staff members). Responsible for managing all IPQA activities, Chemical and Microbiological Laboratories, Regulatory Affairs, Quality Engineering, Documentation Services and Complaints. Ensuring product/Plant is compliant with the requirements of cGMP and BS EN ISO 9002/EN46002 for medical devices. Provide plant direction on Quality Assurance matters and propose systems/procedures/methods to improve plant quality. Supervise and develop Quality Assurance team, (Quality Engineers, Laboratory staff and Complaints/Compliance staff). Management of Notified Body CE Mark audits.

### **Regulatory Affairs Manager, Ethicon Limited (Johnson & Johnson) – 1991 to 1998**

Managing and directing the work of the Regulatory Affairs Department. Preparing, assessing and reviewing Technical Design Dossiers required for CE Mark registration for the EC Medical Device Directive 93/42/EEC. Implementation of aspects of Quality System Standards BS EN ISO9001 and EN46001 as they affect Regulatory Affairs. Management of FDA cGMP audits, preparation of Premarket Approval (PMA) and Premarket Notification (PMN) or 510(k) applications for product registration in the United States. Implementation of Good Manufacturing Practice (GMP) for medicinal product manufacture.

Preparing, assessing and reviewing documentation required for product registration in Ethicon Limited export markets. Registration currently extends to 70 countries worldwide. Qualified person status responsible for approval of the final release of all Ethicon Limited Products. Communicating and liaising with BSi (Notified Body) the Medical Device Directorate (MDD - The Competent Authority) and the Medicines Control Agency (MCA) on all aspects of Regulatory Affairs. Assessing and implementing



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relevant ISO and EN standards as they affect medical devices. Ethicon Limited representative on ABHI Technical Committees and UK Panel for Gamma and Electron Irradiation.

### **Mgr. of Laboratory and Specifications Dept., Ethicon Limited (Johnson & Johnson) – 1989 to 1991**

Managing and directing the work of the Analytical Laboratory and Specifications Department. Overall supervision of the Specifications Department, including documentation review and approval. Overall supervision of the Analytical Laboratory including all aspects of chemical quality assurance and setting and monitoring quality standards.

### **Analytical Laboratory Manager, Ethicon Limited (Johnson & Johnson) – 1980 to 1989**

Overall Management of the Analytical Laboratory including all aspects of Chemical Quality Assurance and setting and monitoring quality standards.

### **Analyst, Ethicon Limited (Johnson & Johnson) – 1980 to 1989**

Development of analytical methods and non-routine procedures aligned to the Company Quality Assurance procedures in addition to carrying out projects related to the Company's environmental surveillance programme.

#### **AREAS OF EXPERTISE:**

- Absorbable and non-absorbable surgical sutures.
- Ophthalmic products, in particular contact lenses and solutions.
- Wound management and orthopaedic products.
- Risk Management and Analysis.
- Registered Qualified Person for release of medicinal products under the provision of EU Council Directive 2001/83/EC (the Pharmaceutical Directive).
- Negotiation skills with worldwide regulatory authorities.
- Educated to degree level with significant quality and regulatory experience in a senior management roles within multinational blue chip companies.
- International registrations of medical devices in particular Middle and Far Eastern markets.
- FDA cGMP requirements and Quality System Inspection Techniques (QSIT).
- Process and equipment validations.
- Expertise in Class I, IIa, IIb and III Medical Devices and Regulatory Affairs with an understanding of Clinical aspects of device registration.
- International regulatory affairs.
- EU Medical Devices Directive and FDA regulatory requirements.
- Quality systems implementation and US cGMP requirements.



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### TRAINING:

- Johnson & Johnson Advanced Management Course – Lausanne, Switzerland.
- ISO 13485:2003 Auditor Training Course.
- Practical Implications of the Medical Device Directives - ABHI.
- Roadmap to European Approval for Medical Devices.
- Regulatory Affairs Professional Society, (RAPS).
- Supervision in the Laboratory: Chemical and Allied Products Industrial Training (CAPIT).
- Radiation Sterilisation with Emphasis on Practical Applications (Harwell).
- Intensive Course on Pharmaceutical Quality Assurance (Heriot Watt University, Edinburgh).
- ABHI Medical Device Labelling in Europe.
- ABHI Design Control and Validation.
- The Application of ISO 9001:2000 and ISO 9004:2000 to Pharmaceutical Packaging Materials. (The Institute of Quality Assurance, the Pharmaceutical Society and BSI).
- EUCOMED Technical forum.
- EUCOMED Risk Management and Analysis.
- Irradiation Facility Management Course (Nordion International Inc.)
- FDA Approval Process for Medical Devices (January 2007)
- TOPRA Medical Devices Symposium (Budapest 2008 and Copenhagen 2007)

### EDUCATION:

- Post Graduate Diploma in Industrial Pharmaceutical Studies (DIPS) - 1990
- Post Graduate Diploma in Management Studies(DMS) - 1983
- BSc(Hons) Chemistry - 1979

### AFFILIATIONS:

- Lifelong Learning Scheme with TOPRA (the Organisation for Professionals in Regulatory Affairs) - 2007
- Elected to status of Chartered Scientist (CSci) by the Royal Society of Chemistry and the Science Council - 2004
- Elected to Membership of the Organization for Professionals in Regulatory Affairs (TOPRA)- 2004
- Continuing Professional Development Programme conducted in conjunction with The Royal Society of Chemistry - 2000