Gwilym Owen

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Regulatory Affairs and Quality Assurance Medical Devices Specialist.

Regulatory Affairs and Quality Assurance professional with over 20 years of global experience across the medical device sector, including diagnostic, therapeutic, and software-based (SaMD) products. Proven leader in developing and executing RA/QA strategies, securing international regulatory approvals, and building ISO-compliant quality systems. Deep expertise in FDA submissions (pre-subs, 510(k), Q-Subs), EU MDR, and standards including ISO 13485, ISO 14971, IEC 62304, and IEC 82304. Track record of successful engagement with FDA and EU Notified Bodies and authoring and managing submissions for global markets including United States, EU, Turkey, Japan, Korea, Australia, Brazil, and Canada.

Extensive experience of a variety of diagnostic and therapy medical device types for multiple therapeutic areas including oncology, neurology, maternal and neonatal health, orthodontics, electrosurgery. Particular specialism in SaMD diagnostic software devices on multiple platform types including mobile apps, PACS, server and cloud deployments, including AI/ML.

Experienced in building QMS and regulatory infrastructure from the ground up for startups, scaling systems for SMEs, and navigating complex frameworks within large corporations.

Wide range of experience of different device types including software and physical devices including SaMD devices, mobile apps, electrosurgical cutting devices, dental, nasal spray, skin treatment devices, pathology and photo biomodulation devices and more.

Regulatory and Quality skills and experience

Extensive practical experience with the interpretation and implementation of the following standards and regulations:

- 93/42/EEC of 14 June 1993 concerning medical devices (Medical Devices Directive)
- Regulation (EU) 2017/745 of the European Parliament and of the Council (EU MDR)
- Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)
- ISO 13485 Quality Management Systems
- ISO 14971 Medical devices – Application of risk management to medical devices
- IEC 62304 Medical Device Software - Software Lifecycle Processes
- IEC 62366 Application of usability engineering to medical devices
- ISO 14155 Clinical investigation of medical devices for human subjects — Good clinical practice
- DCB 0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems (NHS)
- FDA 21 CFR Parts 807, 812, 801, 803.
- FDA 21 CFR Part 820 QSR
- ISO 27001 Information technology - Security techniques - Information management Systems – Requirements
- Cyber Essentials PLUS
- EU General Data Protection Regulation 2016/679
- (UK GDPR) The Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) (No. 2) Regulations 2019, including Statutory Instrument no. 419 (SI 419).
- The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Experience in product and process risk management, post market surveillance, vigilance and complaints handling. Detailed knowledge of requirements for labelling, including UDI regulations. Experience of technical file compilation and maintenance, company device registration including MHRA, EUDAMED,

national registrations across the EU and US FDA Registration. Highly experienced in QMS and process design and implementation, and QMS and regulatory training.

Direct experience of writing submissions of multiple Class II/IIa/IIb devices for regulatory clearance. Direct experience of regulatory applications for: USA, EU, Canada, Japan, Korea, Turkey, Australia, Brazil and China.

Experience of writing submissions and leading FDA meetings for:

- pre-submissions,
- 10 day calls,
- submission issue requests
- general interaction with FDA review teams
- liaising with the CDRH ombudsman.

Experience of negotiating device classification with EU notified bodies. Experience with devices utilizing artificial intelligence/machine learning techniques. Experience of advising on clinical investigations to support regulatory clearance.

Business skills and experience

Liaising and negotiating with regulatory authorities, 3rd party reviewers, consultants and business-to-business regulatory and quality teams. Technical authoring for regulatory submissions and quality processes. Working in a regulated project environment, Experience of working in a distributed project development environment. Highly skilled at questioning and understanding the underlying commercial and business priorities and needs and developing supporting regulatory and quality system strategies.

Report writing; regulatory and quality contract review, creating and reviewing data processing agreements. Interpersonal skills including negotiation, diplomacy, communication and teamwork; ability to work effectively and consistently under pressure; ability to manage change and multi-task; Developing procedures and processes; ability and determination to achieve objectives; Internal and external audit. Experience of working alongside and providing advice to functions including executive management, marketing and sales, product management, finance, service and customer support as well as clinical research, R&D and software development.

Employment History

April 2023 – June 2025: Senior Consultant, Global Regulatory Affairs, EVERSANA
Provided strategic regulatory consulting services to medical device and life sciences clients, serving as the primary liaison and embedded team member to ensure alignment between product development goals and global regulatory requirements. Led the development and execution of regulatory strategies by translating complex technical concepts into risk-balanced, actionable plans taking account of client product status, budget, commercial priorities and timescales. Provided input on strategic direction and technical design modifications to enhance regulatory approval prospects and commercial viability. Authored regulatory documentation and engaged directly with regulatory authorities to facilitate product approvals across multiple regions. Managed end-to-end regulatory projects, breaking down complex deliverables into trackable tasks to meet timelines and client expectations. Built and maintained client relationships through high-quality service and proactive communication, resulting in repeat business. Supported EVERSANA business development as a subject matter expert by contributing to sales presentations and proposals.

Aug 2018 – April 2023: Head of Quality Assurance and Regulatory Affairs, Brainomix Limited
Member of the executive management team and reporting to the CEO. Responsible for all Regulatory and

Quality activity including standards and regulatory compliance, quality management system development and management, regulatory submissions for multiple Class II/IIa/IIb standalone software products internationally. Responsible for liaising, communicating and negotiating with regulatory authorities and notified bodies for submissions and vigilance. Led all regulatory and quality activities including strategic planning and budgeting, process improvement and development, CAPA system design and management, and conducting and managing internal and external audits. Responsible for all vigilance and post-market surveillance activity and reporting. Responsible for management of Clinical Evaluation Reports, PSURS, Product and process risk management and NHS Clinical Risk Management compliance.

Recruited and led a team of two Regulatory Managers and one Quality Manager.

Additional Roles:

Information Security Manager, Data Protection Officer.
Responsible for GDPR and UK data protection compliance, policy and procedure development and implementation of the Information Security Management system. Additionally, responsible for UK NHS Data Protection Toolkit compliance and oversight of company and product cybersecurity development.

Person Responsible for Regulatory Compliance.
Appointed in accordance with MDR requirements.

Jan 2009 – Aug 2018: Mirada Medical Ltd

Joining as one of the founding employees as a start-up, multiple positions culminating in **Head of Regulatory Affairs and Quality Assurance.**
Reporting to the CEO, ultimately with two direct reports. Responsible for all Regulatory and Quality activity and participation in general executive management. Responsible for all regulatory submissions for multiple standalone, accessory and integrated software devices; oversight of Post-market surveillance and CER process for all products, liaising with regulatory authorities, distributors, Notified Bodies and partner companies, preparation for transition to EU MDR including the up-rating of device classification, preparation for transition to MDSAP (Canada), making regulatory classification determinations and submissions including for bespoke products as a contract manufacturer on behalf of reseller organizations.

Management Representative for Quality and embedded in software development teams to plan and carry out all Project QA Activities for all development projects including reviewing and approving project documentation e.g. Design specifications, Requirements documentation, component documentation for all projects; chairing project phase review meetings for all development projects, conducting project risk Analysis for all development projects; management and resolution of nonconformities through CAPA processes; leading process development and QMS training activities, leading audits and managing the audit process – internal, external and supplier.

Additional Roles:

Senior Manager, Operations and Service
Responsible for production and service provision and delivery to customers including; creating and managing Sales Orders for global sales, Co-coordinating installations for global sales, liaising with customers throughout order fulfillment process. Functional management of global customer support team and, latterly, EMEA Installations and support team.

April 2005 – Jan 2009: Siemens Molecular Imaging (now Siemens Heathineers)

Multiple positions culminating in **Quality Engineer**.

Project Quality Assurance representative for development projects, working with and advising Project Managers, Software Engineers and Test Engineers to ensure that projects run smoothly while adhering to the development process and required quality standards.

Duties included writing and reviewing Quality Management Plans to ensure projects meet defined quality criteria; working with Regulatory Affairs to ensure the correct documentation is made available for FDA 510(k) submissions; Participating in gate reviews to ensure a project is of sufficient quality to progress to the next stage in the development process; membership of project Change Control Boards to monitor and ensure defects and requirements changes are properly managed; reviewing technical and project management documentation with a focus on quality compliance; reviewing project FMEcA and hazard documentation to ensure that risks and hazards have been identified and mitigated where required; Ensuring that project traceability meets the guidelines specified by the development process and Quality guidelines; implementing and driving improvements to Quality System Documentation and procedures to make the system as efficient and appropriate as possible; Creation, dissemination and maintenance of training records; tracking and closing issues in support of the CAPA process; Collating and utilising Key Performance Indicators; providing support for, and assisting with, the co-ordination of software component build and dependency management.

Courses and Training

- SGS Medical Device Regulation Implementation Training Course (EU) 2017/745
- MDTI Applying the Regulations: Creating Safe & Secure Health Apps and Medical Device Software BSI Creating and Maintaining Compliant Technical Files and Dossiers
- BSI Clinical Evaluation for Medical Devices
- Chartered Quality Institute – Process Design and Improvement
  Chartered Quality Institute – Root Cause Analysis
- Chartered Quality Institute – Tools and Techniques for Performance
  Improvement Oxford Brookes University – Management and Leadership
  Development Program Essential Employment Law at Work
- AAMI Design Control Requirements and Industry Practice

Qualifications

- IRCA Certified Quality Management Systems Auditor/Lead Auditor (Oct 2014)
- APM Introductory Certificate in Project Management.
- Certified General Data Protection Regulation Foundation (GDPR)

Sept 2003 - Sept 2004: Masters Degree:
University of Wales Aberystwyth - MScEcon International Politics and Terrorism.

Sept 1999 - June 2002: Undergraduate Degree:
University of Wales, Aberystwyth - BscEcon (hons) International Politics and Strategic Studies: 2:1.