



Kevin Webb

Head of Regulatory and QA

Kevin Webb has 18 years experience in pharmaceutical and medical device industries. He managed and provided regulatory consultancy services to manufacturers of medical devices and human tissue-derived therapeutic products. This has included the generation and review of regulatory approval strategies, enabling timely and cost effective international market entrance of clients' products. He has made applications for international regulatory approvals (including compilation and submission of product dossiers, answering queries in relation to the application and liaison with international regulatory authorities).

EXPERIENCE:

Head of Regulatory and QA, Emergo UK (formerly Mediqol Limited) – 2002 to Present

Responsible for provision of regulatory consultancy services to manufacturers of medical devices and human tissue-derived therapeutic products. Generation and review of regulatory approval strategies, to enable timely and cost effective international market entrance of client's products. Identification of general and product-specific regulatory requirements, and provision of technical advice and guidance on meeting these requirements. Auditing of client's compliance with identified regulatory and quality system requirements. Management of applications for international regulatory approval (inc. compilation & submission of product dossiers, answering queries in relation to the application and liaison with international regulatory authorities).

Preparation of risk management reports to ISO 14971. Preparation of clinical evaluation literature reports to meet requirements of MEDDEV 2.7.1. Generation and review of design and process verification / validation testing strategies, protocols and reports (incl. in biocompatibility, packaging and sterilisation). Representing the client at meetings with regulatory authorities. Review of medical devices manufacturers' submissions prior to formal submission. Review of intellectual property documents (applications, patents, search reports) and license agreements. Review of manufacturers CE Marking design dossiers for UK Notified Bodies. Day-to-day management of the Medical Regulatory and QA team (8 people).

Technical Manager, Tissuemed Limited – 1999 to 2002

Responsible for management of global regulatory affairs for Tissuemed's wound care and sealant products. Provision of technical management and regulatory support to the R&D Technical Director and the QA Manager in the development of implantable wound care and sealant medical devices. Management of Tissuemed's global intellectual property portfolio for its wound care and sealant products.



Kevin Webb, continued...

R & D Project Manager, Tissuemed Limited – 1998 to 1999

Responsible for management of the biocompatibility and microbiological / sterilisation aspects of Tissuemed's development programmes for implantable wound care and sealants. Management of a multi-centre project to develop a tissue-engineered bio-synthetic vascular graft.

Senior Process Scientist, Schering-Plough Animal Health – 1998 to 1994

Responsible for management of microbiological testing and sterilisation validation programmes in the development of bacterial, viral and parasite vaccines. Research, development and pilot production of bacterial, viral and parasite vaccines.

Chief Scientific Officer, Pitman-Moore Ltd. (formerly Glaxo Animal Health Ltd) – 1981 to 1983

Sr. Scientific Officer, Pitman-Moore Ltd. (formerly Glaxo Animal Health Ltd) – 1981 to 1983

Scientific Officer, Pitman-Moore Ltd. (formerly Glaxo Animal Health Ltd) – 1981 to 1983

AREAS OF EXPERTISE:

- Cardiovascular devices
- Orthopaedic devices
- Tissue sealant devices
- Tissue-engineered devices
- CE marking strategies
- Design dossier preparation and review
- Biocompatibility and sterilisation issues

TRAINING:

- Medical Devices Clinical Research Update - Tower Mains

EDUCATION:

- B.Sc. (Honours) Applied Biology (Biochemistry) - The Hatfield Polytechnic - 1986