



Sarah Ramsey

Regulatory Consultant

Sarah Ramsay has over six years experience in regulatory affairs, with significant experience of technical files, design dossiers and US 510(k) applications for orthopaedic implants (including devices intended for implantation in the spine). Previously, Sarah was with UK bone cement manufacturer DePuy CMW, where she was responsible for preparation of regulatory applications and compliance with regulatory requirements for European, Canadian, Australian and US markets.

EXPERIENCE:

Regulatory Consultant, Emergo UK (formerly Mediqol Limited) – 2006 to Present

Responsible for: Generation of regulatory strategies for International markets, identification of regulatory requirements, management of International applications for regulatory approval, compilation of regulatory documentation including, Risk Management Reports, product dossiers and worldwide registration documentation.

Senior Regulatory Affairs Associate DePuy CMW, Blackpool – 2002 to 2006

A Johnson & Johnson Company. Responsible for managing vigilance, MAP's (Management Action Plans) and Asian Pacific Latin American, South Africa, Canada, Australia and New Zealand country registrations, CE Marking of both Medical Device and Drug Device combination products, compiling and submitting US traditional and special 510(k) applications, providing regulatory support for new product development and product changes, presenting at worldwide meetings, presentations at board level, internal auditing.

December 2002 – August 2003 deputised for Regulatory Manager assuming full responsibility for running of department.

Regulatory Affairs Associate, DePuy CMW, Blackpool – 2001 to 2002

Responsible for: Compiling CE Mark Design Dossiers and Technical Files. Worldwide registrations and renewals. Providing regulatory input for new projects. Labelling and generation of instructions for use text.

Regulatory Affairs Assistant DePuy CMW, Blackpool – 2000 to 2001

Responsible for: Worldwide registrations.

AREA OF EXPERTISE:

- Technical files and design dossier compilation
- US, Australian and Far Eastern product registrations
- Orthopaedics
- Vigilance procedures and reporting



Sarah Ramsey, continued...

TRAINING and CERTIFICATIONS:

- Vigilance and Post Market Surveillance
- Labelling and Packaging
- Introduction to the Medical Devices Directive,
- US 510(k) Submissions
- Global Medical Device Regulations: Market Access and Registration (including Japan Regs),
Emergency First Aid (in the workplace)
- ISO 9000:2000 Quality Auditor training
- Risk Management

EDUCATION:

- BSc (Hons) Biological Sciences