



Tina Mistry

Senior Clinical Consultant

Tina Mistry has worked on a wide range of regulatory and clinical projects and continues to gain experience in medical device consultancy. Formerly with the MHRA, she was responsible for the technical handling of clinical investigation notifications and the regulation of medical devices. Whilst at MHRA, she maintained a register of UK manufacturers of low risk devices and in-vitro diagnostic devices and assisted in the operation of the vigilance system for adverse incidents reported by manufacturers with regards to those occurring within clinical trials and handled code of practice queries on the medical device regulations. Tina is an experienced in EU and US medical device regulation, as well as a clinical trial monitor.

EXPERIENCE:

Regulatory and Clinical Consultant, Emergo UK (formerly Mediqol Limited) – 2004 to Present

Working with numerous clients, from multi-national corporations to SMEs, which manufacture products varying from low risk to high risk medical devices. Consultancy has involved both European and United States medical device regulations covering regulatory and clinical aspects, and UK reimbursement. Below is a summary of the types of projects that have been managed and completed.

Regulatory:

- Medical device regulatory documentation - Production, compilation, consolidation and management of medical device technical files, design dossiers and GHTF Summary Technical Documentation (STED)
- Preparation and management of MHRA RG2 medical device registrations
- Preparation of risk analysis reports in accordance with ISO 14971
- Generation of clinical evaluation reports - Production of critical evaluation of relevant scientific literature reports for inclusion in CE marking regulatory submissions to address clinical data requirements in accordance with MEDDEV 2.7, involving comprehensive literature searches for Class I, IIa, IIb and III medical devices, including surgical instruments, catheter introducers and orthopaedic devices
- Management of medical device recalls - Managing the recall process; undertaking a variety of tasks associated with recalls in the UK involving assisting with tracing the location of affected devices, contacting (including visits) with UK customers (including hospitals, retailers and surgeons); arranging device returns/replacement, preparing and/or reviewing regulatory documentation pertaining to the recall including that for submission to the MHRA
- Compilation and management of Design History Files as per US requirements in preparation for US FDA audits



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- US FDA 510K submissions - Including assistance with identification and selection of potential predicate device(s), preparation of regulatory submission, assistance with selection of US Agent, establishment registration and device listing
- Provision of interim regulatory support - Regulatory cover to support a number of regulatory obligations including responding to questions from the Notified Body as part of the 5-yearly EC Design Examination Certificate renewal, addressing regulatory requirements relating to a recall situations, responding to requests from personnel for regulatory documents concerning medical devices, ensuring change requests are processed in a timely fashion in accordance with company documented procedure

Clinical:

- Third party audits of clinical data to support regulatory submissions
Collating and formatting clinical data within a clinical facility for submission to the US FDA; including preparation of responses to the US FDA questions on data to support US PMA regulatory submissions
- Clinical monitoring
Case Report Form review and data verification for enrolled study participants in accordance to Good Clinical Practice (GCP) standards; including handling of data queries and study site management

Reimbursement:

- Preparation and management of medical device reimbursement (Drug Tariff) applications for England and Wales, Scotland and Northern Ireland

Regulatory Affairs SPC, Medicines and Healthcare products Regulatory Agency – 2002 to 2004

The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health. As the Competent Authority (CA) for medical devices, it is responsible for enforcing the Medical Devices Regulations, which implement the Directives.

Reporting to the European Regulatory Affairs Manager within the devices division, was responsible for assessing notifications from manufacturers intending to run clinical trials of their devices in order to protect the safety of patients and users in the UK, maintaining a register of UK manufacturers of low risk devices and in-vitro diagnostic devices and assisting in the operation of the vigilance system for adverse incidents reported by manufacturers with regards to those occurring within clinical trials. The post involved working with external customers such as medical device service providers and manufacturers, hospitals (nurses, doctors, consultants), trade unions and the general public, as well as internal customers such as the medicines division (formerly the Medicines Control Agency) and other sections within the DoH. Primary duties included acting as the principal technical handler of clinical investigations and ensuring their co-ordination in line with the clinical investigation process.



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Responsibilities included ensuring that investigations were reviewed within the statutory 60 day period, tracking clinical investigation adverse incidents, processing changes to protocols and assisting manufacturers (and others) with regards to the technical interpretation and implementation of the Medical Devices Regulations and Directives. This involved organising and chairing meetings with manufacturers, (including 'grounds for objection meetings' in the absence of senior colleagues) and providing technical advice and support in the registration of medical devices.

Other duties included; ensuring the smooth running of the section, providing input as requested by the business head, producing monthly and quarterly business reports, identifying and tackling potential problems within the section and specific work areas, devising and ensuring the implementation of procedures and the monitoring of internal performance in terms of meeting targets.

Research Assistant, South Manchester University Hospitals (NHS Hospital) – 2002

Reporting to the Supervisor and Consultant Radiologist at the Nightingale Breast Screening Unit. Responsibilities involved planning, preparing, organising and heading research projects based on Mammography. This included the use of digitisers, recruiting and training participants of projects and devising training programmes. In addition to writing proposals and summary reports, research papers and articles for publication in journals, these were also presented at conferences.

AREAS OF EXPERTISE:

- Efficient project management
- Liaising closely with personnel at all levels including within regulatory authorities, notified bodies, small and large medical device companies, agencies and hospitals
- Regulatory requirements for Class I, IIa, IIb and III medical devices
- Clinical trial monitoring

TRAINING:

- Conducting Medical Device Trials in the EU
- European Regulatory Affairs
- Management
- Quality Assurance
- Negotiating and Influencing
- Presentation skills
- Valuing Diversity



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EDUCATION:

- MSc. Medical Technology Regulatory Affairs - In-progress*
*[*All modules passed, Thesis currently pending]*
- MSc. Biomedical Engineering - 2002
- B.Eng. Medical Engineering – 2000

LANGUAGE SKILLS:

- Gujarati - Mother tongue
- English - Fluent
- Hindi - Good