



Joanne Harwood

Senior QA Consultant

Joanne has expertise and experience in the maintenance of QA Systems to ISO 9001 and ISO 13485: 2003 (including the analysis of complaint and CAPA data, conduct of internal audits and representation at Notified Body audits).

She has specific expertise working with Quality Management Systems for start ups and small organizations, as well as expertise in the development and implementation of Quality Management Systems that comply with ISO 13485: 2003, 21 CFR Part 820 (FDA Medical Device Quality System Regulations) and SOR/98 282 (Canadian Medical Device Regulations) and 93/42/EEC Medical Device Directive, as amended by Directive/2000/47/EC.

She is has specific experience in relating to the production, compilation, consolidation and management of medical device technical files; both OBL and full CE Marking technical documentation for a wide range of medical devices.

She also has experience in the preparation and management of MHRA RG2 medical device registrations, preparation of risk analysis reports in accordance with ISO 14971 and Drug Tariff Applications.

EXPERIENCE:

Senior QA Consultant, Emergo UK (formally Mediqol) – August 2005 to Present

Quality Assurance Officer, Tissuemed Limited) – January 1998 to August 2005

Responsible for ensuring the dispatch of stability samples for testing (in-house / test houses) and ensuring results are reported back to senior management. To release finished product. Shipment of finished product (UK & abroad) ensuring packaging, documentation checks all complete. To organise and execute the control of processing records and device history records and perform batch review and failure investigations. To review and evaluate process concessions / waivers relating to finished product. To initiate the procedures relating to batch failure investigations and monitor progress on any associated corrective actions. Develop and maintain product Design History Files. To prepare, distribute and control quality related documents including management of the Document Control System. Responsible for the CAPA system i.e. corrective action follow-up activities, preventive action and internal audits to ensure compliance with ISO 9001: 2000, ISO 13485: 2003 and Company procedures including creating and management of the Internal Audit Schedule. Participate in the Quality System Audit System as an Internal Auditor. Develop and maintain the Training and Development System in conjunction with all departmental managers and supervisors. Represent the company during Notified Body Surveillance Visits. Develop and maintain the Training and Development System in conjunction with all departmental managers and supervisors. Develop and maintain the Approved Supplier System conducting supplier audits when necessary. Responsible for purchasing in its entirety i.e. develop and maintain purchase specifications for new products and liaise where necessary with external sources,



Joanne Harwood, continued...

liaising with suppliers regarding discounts, lead times etc., purchase requisitions, purchase orders. Responsible for Goods Inwards i.e. taking delivery of goods ordered, booking in accordingly ensuring Certificates of Analysis, Material Safety Data Sheets, Materials Certificates etc. are present, prior to releasing goods into stock. Responsible for stock control i.e. releasing items into stock, placing items into quarantine whilst any discrepancies are resolved, maintaining stock control sheets and material request forms for finished stock and raw materials. Management of the Calibration / Maintenance System. Create a QA monthly report and report findings at the monthly Senior Management Meeting.

Engineering Assistant, TOTAL Oil GB Limited – 1996 to January 1998

Dealing with regional insurance in its entirety i.e. placing of works orders, entering details / commitments and liquidations onto a controlled spreadsheet, accrue annual expenditure of grants and agree balances outstanding. Maintain records of all budgets and prepare quarterly budget figures. Carry out accruals on a quarterly basis. Entering invoices onto purchase ledger system for authorisation and forward authorised invoices to HO for payments raising debits and credits accordingly. Control of the interceptor cleaning programmes i.e. payment of invoices, distribution of certificates and recharges. Updating maintenance contract records and submitting recharges to HO on a monthly basis. Controlling non-domestic rates for areas 301-304.

Reception/Secretary, Mr S. B Mehta – 1993 to 1996

Dealing with queries via the telephone. Arranging appointments. Typing of medical reports. Producing invoices / receipts. Photocopying. Dealing with incoming/outgoing mail.

Reception, Metrodome Leisure Centre – 1989 to 1992

Dealing with queries. Arranging appointments. Processing payments for swimming lessons, gym membership, admittance into leisure centre

TRAINING and CERTIFICATIONS:

- City & Guilds – 7430 Quality Assurance (Part I)
- NVQ Business Administration - Part I
- NVQ Business Administration – Part II
- RSA Typewriting Stage 1 (Part 1 & 2)
- 8 GCSEs
- Creating a process-based Management System for BS EN ISO 9001: 2000
- ISO 9001: 2000 Internal Auditor Training
- Quality System Regulation 21 CFR Part 820