

Independent quality and regulatory support for **medical device manufacturers**.

Day rates

Remote or on-site · half days available

SERVICE

RATE

QMS Internal & Supplier Auditing

ISO 13485:2016 · ISO 9001:2015 · audit report and CAPA follow-up

£600 /day

Certification Readiness

Gap analysis, Stage 1 & Stage 2 preparation, mock audits

£600 /day

MDSAP Preparation

1–2 jurisdictions £600 · 3+ jurisdictions £650 (US, CA, BR, AU, JP)

£600–650 /day

Regulatory & Technical Documentation

UK MDR · EU MDR/IVDR technical files · ISO 14971 risk files · FDA · priced by complexity

£600–700 /day

Ad Hoc Advice

Questions, document reviews, regulator or notified body queries (1 hour minimum)

£85 /hr

Introductory rates are available for new clients on request.

FIXED PRICE

ISO 13485 Gap Assessment

Two-day assessment of your QMS against ISO 13485, with a prioritised action plan and debrief.

£1,200

ONGOING SUPPORT

Fractional Quality Lead

Regular QA/RA support covering management review, CAPA, PMS and audit cover. Three-month minimum.

£2,400 /month · 4 days

TRAINING

Regulatory Training

Online modular courses: ISO 13485, ISO 14971, EU MDR, FDA, AI in RA. In-house on request.

£495 /delegate

20 yrs

Medical device quality and regulatory

Notified body

Auditing background



Your internal audits have become a key pillar of the QMS improvements through 2025.

— Head Diagnostics

Rates exclude VAT where applicable. Travel and accommodation for on-site work are charged at cost. Fixed-price quotes are available for defined scopes. Invoiced monthly in arrears on 30-day terms.