



High Edge Consulting Ltd

*Providing regulatory & quality compliance solutions
to the medical device industry*

“Their friendly, practical advice ensured we complied with the regulatory and quality systems in a way that enhanced the manufacturing process without disengaging our workforce. Well done!”

Andrew Debbage— Quality Manager, Lombard Medical Technologies



FS 553361



EMS 553363



Company Membership

A COMMITMENT TO QUALITY





Regulatory Affairs

- ✓ CE Marking
 - Medical Device Directive (93/42/EEC)
 - In Vitro Diagnostic Medical Device Directive (98/79/EC)
 - Active Implantable Medical Devices Directive (90/385/EEC)
- ✓ Technical Files
- ✓ Design Dossiers
- ✓ Risk Management
- ✓ Clinical Reviews
- ✓ Biological Evaluations
- ✓ Country Registrations
- ✓ Auditing to MDDs
- ✓ Worldwide compliance including
 - USA -510K, PMA, 483s
 - Canada—CMDCAS & SOR/98-282
- ✓ Training



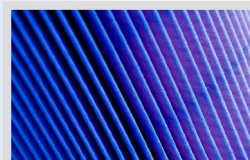
Quality Assurance

- ✓ ISO 13485
- ✓ ISO 9001
- ✓ 21 CFR 820
- ✓ Internal & supplier Auditing
- ✓ Gap Analysis
- ✓ Training



Training

- ✓ Regulatory courses
- ✓ Quality courses
- ✓ GMP courses
- ✓ Public & In house



Microbiology

- ✓ Results review & trending
- ✓ Sterilisation validation
- ✓ Cleanroom & Contamination control
- ✓ Training

How do we get our product CE marked?



We are new to medical devices manufacturing – what do we need to do?

Vio Healthcare

Design Dossiers are a mystery to us—we need someone who knows and can do them for us

What ever your question or needs

We need expert help for this



Call us

0115 921 6200

We need help to do to get our product into the USA and Australia

We need a gap analysis between ISO 9001 & ISO 13485



We need someone to oversee our Sterilisation validation



We are behind in our internal audits and need to outsource them

We need someone to cover this for 3 or 4 months



Solutions in Healthcare Packaging

How do we know who is the best candidate to employ when we do not know enough about regulatory affairs



A training programme to raise our skill levels is what we need

We need someone to work with us on our risk assessments for our devices



'Having worked with High Edge for a number of years I have always found them helpful and willing to offer relevant advice to the situation we are working on. High Edge bring a fantastic mix of professionalism and personality making the issues we face seem less daunting and more manageable.'

Neil Campbell - Managing Director, Inspiration Healthcare

“We were faced with a challenging validation project which required some ‘out of the box’ thinking and external resources. This is where High Edge came in. What impressed us most was that our High Edge Consultant was prepared to think laterally while still holding true to all the applicable regulations and standards. The result was that we achieved regulatory approval for our new product on target and on budget.”

Chris Brotherston, Regulatory Compliance Manager, Biosil Ltd



Whatman



Amba Medical



RANIER
TECHNOLOGY

Nuffield Orthopaedic Centre **NHS**
NHS Trust

P³ Medical



High Edge Consulting Ltd

Based in Nottingham covering the UK

BioCity Nottingham

Pennyfoot Street

Nottingham

NG1 1GF

Call Peter Rose

Tel 0115 921 6200

peter@highedge.co.uk



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