



High Edge Consulting Ltd

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High Edge Consulting selected as the exclusive supplier of regulatory and quality assurance consultancy to Isotron.

High Edge Consulting and Isotron, providers of contract sterilisation services, are pleased to announce their collaboration in the delivery of QA and RA support to the medical device sector.



Isotron is Europe's leading provider of contract sterilisation services. Through a network of 19 sites in 9 countries across Europe, Asia and South Africa, Isotron provides outsourced services to manufacturers; in particular sterilising single use medical products, enhancing the performance of polymers and providing technical laboratory services.

This collaboration creates invaluable links between Isotron and High Edge Consulting, which will benefit both companies' clients. By working together, the manufacturers of medical devices can now have expert advice on both sterilisation technologies and on compliance to the relevant Directives and Standards.

This collaboration will also enhance the high levels of technical expertise delivered by Isotron's microbiological laboratories, based in Thorne and South Marston in Swindon. The laboratories have 20 years of experience in microbiological testing of medical devices to ISO11137 and ISO11135 plus carrying out routine Bioburden, Sterility, Environmental Monitoring and Pyrogen (LAL) Testing.

Mike Eaton (UK General Manager, Isotron) comments: "This collaboration with High Edge Consulting will enhance the service and support we can offer our clients. Their experience in serving the medical devices sector will complement Isotron's technical expertise and together we will be able to provide an excellent knowledge base with which to support customer requirements. We are very much looking forward to working with High Edge and developing a strong partnership."

Peter Rose (MD of High Edge Consulting) comments: "Isotron are the leading supplier of sterilisation services in Europe. Their commitment to delivering these services at the highest levels of quality and regulatory compliance complements our values. We are looking forward to working with the processing sites and their microbiological laboratories to enhance the knowledge of regulatory and quality compliance in the demanding medical devices sector."

About High Edge Consulting

High Edge Consulting, based in Nottingham, has many years experience in working with the various Directives and Standards, most notably the Medical Devices Directive (MDD) and ISO 13485. High Edge Consulting operates primarily in the UK but has undertaken projects across Europe and USA. Their associates in the USA ensure that they can work fluently with the FDA and other regulatory bodies. In addition, High Edge Consulting has excellent relationships with the many of the Notified Bodies.

Contact

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