

*The Benefits of ISO certification...***MEDICAL EDITION**

Standards – the Difference Between Life and Death

The medical industry is the ultimate service business sector, where mistakes can really make the difference between life and death. The introduction of the ISO Management Standards impacts immediately on any size business within this highly specialized sector. Working in partnership with IMSM one of the leading suppliers in delivering the ISO standards gives to companies a recognizable lift in team spirit, quality delivery and competitive edge. ISO Management Standards are recognized across the world and seen among many successful companies, as a major "must-have" foundation stone to the building and growth of a better business.

A standard-driven culture

"This standard is important for the medical diagnostic industry."

implemented the procedures necessary for achieving ISO certification.

Many of JAS Diagnostics' customers view the quality standards as symbols of competence and will only use suppliers that are registered. It is usual for many of their clients to audit suppliers before agreeing to do business with them. Prior to certification this procedure could be lengthy, but since registration the whole process is much simpler and they are more successful with new tenders – to become a preferred vendor all they have to do is answer a few questions and send off their ISO certificates removing the need for any further questions.

As well as enhancing their company image the standards have helped them to streamline procedures, increase capabilities and retain existing and new business. This has helped them to remain successful during the recession.

Working in a standard-driven culture meant that employees were used to following procedures. This, combined with IMSM's expertise and guidance, ensured that they met and exceeded the requirements for ISO 13485.

"This particular standard is both relevant and important for the medical diagnostic industry. IMSM are very responsive and helped make the entire process stress free. We first decided to use IMSM because of their competitive pricing. However we have also been extremely pleased with the high level of service they have provided. We've had a really good working relationship with them so far and would definitely recommend them to other businesses within the medical industry," comments Sam Burgof, Director.

www.jasdiagnostics.com

International Management Systems Marketing Ltd (IMSM) was founded in 1994 to add value to businesses around the world by providing structured management systems which increase their efficiency and competitiveness, through internationally recognized standards. From its UK headquarters, IMSM has developed a strong network in Europe, USA, Canada, South Africa, and the Asian Pacific region. IMSM's fully trained and experienced team of auditors hold IRCA (International Register of Certified Auditors) qualifications. The company is an active member of business and quality organizations around the world. See website for details.

Accurate assessment

Almost thirty years ago, IMSM customer RJL Systems, based in Michigan, was the first company to develop the use of Bioelectrical Impedance Analysis (BIA) to assess human body composition.

Their BIA analyzers are now recognized and trusted worldwide by professionals such as researchers, clinicians, and government employees. Today their instruments are used for a wide variety of different applications. These include monitoring healthy weight loss in individuals, assisting medical care providers with evaluating the body composition of their patients, and measuring the water content of fruit, vegetables, fish, poultry and meat.

Accuracy is vital in this line of work and it is paramount that only products with the highest quality, safety, and reliability are produced. RJL is always looking to build upon their experience and expertise. This involves a united focus on innovation and quality, as well as continuous improvement of their processes. The ISO 13485 is the most respected quality standard in the medical field. Therefore with IMSM's assistance they undertook the internal work necessary to achieve certification.

They have always had good systems in place but gaining ISO 13485 has given them an even greater confidence in the quality of their products. Their customers are now 100% assured that the rigorous testing, calibration and inspection processes they have in place are amongst the best in the industry. This results in first rate products that their customers can completely trust.

The ISO 13485 is fast becoming the medical industry standard. They have noticed many of their clients now insist that it is in place. They initially chose IMSM because of their competitive price. As IMSM helped prepare them for audit they were also very impressed by their extensive experience and professionalism.

"We are committed to providing innovative, high quality products that completely meet our clients' evolving needs. The nature of our work means that it is vital for us to remain up to date with the latest industry standards. Our experience and expertise combined with our ISO certification place us at the forefront of our industry," concludes Rudy Liedtke, CEO of RJL Systems.

www.rjlsystems.com



"ISO 13485 is fast becoming the medical industry standard"

To date, IMSM has helped more than 8,000 organizations around the world to achieve ISO 9001 certification

www.imsm.com – international standards are our business

Clinical Precision

IMSM had the pleasure of working with International Tube, based in Pottstown, Pennsylvania, to help them implement ISO 13485. The benefits of this standard to the medical device industry include international recognition of compliance with the FDA Quality System Regulations and unique medical industry standards, thereby facilitating global business, creating a more efficient, cost-effective and stable organization and improving process, product and service quality. It also improves documentation of existing processes.

International Tube is a specialty metal tubing company supplying the medical, electronic and industrial markets with high quality products and a personalized service, together with cost-effective solutions. Access to specialized engineers helps the business provide solutions to both current and future requirements in an environment of constant technological change. The company has a proven track record and an extensive knowledge base, with the objective of supplying cost effective products that meet customers' requirements and providing the very best service available, so IMSM knew that they were working with a company who was already committed to its customers.

Talking about the reasons for pursuing compliance to ISO 13485 and the perceived benefits, Lance Heft, President said, "There is a trend among medical device companies to

require compliance to this standard. However, our main desire was to further improve our internal accountability and processes."

The benefits derived from being ISO certified are improved internal processes, better relationships with customers and better understanding by employees of the company's quality requirements.

Lance concluded by saying, "IMSM were with us every step of the process, provided clear objectives, explanations and expectations and were great to work with. All in all, very professional."

www.internationaltube.com



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A natural choice

JADAK LLC has been working with IMSM for more than 6 years on its ISO 9001, so IMSM was a natural choice when the company decided to pursue compliance to ISO 13485.

Headquartered in Syracuse, New York, JADAK was founded in 2000 to address the unique needs of health care companies requiring innovative, low-risk and cost-effective solutions. The company has grown to provide both off-the-shelf and customer specific data collection and machine vision technologies to a majority of the top global health care companies, while focusing specifically on medical device manufacturers. JADAK solutions include bar code, RFID, machine vision and data communication technologies for a wide range of medical devices, and include full product development and manufacture on behalf of its OEM customers. Engineering, customer support and product support personnel in the US and in Europe provide worldwide product and customer service from North America to East Asia.

David P. Miller, President said, "JADAK is always striving to improve its operations and ISO 13485 seemed a natural and beneficial progression. We utilize ISO 13485 as another tool to ensure that we have the proper disciplines and procedures required to work intimately with our health care customers."

"Our global customer base requires us to constantly improve our product realization process and to be able to communicate improvements and innovation in a way that is salient for our customer - and theirs - in a wide variety of markets that are constantly in change. We see our compliance to ISO 13485 helping to improve communications with our customers about our quality procedures and product reliability, from development to delivery."

The company's customers often have unique requirements that demand creative solutions; as a result it has created the Flexpoint™ family of reference designs and platforms. Flexpoint enables customers to use JADAK's existing designs, which reduces design time and expenses when compared to brand new, ground-up designs.

David added, "Compliance to ISO 13485 is something all JADAK employees are proud of, and it enhances our dedication to providing world class quality solutions for our healthcare customers.

"IMSM's service and staff are excellent. We have mentored some of our suppliers through the ISO 13485 process and have encouraged them to use IMSM."

www.jadaktech.com



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Commitment to Excellence



IMSM Limited is delighted to announce that the company has achieved the European Foundation for Quality Management [EFQM] Recognized for Excellence Award. This internationally recognized Award acknowledges that IMSM is a high performing organization, which operates

within a management framework, defining what they do and explaining why they do it. The EFQM Excellence Model is the most widely used organizational framework in Europe, and the basis for the majority of national and regional Quality Awards.



Email: enquiries@imsm.com
Web: www.imsm.com

Your Local Business Manager: