

The Full BSI Solution allows Groupe Bertec to penetrate new markets and maintain a competitive advantage



"We have been using Entropy since the launch of our new company. It has been a big plus for us. BSI was a partner for years; the trust was there to continue working with them for the ISO 9001 & 13485 Certifications, and through the Entropy implementation."

Marie-Sarah Brunet
Regulatory Affairs Representative
Groupe Bertec Inc.

Customer needs

The management of Groupe Bertec understood that, in order to successfully establish their own new business, they would need a software system in place to manage their quality system. There was also time sensitivity as the new Groupe Bertec was set to launch as an independent entity in June 2012.

Customer benefits

The ISO 13485 Certification allowed Groupe Bertec to be able to sell in the United States. Entropy helps them with the document control (including change control), management reviews, audits, corrective

and preventive actions, non-conformities, calibrations and training. That helped the staff get up to speed with the new system.

Because of the Entropy solution, they are now paperless. They are faster on their feet when getting requests for documentation. They can easily look at documents, calibration, audit results and follow-up, corrective and preventive actions. There is a reduction in risk as there is a decrease in lost or miss filed documentation.

Even though Groupe Bertec is a small company, they work as effectively as a large one, and this allows them to have a competitive advantage.

Customer Background:

Groupe Bertec is made up of a talented and specialized team in the field of medical devices. Certified ISO 9001:2008 and ISO 13485:2003 CMDCAS, and registered with Health Canada and the FDA, the company has the experience it takes to develop and bring into production all kinds of medical equipment. Their core competencies are innovation, metal fabrication, mechanical assembly and electronics. Previously a division of a multinational, Groupe Bertec has been an independent company since June 2012.

In 2012, Groupe Bertec was in the midst of transitioning from a multinational as they worked to become an independent body, which meant they would leave behind the platforms and applications that were part of the multinational umbrella. They knew that in building their own business, they would need a software system in place to manage their Quality system.

The key values of the organization are Service, Quality, Innovation, Responsibility, Integrity, and Respect.

Core offerings of the organization

- Core Offerings: Hospital beds, expertise in manufacturing, design and servicing of medical device
- Core markets: Customer segments: Healthcare environment (homecare, hospitals, long term or acute care establishments, rehabilitation centres).
- Locations : L'Islet, 45 minutes east from Quebec city
- No. of staff : 90 employees
- Industry/sector: Medical Devices
- Annual turnover/sales: \$12 million
- Key values of organization: Servicing, quality, innovation, responsibility, integrity, respect
- Strategic direction of organization: Maintain presence in Medical Device Sector but develop new expertise within alternative markets.

Needs / Drivers / Challenges faced by your Organization

One of Groupe Bertec's strategic goals was to be able to sell into the US Market. In order to do this, ISO 13485 Certification was a requirement. As well, export to the US demanded that the company be 820 CFR 11 compliant, in regards to their documentation. Moreover, they wanted to be efficient, safe, and fast as they went to market. As the Medical Device Sector is highly regulated, the need for a document control system became increasingly necessary.

The Full BSI Solution

BSI had been Groupe Bertec's Certification Body and had been conducting their ISO 9001 and ISO 13485 surveillance audits for years. They had a good working relationship, built through trust and support over the years. When it came time for re-certification, Groupe Bertec turned to BSI again.

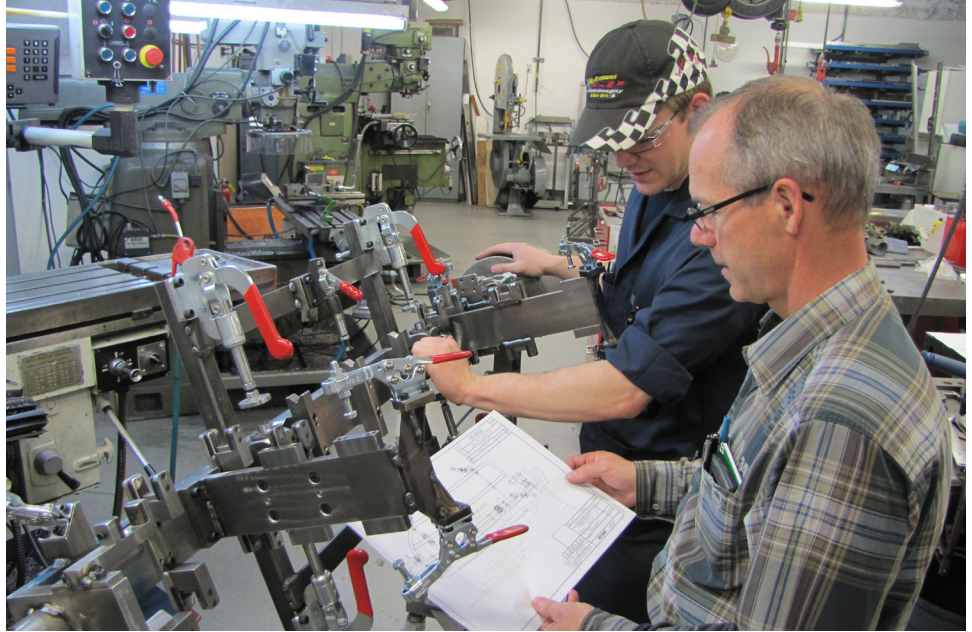


The Groupe Bertec Entropy opportunity started with a meeting during a trade show in November 2011. Groupe Bertec was in the midst of transitioning from the multinational subsidiary to an independent body, which meant they would leave behind the platforms and applications that were part of the multi-national. They knew that in building their own business, they would need a great solution to be as efficient as their competitors. There was also time sensitivity as Groupe Bertec was set to launch as an independent body in June 2012. They needed an affordable yet comprehensive solution that answered their business needs: to penetrate the US Market, to be competitive, to be efficient and paperless in the process.

Why BSI?

BSI responded immediately with the Entropy Solution. Meetings were set up between the two groups, who engaged many of their management team, including IT and Quality. The BSI team worked diligently on this deal, bringing in support from the Sales Support team and Sales Engineers, who conducted demos and provided full information on the system and answered questions thoroughly, allowing the Groupe Bertec to feel confident about their decision.

As BSI was a partner for years; the trust was there to continue working with them for the ISO re-certifications, and through the Entropy implementation.



ISO 13485 and Entropy Implementation

Because of past work as a multinational, Groupe Bertec had the experience and best practices in place to make sure they were able to maintain their ISO 9001 & ISO 13485 Certifications.

They put in place a team of 6 persons, who were in charge of implementing the Entropy system. This team had, as a mandate, to input all of the documentation and information needed, and then, train the rest of the organization.

The Entropy implementation team of 6 did the main part of the job but the IT department was also part of the implementation. After the base was created, every employee was able to add the required documentation and information to stabilize the system. Although every staff member was involved in some way, the Quality,

Regulatory, IT, and HR departments were the most involved in the Entropy set up.

Since Groupe Bertec was well prepared, the development process was easier than expected. Training helped the staff get up to speed with the new system. As Groupe Bertec already had their documentation structure in place, it took less than 3 weeks to get the Entropy system up and running.

Through the implementation, the BSI team was always there and gave Groupe Bertec great support and recommendations. Moreover, Groupe Bertec had the opportunity to have discussions with other companies that had already implemented Entropy; they provided some guidance and direction.

Existing Solutions

Groupe Bertec is certified ISO 9001 and ISO 13485. They also work with ISO 14971 (risk management), the IEC 60601-1, IEC 60601-2-52, CE Mark standards (for the European market), and NAWI standards.

For the Training needs, Groupe Bertec placed all the information on their staff and courses in Entropy. This simplified the paperwork and the follow-up for training.

Every internal and supplier audit are created, filled-in and followed in the Entropy system. The system allows for easy overview of the supplier quality situation.

Long term benefits of the Full BSI Solution

The ISO 13485 Certification has allowed Groupe Bertec to be able to sell in the United States and easily prepare for launch into the European market. Entropy helps them with document control (including change control), management reviews, audits, corrective and preventive actions, non-conformities, calibrations and training. It helped the staff get up to speed with the new system.

They are now paperless. They are faster on their feet when getting requests for documentation. They can easily look at documents, calibration, audit follow-up and results, corrective and preventive actions. There is a reduction in risk as there is a decrease in lost or misfiled documentation.

Even though Groupe Bertec is still a small company, they work as effectively as a large one, and this provides them with a competitive advantage.

Groupe Bertec has achieved the stability and functionality of big start-up company in just a few weeks. They are continuing to look for more ways to work with BSI and the Entropy system in areas not yet optimized.

BSI and Groupe Bertec, a successful partnership

In the end, the speedy and effective response of the BSI team to a time sensitive and urgent customer need resulted in a quick and successful Entropy implementation, allowing the customer to fulfil their strategic objectives. The Full BSI Solution, of Certification, Entropy, and Training, allowed Groupe Bertec to achieve & maintain their ISO Certifications, train their people, and expand into new markets, making their new business successful and competitive.



Your business could benefit from the BSI Full Solution: Certification, Entropy, & Training, just like Groupe Bertec, Inc.

To find out more, visit www.bsigroup.ca/quality or call 800 862 6752 for details.

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The mark shall never be applied directly on the product or service.