opSens | Medical

Global market access with a global regulator

"Negotiating regulatory hurdles in different markets can be challenging; working with BSI has streamlined the process and eased the pressures on our business."

Vanessa Mootoosamy,
Quality Manager at Opsens Inc.

Which markets does BSI work in?

- Europe
- Japan
- Hong Kong
- United States
- Brazil
- Taiwan
- Canada
- Malaysia
- Australia

Opsens at a glance

Opsens Inc. is a Canadian-based manufacturer of fibre optic sensing solutions. Opsens' primary focus is on the measure of Fractional Flow Reserve ("FFR") in interventional cardiology. Their key product offering includes an optical-based pressure guidewire, aimed at improving the clinical outcome of patients with coronary artery disease.

Opsens is also involved in industrial activities, providing fibre optic sensing solutions for demanding industrial applications, such as the monitoring of oil wells.

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Opsens is active in a number of countries, and therefore is required to meet the regulatory requirements of each market, including

- Canadian Medical Devices Conformity Assessment System (CMDCAS)
- European CE Marking,
- Japanese Pharmaceutical and Medical Devices Agency (PMDA) requirements (previously the Japanese Pharmaceutical Affairs Law, or JPAL).

Opsens also need to demonstrate an appropriate Quality Management System (QMS). By selecting BSI as its regulator, Opsens is able to meet these global requirements with the knowledge of a dedicated, expert team.

Global market access: the regulatory hurdles

Varying medical devices regulations across the global markets have always caused challenges to international medical device manufacturers. Not only are there a number of different regulatory requirements to meet, but the associated audits and internal preparations for each market can be time consuming.

There are a number of necessary international, regional and national standards that are required to be met, coordination of which adds another level of complexity to the process.

Despite the regulatory bodies of each market having similar goals, the requirements of each market vary, making the preparation for application more challenging. As the number of countries issuing requirements for medical devices increases, the challenges of meeting and managing these requirements also increases.

As an international manufacturer, Opsens requires a Notified Body in the EU, a CMDCAS Registrar in Canada, and a Registered Certification Body (RCB) in Japan. As Opsens expanded its business globally and began to enter more markets, the decision was taken to use one regulatory body for these activities. This would allow for more streamlined and efficient regulatory processes, and easier management of its regulatory affairs.

Working with BSI: realising the benefits of excellence as a habit

BSI's reputation as a long-standing global leader in regulatory compliance led to Opsens choosing BSI as a regulatory body. Already used by number of Opsens' business partners, Opsens had faith BSI could meet its regulatory needs.

BSI can act as your:

- EU Notified Body
- QMS Assessment body
- Medical Device Single Audit Program (MDSAP) Auditor
- Canadian CMDCAS Registrar
- Registered Certification Body in Japan
- Brazilian National Institute of Metrology, Quality and Technology (INMETRO) Auditor
- Good Manufacturing Processes Auditor in Brazil and Taiwan
- Conformity Assessment Body in Australia, Hong Kong and Malaysia

Having chosen BSI, Opsens now has CMDCAS accreditation, permitting access to the Canadian market, CE certification and QMS accreditation, granting market access to the EU, and JPAL accreditation, allowing access to the Japanese market. This required a review of technical documentation, QMS and microbiology audits, to achieve product certification.

The complex regulatory requirements of the different markets, and the need to synchronise the necessary review and audit activities, requires an experienced regulator. BSI is able to offer expertise in managing these processes from years of experience working with international manufacturers. BSI acts as a regulatory body in a number of markets, for example as a Notified Body, a Conformity Assessment Body or a Registered Certification Body. The combination of this experience, along with robust technical expertise from an extensive range of product experts, allows BSI to offer rapid and efficient service to Opsens throughout the certification and/or accreditation process. "The technical and regulatory expertise at BSI has helped us to manage the challenges of accessing multiple global markets", said Vanessa Mootoosamy, Quality Manager at Opsens. "Opsens does not hesitate to contact the relevant personnel to ask for clarifications and technical support, if needed... This method has proved to be very efficient for Opsens."

Long term implications: improving business processes

Working with an experienced regulator not only allows timely, efficient and smooth market access, but provides other, longer term benefits in the running of a business.

Achieving market access has allowed Opsens to expand into wider markets, and to increase its revenue as a result. Using BSI as its regulator has afforded customer loyalty and trust in its products. Additionally, the experience that BSI has in these markets, and in managing international clients, along with a large number of technical experts within the team, affords swift and efficient market access, allowing Opsens a competitive advantage.

Opsens is also able to run more effective processes and can have confidence that its processes are compliant. Working with practiced and knowledgeable auditors

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allows Opsens to continually improve its quality management system, providing security to its customers that product quality is consistent.

Benefits to the wider business:

Compliance benefits

Compliance with QMS and regulatory requirements can aid entry into other global markets, can help to secure relationships with business partners, and can inspire customer confidence and loyalty. It ensures that processes are efficient and compliant, leading to cost savings.

Increased Return On Investment (ROI)

By achieving international market access, Opsens now has more revenue-generating opportunities, and is able to market products with confidence of compliance. Reaching more customers with safe and effective products will improve the RoI for Opsens.

Risk reduction

There are a number of regulatory bodies that offer products and services to allow market access and to ensure compliance. BSI has over 1,750 years of experience, and has a large, knowledgeable team of experts to provide the certification and audit services. Opsens can be secure in the knowledge that it is working with a practised regulator, and can take confidence in BSI's own processes in providing certification, reducing the risk in its regulatory affairs.

In addition to receiving product and system certification from BSI, Opsens is able to take advantage of a range of other products and services available to them. This includes purchase of the relevant Standards and training from experts on regulatory requirements.

Looking forward to further benefits

The challenges of entering global markets have been recognised by the regulatory authorities, and this has led to development of the Medical Devices Single Audit Program (MDSAP) by the International Medical Device Regulators Forum (IMDRF). This program aims to provide one audit to assess against multiple Standards and Regulations, improving the efficiency of compliance processes for international manufacturers. The program includes the United States, Japan, Brazil and Australia; Canada will replace the requirement for CMDCAS with MDSAP from January 2017. As a global regulator with experience in these markets, BSI was well placed to become an accredited MDSAP Auditing Organization, and has been involved in the program during the pilot phase.

Opsens will require MDSAP assessment in place of its CMDCAS accreditation, and this will further streamline its processes in other markets, including Japan. Using BSI as its MDSAP assessor is favourable to Opsens, as this prevents the need for an additional regulatory body, and ensures processes and communications can remain efficient. Opsens also has confidence in BSI from previous experience, and mitigates the risk of introducing an additional regulator.

BSI's position as a respected global regulator provides its customers with confidence that it will be able to support a range of regulatory needs. Whether your business already trades internationally, or will require scalability of regulatory support in the future, BSI can offer the necessary services and support throughout global markets.

In addition to allowing market access, Opsens has found that BSI provides them with international recognition, and a competitive advantage. Mootoosamy explains "Working with BSI gives our customers confidence in the products they're purchasing from us, because of BSI's reputation as a robust and trusted regulator."

Talk to BSI

We believe excellence should follow in everything we do, so if you would like to find out more about global market access through BSI, please call or email us for an initial conversation

Call: **+44 345 080 9000**
Email: **eu.medicaldevices@bsigroup.com**
or visit: **bsigroup.com/medical-devices**

BSI Group America Inc.
12950 Worldgate Drive,
Suite 800,
Herndon,
VA 20170
USA

T: +1 800 862 4977/703 437 9000
F: +1 703 437 9001
E: us.medicaldevices@bsigroup.com

BSI Group - EMEA
Kitemark Court,
Davy Avenue,
Knowlhill,
Milton Keynes MK5 8PP
United Kingdom

T: +44 345 080 9000
F: +44 1908 814920
E: eu.medicaldevices@bsigroup.com

BSI Group Asia Pac
BSI Group - Hong Kong
23rd Floor, Cambridge House
TaiKoo Place,
979 King's Road,
Island East, Hong Kong

T: +852 3149 3320
F: +852 2743 8727
E: hk@bsigroup.com