



Specsavers Case Study

A standards solution for a global network
of locally run businesses

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A standards solution for a global network of locally run businesses

Martin Lockton, Regulatory Affairs Manager at Specsavers looks at the challenges of certification and compliance for a major high street retailer and manufacturer.

Specsavers is a partnership of nearly 2,000 locally run businesses. Founded over 30 years ago by Doug and Dame Mary Perkins, our business pioneered the optical joint venture partnership model and we now provide product, support and marketing to over 2,300 partners and 30,000 people working across stores, offices, laboratories and factories worldwide.

We are growing globally, and at the latest count we were serving 30 million customers in the UK, Ireland, Denmark, Sweden, Norway, Finland, Holland, Spain, Australia and New Zealand. All of our frames and lenses are classified as medical devices and this makes it a legislative requirement for us to be registered with a notified body.

Every partner operating in each country needs to have complete trust in the products they are supplying, which means we need to be able to demonstrate legislative compliance in every market we are operating in. Unfortunately, there is no one size fits all solution and each of these markets has its own individual requirements and idiosyncrasies. Also, to further complicate matters, our manufacturing takes place across multiple sites, with some stores also creating products in their own laboratories.

Our driving ethos is, and always has been, to make eye-care (and our other services) affordable to everyone. We are constantly interrogating every possible opportunity to improve and refine how we operate. This includes ensuring that we can provide and access standards in the most efficient way possible throughout our supply chain.

Working with BSI is essential to achieve these efficiencies. Over the past year we have been able to consolidate nearly all of our certification and compliance with BSI. Moving from two, to using just one notification body has meant we are no longer duplicating processes such as audits in multiple sites. BSI visits our premises and analyses our technical files, delivering full surveillance audits to ensure we are always compliant.

By subscribing to British Standards Online (BSOL), we are able to provide all of our staff and partners with access to a full suite of standards (without having to buy individual standards for each site, which is a huge saving). We currently subscribe to BSOL where we can add up 50 different standards to our package.

We have 42 standards, having added three in the last year, it being very easy to add new standards when the need arises. BSOL also updates automatically, alerting us to any changes to the standards in our collection. Knowing that we are being proactively kept up to speed with any changes gives ultimate reassurance that we are always fully compliant and operating in the best possible way.

Everyone should use standards. From the person working from their shed at the bottom of the garden to a worldwide company like ours, standards provide a baseline for quality control – a strong and secure foundation on which the business can grow.

About the new ISO 13485 2016

The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a QMS. Adopting ISO 13485 provides a practical foundation for manufacturers to address the Medical Device Directives, regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices. It helps to establish and maintain the effectiveness of a manufacturer's processes to ensure the consistent design, development, production, installation, and delivery of medical devices, or related services.

“Everyone should use standards... standards provide a baseline for quality control – a strong and secure foundation on which the business can grow.”

We use standards to inform all aspects of our business, from the medical standards, which are a legislative requirement, to those covering environmental and quality management systems and health and safety. We are able to define the quality we expect of our products, wherever they are being manufactured, right down to the tiniest scratch, ensuring consistency right across our production lines.

We signed up to our BSOL subscription in February 2015 and, as of May 2016, 250 standards have been downloaded by 23 users across 14 sites. Very soon, BSI will be our sole notification body.

We have chosen to work with BSI for all of the reasons I have outlined above. But more than that, we have chosen them [BSI] because they are not a scary regulatory authority but an advisory service with their customer's best interests at heart.

Whether in terms of testing, submitting products or interpreting the standards themselves, there is always someone at the end of the line at BSI to provide help and advice, and for me, it's that human touch that seals the deal.

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BSOL
Standards Online



British Standards Online (BSOL) is the online standards database that makes using standards easier and more cost effective. You can access a comprehensive library of over 90,000 internationally recognized standards.

Specsavers' BSOL subscription includes:

- ✓ A custom collection of up to 50 standards
- ✓ 42 standards in their collection currently
- ✓ 23 users across 14 sites

Relevant industry standards commonly used by **Specsavers**

ISO 13485	QMS (Quality Medical Standard) for medical device industry.
ISO 14971	Application of risk management to medical devices.
ISO 15223	Packaging and labeling standards: symbols to be used with medical device labels.
BS EN 166:2002	Personal eye protection. Specifications.
BS EN ISO 8980-1:2004	Ophthalmic optics. Uncut finished spectacle lenses. Specifications for single-vision and multi-focal lenses.
BS EN ISO 12312-1:2013	Eye and face protection. Sunglasses and related eyewear. Sunglasses for general use.
BS EN ISO 21987:2009	Ophthalmic optics. Mounted spectacle lenses.
BS EN ISO 12870:2014	Ophthalmic optics. Spectacle frames. Requirements and test methods.
BS EN ISO 12311:2013	Personal protective equipment. Test methods for sunglasses and related eyewear.
BS EN 168:2002	Personal eye protection. Non-optical test methods.
BS EN ISO 14001:2015	Environmental Management systems. Requirements with guidance for use.
BS EN ISO 9001:2015	Quality management systems. Requirements.
BS OHSAS 18001:2007	Occupational health and safety management systems.

At a glance: SPECSAVERS AND STANDARDS

SPECSAVERS HAS:

31 million customers



Sold **374 million** contact lenses



Sold **17.3 million** frames (glasses)

2,300 partners worldwide

More than **30,000** people working across its stores, support offices and supply chain

Specsavers

Opticians



Sold **221,000** hearing aids

1,767 optical stores and hearing centers



Raised more than **£2.2 million** across the world supporting local communities



If you would like to find out more about
creating your own digital standards collection
via BSOL please get in touch:

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