

CE-ONSITE FASTTRACK REVIEWS

Real-Time Reviews for Real-Time Results



CE-Onsite Review Benefits

- Experienced Product Experts Visit Client's Site
- CE Marking for Class III Medical Devices
- Reviews in 45 Working Days
- Patients get Faster Access to Products They Need
- Contributes to Meeting Corporate Objectives
- Dynamic Exchange of Information
- Global Launch Capability

Speed, expertise and predictability are essential attributes to stay competitive in today's medical device market place. The demanding challenges of navigating the global regulatory maze, at the same time meeting corporate objectives requires "real time reviews for real time results." To help meet these challenges, BSI, Healthcare brings you our latest FastTrack Review Program—the CE-Onsite. It is a part of our innovative Speed-to-Market Programs* developed for medical devices needing Design Dossier Reviews for European Markets.

CE-Onsite Review* is conducted at the customer's premises, in which BSI Product Experts visit the facility for a dedicated period of time. This expedited premium, interactive service works toward a CE Marking target of **45 working days or less** from submission. Performing reviews onsite allows for a much faster timeline while still maintaining the same high quality review. We offer face-to-face opportunities for dynamic exchange of information and immediate response to questions.

raising standards worldwide™

Meeting the Board's Imperatives and Improving Patient Outcomes

BSI is fully aware of the acute need for "Speed-to-Market" to recoup the significant investment in resource and cost associated with new product introductions, while achieving the overriding objective of introducing effective and safe medical devices to market. The need for the CEO and Board to achieve this and keep the corporation in a competitive position in today's market is paramount.

There is also increasing recognition within broader society and government of the need to deliver better healthcare outcomes by providing improved "Patient Access to New Technology" in a timely manner. CE-Onsite meets both needs: driving efficiency and compressing timelines resulting in a potentially earlier product launch, thereby meeting fiscal imperatives and, more importantly, getting technology to patients sooner!

Compressing CE marking review timelines can result in rapid Product Launch, faster Patient Access to new technology and contributing to Fiscal Imperatives.





Why Choose BSI, Healthcare

BSI, Healthcare is a respected, world-class Notified Body dedicated to providing thorough and pragmatic regulatory and quality management reviews and product certifications for medical device manufacturers.

Product Expertise – Our professional, knowledgeable and responsive Team of Experts include product specialists, engineers, clinicians, microbiologists, quality and regulatory affairs experts that provide in-depth understanding of complex, high-risk medical device technologies.

Global Access – We have more than 100 years of experience and operate in over 100 countries with offices around the world to serve you.

Speed-to-Market – We provide solutions for medical device manufacturers needing accelerated pathways to global markets. Our Speed-to-Market programs include CE-90, CE-45 and CE-Onsite.

Confidence – Clients around the globe trust us to deliver value, confident that our technical capabilities and thorough, robust reviews will stand up to scrutiny in the medical device industry.

Partnership – Establishing a long-term partnership with each client is a vital part of the BSI philosophy. We focus on open communications throughout the review while helping manufacturers understand the processes needed to place compliant products on global markets. We balance independence with partnership to ensure reviews stand up to scrutiny while at the same time working together with you to meet your corporate goals.

Contact BSI to assist you in choosing the right program to meet your objectives:

Tel: 800 862 4977
 Email: Healthcare@bsigroup.com
 Web: www.bsiamerica.com

Team Approach

CE-Onsite helps to harness the power of full team engagement. BSI Product Experts have access to everyone on your team, from designers to regulators, allowing for an accelerated process using “real-time” communication. Plus, our Experts can view your medical devices in-person to gain a more rapid understanding of their function.

Global Launches

Companies using CE-Onsite have expressed the importance of being able to launch their products globally, such as in the US and Europe concurrently. They were able to take advantage of major cost savings in their manufacturing, labeling and translation processes.

Companies that Benefit

Many factors may impact the delivery timeframe, such as the degree to which the customer is organized and prepared. Companies that benefit from CE-Onsite have a high priority of getting their product to market, excellent documentation, along with being well-organized and responsive to questions.

*Our Programs do not guarantee a CE Marking certificate will be issued in a certain amount of working days, but is based on completing the review process with either a positive or negative recommendation. It excludes reviews outside BSI's control (e.g., medicinal, animal, and/or blood products).

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