Regulatory Strategy Review

Ensure you start with Excellence

BSI Regulatory Strategy Review

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...making excellence a habit.™

What is the Regulatory Strategy Review?

A High Level of Confidence

Achieving agreement between a manufacturer and their Notified Body is essential in determining regulatory strategy and represents a major milestone in helping to demonstrate the product launch is on target. This holds true whether you are a multinational corporation with substantial resources or a newly emerging company seeking capital.

Our highly trained BSI Product Experts have the knowledge, background and skill to conduct thorough reviews giving you a high level of confidence that your regulatory strategy is on-track.

BSI provides a written gap analysis report against the relevant requirements, supplying feedback on your Strategy Plan based on the latest European Regulations, Standards and Guidance.

Based on the information supplied, this report can help identify deficiencies within your technical documentation and compliance with the regulatory requirements. In addition, knowledge upfront provides a cost-effective and timely opportunity to amend your strategy if needed.

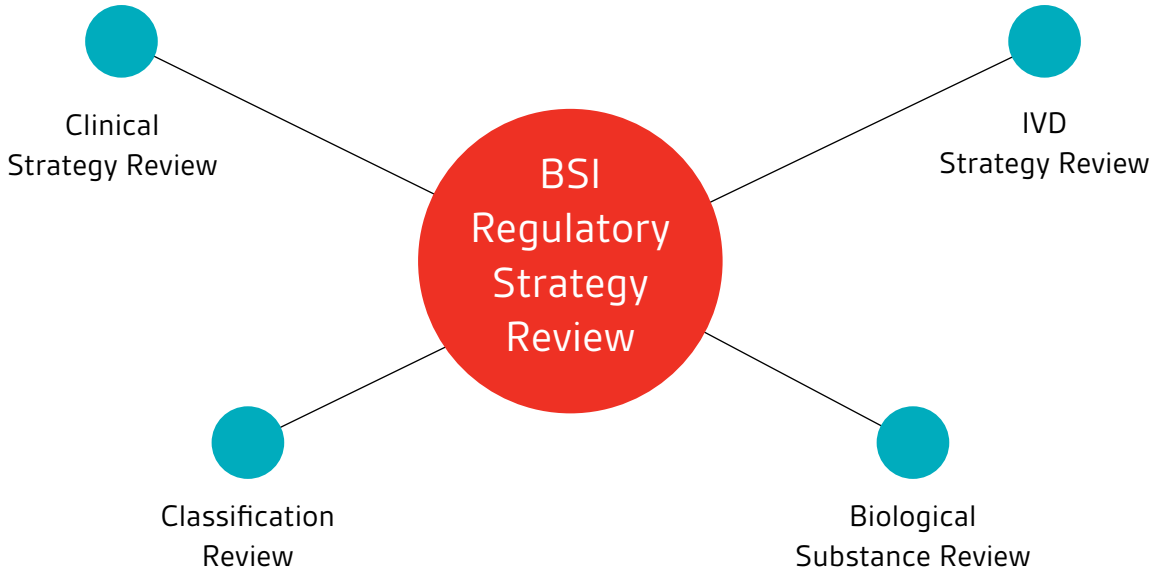
BSI's policy on consultancy

Notified Body personnel (whether directly employed or subcontracted) shall not offer or provide (or have offered or provided) consultancy or advice to the manufacturer, the authorised representative, a supplier or their commercial competitor as regards the design, construction, marketing or maintenance of the products under assessment.

Modular Approach

The Regulatory Strategy Review is made up of four subsets, that you can choose for review. You can request more than one service, all of the services are available only as part of the BSI CE marking process; **only Manufacturers who have committed to CE marking their product with BSI can make use of the service.** In line with BSI's policy on consultancy the early review is a gap analysis between what the manufacturer proposes and the requirements of the current Directives, Standards or Guidance. The Regulatory Strategy Review is available through BSI UK Notified Body, 0086.

As a manufacturer, you are in a much better position to meet or improve your time-to-market goals having your regulatory plan reviewed against the requirements prior to execution. It increases predictability, minimizes risks of unexpected questions, requirements or surprises just prior to the scheduled launch. If concerns are identified they can be addressed early on in the development cycle.



BSI Clinical Strategy Review

Manufacturer evaluates all relevant available clinical data

Manufacturer determines if sufficient clinical evidence exists to support CE marking through the equivalence route if a clinical investigation is needed, or if additional clinical data is required

Manufacturer submits Clinical Evaluation Plan and supporting evidence to BSI

BSI conducts Clinical Strategy Review based on plan

BSI provides feedback on the manufacturer's conclusion on their clinical data

Manufacturer attains a high level of confidence

Manufacturer completes clinical evaluation according to their plan and prepares final Clinical Evaluation Report in accordance with relevant Directives, Guidance, Regulations and Standards.

Manufacturer submits full Clinical Evaluation Report to BSI as part of their normal Technical/Dossier Review.

BSI conducts a full Technical/Dossier Review to determine compliance to the Directive. If consistent with expectations, the potential for nonconformities, and therefore delays to certification, will be reduced. If approved by BSI, the manufacturer can then affix CE marking.

Note: *The Clinical Strategy Review is based on the manufacturers' successful achievement of its clinical plan, the version of the Directive and related guidance used at the time to review. Regulations and their interpretations may have changed by the time the clinical investigations are complete which may invalidate the review or require updating. BSI will not perform more than one CSR for a given device.*

Clinical Strategy Review

The clinical evaluation is a critical element in the CE marking regulatory pathway for placing a new medical device on the European market. It can be expensive, time-consuming and challenging. The Medical Device Directives (MDD and AIMDD), place emphasis on a sound clinical evaluation as part of a technical document submission for all risk classes, especially high risk Class III and implantable devices.

As a Notified Body, BSI's clinical strategy review will identify shortcomings or potential pitfalls in manufacturers clinical strategy or literature data, which do not meet the requirements outlined in the relevant Directives, Standards and Guidance used by the Notified Body. We offer this Service for the full range of Medical and Active Implantable Devices.

Note: *CSR cannot be completed on the Medicinal substance in a Device Drug Combination product.*

BSI is expressing our Notified Body opinion on the data that we might anticipate to be acceptable to support CE Marking based on the information shared, however, within EU Member States approval of proposed clinical investigations and the supporting protocols/plans is the responsibility of the local Competent Authority.

BSI cannot review a proposed Clinical Investigation Plan, this needs to be agreed with the relevant Competent Authority.

Classification Review

The classification of medical devices is a 'risk based' system based on the vulnerability of the human body taking account of the potential risks associated with the devices. This approach allows the use of a set of criteria that can be combined in various ways in order to determine classification, e.g. duration of contact with the body, degree of invasiveness and local vs. systemic effect.

These criteria can then be applied to the complete range of different medical devices and technologies. These are referred to as the 'classification rules' and are set out in Medical Device Directives.

It is recognized that although the existing rules will adequately classify the vast majority of existing devices, a number of products may be more difficult to classify. Such cases may in particular include devices which are borderline cases between two different classes of medical devices. In addition, there may be devices that cannot be classified by the existing rules because of their unusual nature or situations where the classification would result in the wrong level of conformity assessment in light of the hazard represented by the device.

It is critical to identify the classification of the your product early on in the design process, so if you have a borderline product or just need clarification that your current classification will enable your products to meet the requirements of the directives this service can provide you with the analysis required.

Biological Substance Review

BSI recognizes that regulatory requirements for manufacturers of medical devices incorporating materials of biological origin (e.g. animal tissue / derivatives, human blood derivatives) can be challenging. BSI understands that the utilization of materials of biological origin in your device can bring added benefits but that the regulatory process will be subject to increased scrutiny.

Additional demands include justification for the use of the tissue or derivative, and information relating to sourcing and processing controls.

Early review of your strategy will ensure your plans will meet the strict requirements in this complicated area.

IVD Strategy Review

The IVD Directive lists "Essential Requirements" to which all IVDs must comply before being placed on the market. These requirements address the design, production, labelling and instructions for use.

BSI offers regulatory strategy review to BSI customers, who will receive a written gap analysis report against the relevant requirements, supplying feedback on your Strategy Plan based on the latest European Regulations, Standards and Guidance.

Benefits of Regulatory Strategy Review

- Gain a clear understanding of what the Notified Body expects early in the product development process
- Experienced and knowledgeable Product Experts
- Meet your timelines by minimizing risks of unexpected questions or requirements just prior to your scheduled launch
- In the early stages, achieve a high level of confidence your regulatory strategy is on-track
- Receive a BSI Report of our review against the requirements for your plans
- Emerging companies that reach clinical strategy agreement may use it as a milestone for the next round of funding.
- The RSR increases confidence and predictability in a dynamic market that is subject to every increasing expectations for clinical and regulatory compliance.

Talk to BSI

We believe excellence should follow in everything we do, so if you would like to find out more about BSI 's Regulatory Strategy Review please **call or email us for an initial conversation**

Your partner in worldwide compliance:

Call BSI today on +1 800 862 6752 or visit: www.bsigroup.ca/medical

The Regulatory Strategy Review service is subject to reasonable efforts made by the manufacturer following the review to proceed with CE marking application using BSI as the Notified Body. The Strategy Review is pursuant to an application for CE marking. In the event that an application for CE marking with BSI has not been made, The Regulatory Strategy Review may be obligated to inform the Competent Authority that the application has been withdrawn, and include details of the review outcome. *In line with BSI's policy on consultancy the early review is a gap analysis between what the manufacturer proposes and the requirements of the current Directives, Standards or Guidance.*

The clinical and/or regulatory strategy review does not constitute compliance with the Notified Body conformity assessment processes of the European Medical Device Directives and as such does not support the application of CE marking on the product to which the Strategy Review applies.
The clinical and/or regulatory strategy review does not guarantee successful EC certification. All certification services to be provided by BSI shall be subject to the standard terms and conditions of BSI for such services and shall be separate from the terms in this Strategy Review.

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